DRAFT ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION FOR NICKEL SULPHATE

Substance name: Nickel sulphate
EC number: 232-104-9
CAS number: 7786-81-4

Submitted by: FRANCE (Anses - French Mandated National Institute)
Date: April 2014

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Nickel sulphate ($NiSO_4$) belongs to the family of nickel compounds including nickel metal, nickel salts, organometallic nickel substances, etc. More than a hundred are classified under the CLP Regulation. At least 26 nickel compounds are registered under REACH[1], 16 as full dossiers (REACH Article 10), 8 as intermediate dossiers (REACH article 18) and 2 with both full and intermediate dossiers (see Appendix 1). Additional registrations can also be expected. From those 26 nickel compounds, 6 have been selected by the French Competent Authority, on the basis of Anses's proposal, for further assessment (nickel sulphate, hydroxycarbonate, dichloride, dinitrate, bis(hydrogen)phosphate and monoxide). Substances registered only as intermediate have been excluded at this stage. In a first approach, risk management option analysis (RMOA) are carried out on $NiSO_4$ and nickel monoxide as both salts cover substantially the majority the uses reported for nickel compounds.

The Nickel Institute groups nickel containing chemicals into five main classes: metallic nickel, nickel carbonyl, oxidic nickel (e.g. nickel oxides, hydroxide, silicates, carbonates, complex nickel oxides), sulfidic nickel (e.g. nickel sulfide, nickel subsulfide) and water-soluble nickel containing chemicals (e.g. nickel sulfate hexahydrate, nickel chloride hexahydrate). The group of "oxidic nickel" includes substances with a range of different water solubility, from chemicals of very low solubility (e.g. nickel oxide) to chemicals with a water solubility a hundred times greater (e.g. nickel hydroxide). Insoluble nickel containing chemicals include nickel oxide, nickel sulfide and nickel subsulfide.

1 BACKGROUND INFORMATION

1.1 Substance identity

Nickel sulphate is one of the most soluble nickel compounds with the chloride, the nitrate and the sulphamate salts.

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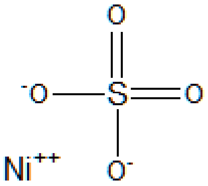
[1] The ECHA database provides additional nickel containing compounds (reaction mass, NONs substances, pigments, leachates, etc.) that are not considered here.

Nickel sulphate (or Nickel (II) sulphate) is produced by dissolving nickel metal (or nickel oxide) in sulphuric acid. It is most widely used in its salt form but can also be available in solution. It is a highly soluble salt that is most commonly produced in hydrated (hexahydrate or heptahydrate) form with a blue-green colour. In its anhydrous form the salt is yellow in colour.

Table 1: Substance identity[2]

Public Name	Nickel sulphate
EC number	232-104-9
EC name	Nickel sulphate
CAS number (in the EC inventory)	7786-81-4 (anhydrous) 10101-97-0 (hexahydrate) 10101-98-1 (heptahydrate)
CAS name	Nickel sulphate Nickel sulfate (solution)
IUPAC name	Nickel(+2)sulfate
Index number in Annex VI of the CLP Regulation	028-009-00-5
Molecular formula	Ni SO4
Molecular weight range	154.756
Synonyms	nickel monosulphate; nickelous sulphate; nickel sulphate (1:1); nickel (II) sulphate; nickel (2+) sulphate; sulphuric acid, nickel (2+) salt (1:1)

Structural formula:



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[2] The criteria for reporting for the EINECS Inventory states in Point 14:"Hydrates of a substance or hydrated ions, formed by association of a substance with water should not be reported. The anhydrous form can be reported and will, by implication, represent all hydrated forms." The EINECS inventory therefore lists the CAS number for the anhydrous form (7786-81-4) together with the EINECS number (232-104-9) associated with this CAS number. As the rule quoted above indicates, this EINECS number represents by implication all hydrated forms.

1.2 Classification and labelling

$NiSO_4$ is currently classified under Annex VI of the CLP Regulation (EC No.1272/2008) as follow.

Table 2. Harmonized classification of $NiSO_4$ in Annex VI of the CLP Regulation (EC No.1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
028-009-00-5	Nickel sulphate	232-104-9	7786-81-4	Acute tox. 4	H302	Skin Sens. 1; H317: C ≥ 0,01% STOT RE 1; H373: C ≥ 1% STOT RE 2; H373: 0,1% ≤ C < 1% Skin Irrit. 2; H315: C ≥ 20% M=1	none
				Skin Irrit. 2	H315		
				Skin Sens. 1	H317		
				Acute Tox. 4	H332		
				Resp Sens. 1	H334		
				Muta. 2	H341		
				Carc. 1A	H350i		
				Repr. 1B	H360D		
				STOT RE 1	H372		
				Aquatic acute 1	H400		
				Aquatic chronic 1	H410		

$NiSO_4$ is not classified for any physical-chemical properties.

1.3 Information on the REACH registration status

1.3.1 Registration status

$NiSO_4$ is registered in accordance with Article 10 (i.e. full registration dossier) and also with Article 18 (i.e. registration of transported isolated intermediates - TII). Twelve full dossiers and four TII dossiers are registered under REACH (last check dated December 2013). The risk management option analysis (RMOA) has been carried out on the last available update from the lead registrant, dated 31 July 2013.

Nickel sulphate is registered with a public tonnage band of 10,000 to 100,000 tonnes per year. Volumes manufactured and used are provided in section 2.

1.3.2 Registrants' identity

Registrants and suppliers publically identified on ECHA dissemination website are the following[3]:

A.M.P.E.R.E. INDUSTRIE 5-7 Rue de Bretagne Z.I. des Béthunes, 95310, SAINT-OUEN-L'AUMONE VAL D'OISE, France

Aurubis AG Hovestrasse 50, 20539, Hamburg Hamburg, Germany

Bochemie a.s. Lidicka 326, 735 95, Bohumin, Czech Republic

Boliden Harjavalta Oy Teollisuuskatu 1, 29200, Harjavalta, Finland

Boliden Mineral AB Rönnskärsverken, 93281, Skelleftehamn, Sweden

Hainan, S.L. Pol. Ind. "La Timba", Ctra. N-260, Km. 41,2, 17742, Avinyonet de Puigventós Figueres, Catalunya, SpainHalma Export & Import GmbH Reichsratsstrasse 11/3A, 1010, Vienna, Austria

KGHM Polska Miedz S.A. M. Sklodowskiej-Curie 48, 59301, Lubin, Poland

Königswarter & Ebell, Chemische Fabrik GmbH Im Ennepetal 19-21, 58135, Hagen, Germany

Montanwerke Brixlegg AG Werkstraße 1-3, 6230, Brixlegg Tirol, Austria

Nickelhütte Aue GmbH Rudolf-Breitscheid-Straße, D-08280, Aue, Germany

Norilsk Nickel Harjavalta Oy Teollisuuskatu 1, FI-29200, Harjavalta, Finland

SAFT AB Jungnergatan - Box 709, 572 28, OSKARSHAMN, Sweden

TODINI AND CO. SPA Corso Milano 46 B, 20900, MONZA ITALIA, Italy

Umicore NV/SA Rue du Marais 31, 1000, Brussels, Belgium

Vale Europe Limited Acton Refinery Bashley Road, NW10 6SN, London GB, United Kingdom

1.4 Information on any previous risk assessment, risk reduction strategy and RMO analyses

1.4.1 Previous risk assessment carried out under Council Regulation 793/93

A risk assessment has been carried out in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances for five nickel compounds. Indeed nickel metal, nickel sulphate, nickel dichloride, nickel dinitrate and nickel carbonate have been included in the third and the fourth priority lists of substances for assessment under this Regulation due to concerns for human health and the large annual quantities used. The final approved version of the risk assessment report (RAR) is dated May 2009; the chapter 4 (Addendum 2-year inhalation study in rats) has been added in November 2009.

The work assessed the effects and risks

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[3] Updated July 2014

- on the environment and human exposed indirectly via environment for nickel (metal) and the four nickel salts,
- on the human health for $NiSO_4$ (workers and consumers).

The risk assessment covered the following occupational uses of the five compounds (those flagged with * were relevant for $NiSO_4$)

- production of nickel metal* and nickel salts*,
- alloy production including nickel plating* activities and chemical pre-treatments of plated metals,
- battery production,
- catalyst production*,
- production of nickel-containing chemicals*,
- use in coins,
- contact with tools and other nickel-releasing surfaces,
- end-uses of nickel-containing products (batteries, catalysts, welding rods).

The main risks identified by the risk assessment are the occupational inhalation exposure and the skin sensitisation of consumers. Main results are reported in appendix 3 of this document.

1.4.1.1 Risk assessment outcome for workers

Risks were identified for all the following manufacture and use scenarios considered in the risk assessment (those flagged with * were relevant for $NiSO_4$):

1. Production of nickel metal: refining*
2. Production of nickel salts*
3. Production of alloys
    - melting and foundry techniques,
    - powder metallurgy,
    - nickel plating*
    - chemical pre-treatment of metals*
4. Battery production
5. Catalyst production*
6. Production of nickel-containing chemicals*

Based on the information and the classification available at that time (identified uses and exposure levels, hazard characterization and subsequent classification, agreed DNELs, etc.), risks were identified for workers based on inhalation exposure (to nickel salts) and on the following health effects (see table3):

- acute inhalational toxicity (short-term peak exposures to nickel salts),
- respiratory sensitisation (occupational asthma following inhalation exposure to nickel salts),
- chronic inhalational toxicity (full-shift exposure),
- inhalational carcinogenicity (for all scenarios except those where the exposure is purely to metallic nickel),
- reproductive toxicity (fertility and developmental toxicity following inhalation).

Note that there were no concern for workers after oral exposure, as it was assumed that this is prevented by personal hygiene measures.

Table 3: Summary of the RAR conclusion on the occupational risk assessment for $NiSO_4$

Conclusion	**Endpoints of concern**	**Reasoning**
(i) on hold. There is need for further information and/or testing	Effects on fertility and development	There is need for further studies to evaluate the possible effects of nickel sulphate on germ cells, but further testing is not considered practicable
(iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account	Acute toxicity, respiratory sensitisation, repeated dose toxicity, carcinogenicity, effects on fertility and development	The risk assessment has shown that a concern with inhalational exposure is expressed for all inhalational exposure scenarios in relation to worst case exposure levels. For typical exposure levels concern is expressed to the majority of the endpoints/exposure scenarios
(ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied	Effects on fertility and development, dermal exposures for acute and repeated dose toxicity, irritation, sensitisation, carcinogenicity and reproductive toxicity	The risk assessment has shown that following typical inhalational exposure for some scenarios (effects on fertility and development, and for all scenarios for dermal exposures for acute and repeated dose toxicity, irritation, sensitisation, carcinogenicity and reproductive toxicity) there is no need for limiting the risks taking into account the risk reduction measures that are already being applied

1.4.1.2 Risk assessment outcome for dermal exposure and skin sensitization

There appeared to be little concern for induction of skin allergy from contact with nickel-containing chemicals in the workforce, or for any other health effects related to dermal exposure. With respect to metallic nickel, whilst release of nickel from the metal or nickel-containing alloys during occupational exposure is possible, skin contact to these materials is unlikely to be prolonged, and therefore the possibility of induction of sensitization is much reduced compared to soluble nickel compounds.

Thus a conclusion (ii) has been considered justified for all workplace scenarios for induction of nickel allergy. The exposure levels were also considered sufficiently low to justify a conclusion (ii) for the elicitation of symptoms of nickel allergy in previously sensitised individuals for workplace exposure.

1.4.1.3 Risk assessment outcome for welding activities

The risk assessment reflects agreement with the conclusions drawn by IARC (1990) and Cross et al. (1999) that there is a concern for the welding process, although the concern is not specifically associated with the presence of nickel alone in either the materials used for welding or the materials being welded. Several substances potentially hazardous to health are present both as part of the welding materials (rod, core etc.) and as components of the surfaces to be welded. The hazards associated with the process are primarily associated with the fumes generated, exposure to nickel by inhalation cannot be excluded when nickel metal of nickel salts are involved in the welding process. Nevertheless, the composition of these fumes depends on the components of the welding process, as well as on the welding method used. Therefore no targeted risk characterisation has been carried out for the use of nickel in welding.

1.4.1.4 Risk assessment outcome for consumers

Concerns for consumers are very different than from workers. Consumers are mainly exposed by skin contact (to nickel metal) and oral exposure (to nickel salts). Whilst dermal exposure is to nickel metal, oral exposure is to soluble nickel. There is indeed no significant inhalational exposure to nickel or nickel compounds for consumers. Both the induction of nickel allergy in non-sensitive people and the elicitation of allergic reactions in people already sensitive to nickel have been considered for the risk assessment.

The main concern is related to direct and prolonged skin exposure to nickel(metal)-containing objects such as coins, earrings, clasps of necklaces, zippers, finger rings, medallions, metal identification tags, buttons, wire support of bra cups, buttons on jeans, watchbands, bracelets, spectacle frames etc. as well as to piercing posts used for ear-piercing and piercing of other parts of the body.

Consumers can also be exposed to nickel orally from nickel released to food, nickel released from water heating devices (kettles), nickel released to drinking water, nickel in mineral supplements. With the exception of the use of $NiSO_4$ and $NiCl_2$ as a source of nickel in food supplements, there would appear to be little or no consumer exposure to nickel sulphate, chloride, nitrate or carbonate.

The risk assessment concluded that there is no concern for consumers for systemic effects by dermal exposure. The population at risk of developing symptoms after oral challenge are patients with severe nickel sensitization only.

It was indeed agreed that the main group of people where there is particular concern are those who are already nickel-sensitive, and this is a group especially at risk from both dermal and oral exposure to nickel. However EU legislation has come into force (cf. Section 1.5.3) and has been considered adequate to prevent new cases of nickel allergy as well as to reduce the incidence of elicitation in consumers who are already sensitised to nickel from both objects in direct and prolonged contact with the skin as well as piercing posts.

Note that the risk assessment for humans exposed to the environment has not been completed but it has been suggested that the sources of nickel, should this give rise to concern, would be controlled by any risk reduction measures required for concerns for the environment. Therefore no additional risk for humans from the environment was expected.

1.4.2 Previous risk reduction strategy carried out under Council Regulation 793/93

In order to identify appropriate measures to address the risks to human health raised in the risk assessment reports, a risk reduction strategy with respect to human health has been prepared by Denmark in 2007 in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

The report stated that nickel and nickel compounds were already widely regulated under EU legislation. The following risk reduction measures were proposed in relation to obligations under Community law:

- to set occupational exposure limits for nickel metal and nickel compounds in the form of inhalable dust/aerosols under Directive 98/24/EC (chemicals at work) or Directive 2004/37/EC (carcinogens at work) as appropriate,

- to establish at Community level an occupational exposure limit or limits for welding fumes, according to Directive 98/24/EC or Directive 2004/37/EC as appropriate, taking into account information in the nickel RAR, as well as other risk assessments on chromium(VI) compounds and zinc,
- to establish at Community level an occupational exposure limit or limits for welding fumes, according to Directive 98/24/EC or Directive 2004/37/EC as appropriate, taking into account information in the nickel RAR, as well as other risk assessments on chromium(VI) compounds and zinc,
- to consider the validity of derogations for the use of $NiSO_4$ and NiCl2 under Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

The following measures were proposed in relation to non-regulatory outcomes:

- practical sector-specific guidance of a non-binding nature should be drawn up by the Commission for uses of nickel identified as a concern in the risk assessment, as foreseen under Article 12(2) of Directive 98/24/EC,
- consideration of an exchange of information organised by the Commission to ensure proper guidance to severely nickel-sensitised individuals through the Community,
- the effects of Directive 94/27/EC (relating to restrictions on the marketing and use of certain dangerous substances and preparations) as amended and the associated EN 1811 standard should be monitored in the wider EU population to ensure that the threshold set in the Directive is adequate to prevent new cases of nickel allergy and is also sufficient to prevent elicitation of symptoms in a significant proportion of nickel-sensitised individuals caused by the release of nickel from objects in direct and prolonged contact with the skin and piercing posts.

1.4.3 Previous RMO analysis carried out on environment by Denmark

A risk assessment for the environment and human exposed via the environment and a RMOA has been conducted by Denmark under Council Regulation 793/93 on nickel (metal) and nickel compounds (nickel sulphate, nickel [hydroxy]carbonate, nickel chloride, nickel dinitrate). This report is dated May 2008.

The work has been completed in 2012 on the sediment compartment on the basis of new information that was formerly required in COM Reg. 466/2008 on the chronic effects (and potential risks) to freshwaters sediment organisms. A conclusion of substance evaluation (for those five compounds) drafted the 19th of December 2012 has been made available to Member States according to transitional measures described in Article 135, 136 and 48 of the REACH regulation. This conclusion is regarded as a risk management option analysis that complete the existing environmental risk assessment for nickel compounds.

Denmark considers that no risk management measure is appropriate under the REACH regulation but expresses the need for other community-wide measures:

- to propose the establishment of an EQS freshwater sediment under the Water Framework Directive (WFD) including potential use of an AVS-based bioavailability normalisation approach,
- to initiate that further Guidance is being developed under WFD for refined assessment when initially $EQS_{freshwater\ sediment}$ seems to be exceeded. It is proposed to base such a further development on the refinement approach of the summary

report which includes bioavailability normalisation and refinement of the emission/exposure assessment,
- to consider proposing a revision of the BREF note for nickel plating to also protecting specifically the freshwater sediment compartment under the Industrial Emission Directive.

Denmark also recommends registrants of nickel to update nickel registration dossiers without undue delay taking into account:

- the new hazard data on freshwater sediment organisms,
- that an assessment factor of 2 is recommended to derive PNEC $_{\text{freshwater sediment}}$= 47 mg Ni/kg sed. dw,
- using established bioavailability approach i.e. the prescribed use of AVS normalisation models and/ or reducing exposure and/or refining emission/exposure assessment if initially calculated RCR $_{\text{freshwater sediment}}$ >1 to prove safe use (i.e. RCR $_{\text{freshwater sediment}}$ <1 for refined assessment).

Denmark finally expresses the need for action at national level by Member States Competent Authorities (in future if/when EQS $_{\text{freshwater sediment}}$ and bioavailability normalisation approach have been adopted under the WFD and employed by registrants under REACH):

- implement BAT in relevant industrial sector,
- monitor if the proposed EQS for freshwater sediment is complied with for all industrial nickel emitting local sites,
- enforce compliance under REACH and the Water Framework Directive.

The French Member State Competent Authority agrees with the conclusions of the environmental risk assessment and RMOA conducted by Denmark and considers that no further development of the proposed environmental risk management option is needed.

Therefore the present RMOA doesn’t consider further the environmental risk.

1.5 Current legal requirements for nickel and nickel compounds under REACH and other EU legislations

Nickel metal and nickel compounds are existing substances with a long history of production, uses and also hazard and risk characterization. Therefore a number of general and targeted legislative controls are currently in place in the EU. Only those that explicitly cover $NiSO_4$ directly or indirectly are listed below.

Discussion on the content, the relevance and the consistency of those legal requirements for adequately managing the risk for $NiSO_4$ is provided in section 4 of this document.

1.5.1 EU general legislations on dangerous chemicals covering nickel compounds

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations).

Directive 94/27/EC of 30 June 1994 (amending for the 12th time Directive 76/769/EEC) and Directive 94/60/EC of 20 December 1994 (amending for the 14th time Directive

76/769/EEC) relating to restrictions on the marketing and use of certain dangerous substances and preparations (also called Nickel Directive).

1.5.2 EU workplace legislation regarding occupational health and safety

Directive 90/394/EEC Protection of Workers from Risks to Exposure to Carcinogens at Work and, in its codified version, Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work (informal and binding OELs) and Directive 89/391/EC, Framework Directive (called OSH "Framework directive").

In addition to the OEL legislation and to Directive 2004/37/EC, the risks at the workplace arising from exposure to hazardous substances are controlled at European level by a number of the Directives (see below) related to the protection of occupational safety and health. They impose minimum standards for health and safety of workers and provide a framework of directions and safeguards to ensure that the risks in the workplace to health from hazardous substances are managed. Most of them cover indirectly nickel and its compounds regarding to their classification as hazardous substances.

- Directive 2001/58/EC on "Safety Data Sheets" and Directive 1999/45/EC relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets).
- Directive 89/656/EEC on the use of personal protective equipment (PPE).
- Directive 92/85/EC (pregnant workers directive) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
- Directive 94/33/EC (young workers directive) on the protection of young people at work.

1.5.3 EU legislation regarding consumer protection

The following is provided for information and not developed further since this RMOA only addresses the occupational risk and not the risk for consumer, considered nonexistent for $NiSO_4$ particularly.

Regulation (EC) No 552/2009 amending the REACH Regulation (EC) No 1907/2006 as regards to Annex XVII: restrictions concerning substances classified Carc. 1A/1B, Muta. 1A/1B and/or repr. 1A/1B under Annex VI of the CLP which shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public.

Regarding $NiSO_4$ specifically, Annex XVII of REACH as amended by Commission regulation 552/2009 provides that nickel and its compounds shall not be used

- in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 μg/cm^2/week (migration limit),
- in articles intended to come into direct and prolonged contact with the skin such as: earrings, necklaces, bracelets and chains, anklets, finger rings, wrist, watch cases, watch straps and tighteners, rivet buttons, tighteners, rivets, zippers and metal marks, when these are used, in garments, if the rate of nickel release from

the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm^2 / week,

- in articles referred to in point (b) where these have a non nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm^2 / week for a period of at least two years of normal use of the article.

This restriction has been amended recently in order to ban the placing on the market for consumers the Do-It-Yourself (DIY)[4] nickel electroplating hobby kits containing $NiSO_4$.

Regulation (EC) No 1223/2009 on cosmetic products that came into force on 11 July 2013 strengthens the safety of cosmetic products and streamlining the framework for all operators in the sector (Nickel and nickel compounds - including $NiSO_4$, entries 455 to 460 of the Annex- are included in the Annex II "List of substances prohibited in cosmetic products".

Directive 2009/48/EC on toys' safety. Chemicals that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under the CLP Regulation No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

1.5.4 EU legislation regarding protection of the environment and/or covering human health safety through environmental exposure

The following is provided for information and not developed further since this document only covers the human health risk and not the risk for the environment that is considered already framed by the Danish RMOA.

As $NiSO_4$ is classified dangerous for the environment (aquatic chronic 1) under Annex VI of the CLP, Industry must comply with the requirements of the following environmental legislations.

- Directive 2010/75/EC on industrial emissions (IED) replacing Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC).
- Directive 96/82/EC on the control of major accident hazards involving dangerous substances (Seveso II Directive).
- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (4th Daughter Directive).
- Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking water).
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive)[5].
- Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (Ground water Directive).

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[4] http://www.nickelinstitute.org/~/media/Files/HealthEnvironmentSafeUse/AdvisoryNotes/EN/AdvisoryNotesDIYPlatingA409rev.ashx

[5] Nickel and nickel compounds are also identified as priority substances in Annex X of the Water Framework Directive, which requires a European-wide Environmental Quality Standard for nickel and nickel compounds in the aquatic environment

- Directive 2008/105/EC on environmental quality standards in the field of water policy (EQS or Priority Substances Directive).
- Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.
- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Batteries Directive).
- Directive 2008/103/EC amending Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators as regards placing batteries and accumulators on the market.

1.5.5 Focus on current instruments setting occupational exposure limit values

1.5.5.1 SCOEL recommendation for nickels' occupational exposure limit values (OELs)

The Scientific Committee on Occupational Exposure Limits (SCOEL) has adopted in June 2011 the following recommendation on indicative OELs for nickel and inorganic nickel compounds.

Exposure to nickel compounds is associated with an increased cancer risk in the lung and nasal cavity, as well as with inflammatory responses/fibrosis in the lung. Since mechanistic data indicate an indirect genotoxic mode of action, nickel is considered as a carcinogen with a practical threshold. The proposed OELs are based on protection from inflammatory effects in the lung, but according to available evidence should also protect against carcinogenic effects.

Based on available long-term inhalation studies in rats showing sever lung damage (fibrosis and inflammation) and taking into account the differences between rats and humans with respect to particle deposition in the alveolar region (higher deposition in humans as compared in rats due to potential toxicodynamic differences) an OEL of 0.005 mg/m^3 is proposed for the respirable fraction (<10 µm).

In addition to chronic inflammation of the lung, the proposed OEL also needs to protect from nickel-induced carcinogenicity. Since epidemiological evidence suggests not only the induction of lung tumours, which may be provoked by respirable particle sizes, but also of nasal tumours, and particles at the workplace are not limited to the respirable fraction, exposure towards inhalable nickel particles needs to be limited for carcinogenic nickel species as well. Based on the available epidemiological studies, an OEL of 0.01 mg Ni/m^3 is proposed for the inhalable fraction (<100 µm) of water soluble as well as poorly water soluble nickel compounds (metallic nickel is excluded) in order to protect from nickel-induced carcinogenicity[6].

Those values are further discussed in section 3 of this document concerning their use in defining DNELs (Derived Non Effect Levels) for the risk assessment carried out on the information provided in the substance registration dossiers.

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[6] Carcinogenicity appears at the lowest doses and is the critical effect to be targeted by the risk management, beyond the reproductive toxicity that appears at a higher dose.

1.5.5.2 Indicative occupational exposure limit values (IOELVs) or binding occupational exposure limit values (BOELVs)

An EU framework for the setting of Indicative Occupational Exposure Limit Values (IOELVs) is defined, inter alia, in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Binding Occupational Exposure Limit Values (BOELVs) are developed when socio-economic and technical feasibility factors are taken into account and may be then set under the Carcinogens Directive (2004/37/EC).

Any chemical agent for which an IOEL value is set at European level, Member States must establish a national exposure limit value, taking into account the Community indicative limit value, determining its nature in accordance with national legislation and practice.

Any chemical agent for which a BOELV value is established at European level, Member States must establish an corresponding national binding OEL value which can be stricter, but cannot exceed the Community limit value.

There are currently no IOELV nor BOELV for nickel and its compounds. However a number of Member States have already set formal national OELs for nickel and nickel compounds. Those national OELs in force generally group the nickel compounds for which OELs apply as either water-insoluble inorganic nickel compounds or as water-soluble nickel species. Since they are part of national legislation, there may be differences across European countries in relation to the legal or advisory framework which affects the way the limit is interpreted and applied. In addition, the legal duties imposed can vary.

Table 4 shows that those national OELs, even close, are not harmonized between Member States and are over the SCOEL recommendation of 0,01 mg Ni/ m^3, except for the nickel carbonyl species and except for Denmark.

Table 4. Occupational Exposure Limits (OEL) for nickel compounds in various countries[7]

Country	OEL (mg Ni/m^3) as Ni	Comments
France	1,0	Nickel carbonate, Nickel dihydroxyde, Nickel subsulfide, Nickel oxide, Nickel sulfide, Nickel trioxyde: 8-h time weighted average exposure limit value
	0,1	Nickel sulphate
	0,12	Nickel carbonyle
Germany[8]	0,5	Metallic nickel, nickel carbonate
	0,5	Nickel dioxide, nickel sulphide and sulphidic ores
	0,05	Nickel compounds as inhalable droplets (e.g. nickel sulphate, nickel chloride, nickel acetate).
Sweden	0,5	Metallic nickel
	0,1 ppm total	Nickel compounds

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[7] Data are from the RAR quoting itself the source "Nipera 1996"; therefore many data could be not up to date; those in bold have been updated in the frame in this RMOA based on the current knowledge

[8] Reported values were in force until 2006 but are no more valid; new threshold values are currently discussed

	dust	
	0,007	Nickel carbonyl (equivalent to 0,001 ppm)
	0,1 ppm total dust	Trinickel disulfide
Poland	0,25	Nickel and its compounds
Belgium	1	Nickel metal
	0,2	Insoluble nickel compounds
	0,12 (0,05 ppm)	Nickel carbonyl
	0,1	Nickel subsulfide
	1	Nickel sulfide (dust and smoke)
Norway	0,007 (0,001 ppm)	Nickel carbonyl and nickel tetracarbonyl
	0,05	Nickel metal and other nickel compounds
Finland	1	Nickel metal
	0,1	Other nickel compounds (except nickel carbonyl)
	0,007 (0,01 ppm)	Nickel carbonyl (8 h)
	0,021(0,003 ppm)	Nickel carbonyl (15 min)
United Kingdom	0,5	Nickel metal and water- insoluble nickel compounds
	0,1	Water- soluble nickel compounds
	0,24	Nickel carbonyl
The Netherlands	1,0	Metallic nickel
	0,1	Nickel oxide, nickel carbonate
	0,1	Soluble nickel compounds
	0,12	Nickel carbonyl
Denmark	0,05	Metallic nickel
	0,05	Insoluble nickel compounds
	0,01	Soluble nickel compounds
	0,007	Nickel carbonyl
Austria	0,05	Nickel metal and alloys, nickel sulphide, sulphidic ores, oxidic nickel and nickel carbonates in inhalable dust, as well as any nickel compound in the form of inhalable droplets
	0,05	Soluble nickel compounds
Ireland	1,0	Insoluble Ni compounds
	0,1	Soluble Ni compounds
	0,12	Nickel carbonyl

Italy[9]	1,5	Ni metal
	0,2	Insoluble Ni compounds
	0,1	Nickel subsulfide
Luxembourg		Cf. German OELs
Portugal	1,0	Insoluble Ni compounds
Spain	1,0	Insoluble Ni compounds
	0,1	Soluble Ni compounds
	0,12	Nickel carbonyl

2 USES, VOLUMES, MARKET PICTURE AND ALTERNATIVES PER MAIN USE

Information provided in this section comes both from the registration dossiers and from Industry documents shared by the Nickel Institute and its members in the frame of a consultation carried out by France. Registrants of $NiSO_4$ are members of the Nickel Institute and have thus contributed to the consultation. Confidential information has been removed from this public version. The aim of the work carried out so far by the Nickel Institute and its consultants is to anticipate a potential implementation of risk management measures under REACH. The authorisation route has especially been targeted considering the current classification of nickel compounds under the CLP Regulation that would allow nickel compounds to be identified as substances of very high concern, included in the candidate list and potentially prioritized for inclusion in Annex XIV of REACH. Therefore the Nickel Institute took the decision to start bringing together the building blocks for an application for authorisation dossier in case that would be required for the uses of $NiSO_4$. Three socioeconomic analysis (SEA) exercises have been carried out and shared with France for the purpose of this RMOA; they cover the production and use of batteries, printing rotary screens and bathroom fittings (for the surface treatment applications). Other documents have also been shared on use description, volumes estimations, etc. As requested by the Nickel Institute, it is underlined that the data used so far by Industry to answer this consultation are dated 2013 for the latest and that some information may not be still up to date (classification of several reported alternative substances, data on the production and applications of $NiSO_{4,}$ etc.).

The International Nickel Study Group reports that global primary nickel usage in 2012 in the EU27 was 331,000 tones. The EU 27 represents 20% of global primary usage and produces around 7% of global production. The main and first use of primary nickel is stainless steel production. At world level, 63% of primary nickel went into stainless steel, 8% in other steel alloys, 10% in nonferrous alloys, and 10% in plating. Chemical applications like batteries and catalysts account for around 6%, the remaining 3% going into specific applications. The entire nickel production chain of nickel is present in Europe, from exploration and mining to the production of chemicals (through smelting and refining).

The total amount of nickel (all forms included) produced and used in Europe in 2000 is estimated at 645,000 tonnes (Reck et al. 2008)[10] but no specific information on the

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[9] When not mandatory, Italian occupational threshod limit values are applied from international agencies such as American Conference of Governmental Industrial Hygienists (ACGIH) for the nickel compounds; reported values are those from ACGIH and dated 2001.

tonnage of $NiSO_4$ is reported in this study. This total tonnage is significantly greater than the value of 22,165 tonnes (all forms included) of nickel that was reported in the RAR which is based on 1994 data.

The volumes estimated for $NiSO_4$ are provided in section 2.1.

In the registration dossiers, uses description is aggregated in "Generic Exposure Scenarios" (GES), designed to provide exposure data and to carry out the chemical safety assessment; uses are not reported in the form of industrial processes as it usually provided in common literature, risk assessment reports and Industry documents. Therefore a correlation table is provided in table 5 in order to translate a GES in one "industrial" generic use that is further described in this chapter.

The RMOA has been drafted based on the 2013 dossier update. The last 2014 update, received after the drafting of this analysis, brings some additional exposure measurements of existing GES but does not change the conclusion of the risk assessment and of the whole RMO analysis.

Table 5. Correlation table between the GES denomination provided in the registration dossiers and the uses discussed in this document.

Global Exposure Scenario	**Uses discussed in the RMOA**
Manufacture of Ni sulphate (copper refinery and smelter)	
GES 1. Nickel sulphate production from copper refining	Nickel sulphate production
GES 2. Solvent extraction of nickel sulphate leachate	
GES 3. Crystallisation from a purified nickel sulphate leachate	
Downstream uses of Nickel Sulphate	
GES 4. Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating	Treatment of metal surfaces
GES 5. Production of batteries using electrodes with nickel containing active material	Batteries manufacturing
GES 6. Production of Ni salts from Ni Sulphate	Production of other nickel salts
GES 7. Use of nickel sulphate for the manufacturing of micronutrient additives for biogas production	(not further developed in section 2)*
GES 8. Production of nickel-containing pigments from NiSO4	(not further developed in section 2)**
GES 9. Selective plating with nickel sulphate	Treatment of metal surfaces
GES 10. Formulation of products for surface treatment of anodised aluminium sheets	
GES 11. Metal surface treatment of anodised aluminium sheets	

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[10] Reck BK, Müller DB, Rostkowski K, Graedel TE (2008) Anthropogenic nickel cycle: insights into use, trade and recycling. Environmental Science and Technology, vol. 42, pp. 3394-3400

* No information has been provided in the frame of the consultation, therefore no use description is developed in section 2 of this document. However this use is covered by the risk assessment in section 3 and the discussion on the potential risk management measures in section 4.

**The production of nickel-containing pigments (GES 8) is usually achieved with nickel oxide (NiO) except for one specific producer in the EU that uses $NiSO_4$ instead of NiO and a priori in identical conditions as for NiO. Please refer to the RMOA on NiO. However this use is covered by the risk assessment in section 3 and the discussion on the potential risk management measures in section 4.

2.1 Volumes manufactured and used in the EU

2.1.1 The data quality issue

In many countries, production of $NiSO_4$ is carried out by one company only, which triggers confidentiality of production and trade statistics. In response to the French consultation, the Nickel Institute tried to reconcile the requirement to respect the confidentiality of individual company data with requests of public reviewers to be able to have an as clear as possible view of the situation in Europe. The Nickel Institute therefore stated the following:

EU trade statistics are computed according to the Harmonised System codes. There is one single code for nickel sulphate or dichloride but oxides and hydroxides are gathered under the same category (2825 40). Other chemicals are grouped and these statistics therefore become useless for product-specific analysis. Some provided mass flows have been calculated from trade statistics. Intra-EEA[11] (European Economic Area) trade should, at least over a decade, be balanced: what EEA countries sell to each other should be equal to what they buy from each other. But this was not the case for the nickel compounds, leading to uncertain data. Thus the mass balance figures have been based on trade with non-EEA countries. Unfortunately these mass flows appear incomplete and have been taken into account with caution in this document.

According to the Nickel Institute, volumes can be easily over or underestimated. There isn’t always a hermetic wall between different chemicals and the way they are reported; downstream users often buy a nickel chemical as an intermediate to produce another nickel chemical; this is the case in the catalyst industry and the batteries’ sector where some nickel chemicals are produced in-house from another nickel containing chemical.

2.1.2 Estimated volumes

Information on $NiSO_4$ volumes manufactured and used are available from the Nickel Institute (SEA, internal consultation of downstream users and Eurostat) and from the REACH registration dossiers (confidential data). In the RAR, from the 22,165 tons of nickel compounds manufactured in the EU, 15,000 tonnes are identified as $NiSO_4$ (hexahydrate) for internal uses. Note that information from the RAR is not up to date.

From the documents provided by the Nickel Institute and based on Eurostat data (mass flows), it is estimated that 33,775 tonnes per year of $NiSO_4$ are manufactured in EU from which 2,390 tonnes are used to manufacture other nickel compounds and 17,900 are

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[11] The European Economic Area (EEA) comprises the member states of the European Union (EU), except Croatia plus Iceland, Liechtenstein and Norway, member states of the European Free Trade Association (EFTA)

consumed by downstream uses (in total 20,290 tonnes are used). However no exportation or other explanation is provided for the remaining non used volume of 13,485 tonnes.

Each registration dossier of $NiSO_4$ provides in the Iuclid file confidential data on tonnages manufactured, imported, exported and tonnage for the registrant's own use. The following estimation is calculated by summing the reported volumes of each registration dossier (see table 6): on a total volume of 55,149 tonnes $NiSO_4$ per year expected to be used within EU, 51,248 tonnes are manufactured in the EU (i.e. 93%) and 3,901 are imported (i.e. 7,1%). No export has been reported. The relevancy of the data shared by registrants is not known; therefore such data should be used as indicative estimations only. The part reported as intermediate is from the registrants' view, according to its own interpretation of the intermediate status; this is further discussed case by case in section 2[12].

Table 6. Data on $NiSO_4$ volumes from the registration dossiers (t/y) (data have been aggregated and are thus not considered confidential)

	Registrations		
Type	Full Art. 10	Intermediate Art. 18	Total
Total number of dossiers	12	4	16
Tonnage band	10,000 to 100,000		
Tonnage total (actual)	47,427	7,722	55,149
Tonnage manufactured	46,318	4,930	51,248
Tonnage imported	1,109	2,792	3,901
Tonnage exported	0	0	0

In the registration dossiers, the CSR also provides data on volumes per GES for the purpose of the chemical safety assessment carried out by the registrants. A common CSA has been carried out for all $NiSO_4$ registrants and only one CSR is provided by the lead registrant; this CSR reports that [confidential] tones $NiSO_4$ are manufactured per year and [confidential] tones are used. Those data are not seen relevant enough to be further considered in this RMOA.

In conclusion and as illustrated by table 7, it is not possible to get a clear picture of the real volumes of $NiSO_4$ manufactured and used within the EU. No exportation is reported by Industry. A range of 20,290 to 55,149 tonnes $NiSO_4$ used per year in the EU is currently identified from the main reliable sources.

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[12] Accordingly the volumes considered as intermediate by MSCA-FR to discuss the appropriate risk management option in section 4 may be different

Table 7. Overall comparison of available data on $NiSO_4$ volumes manufactured and used within the EU (t/y)

	RAR	Eurostat	Registration dossiers (2013)
Volumes manufactured within the EU	/	33,775	51,248
Volumes used within the EU	15,000	20,290	55,149

In the following section, only the volumes provided by Industry in the available SEA are considered.

2.2 Production of nickel sulphate

$NiSO_4$ is produced as a by-product of production of copper and other metals and via the refining of nickel matte and nickel intermediates produced during the recyling of a variety of secondary materials (e.g. spent nickel catalysts, nickel/cobalt residues, copper-nickel alloys and drosses). $NiSO_4$ production is covered by 3 provided GES: $NiSO_4$ production from copper refining, solvent extraction of $NiSO_4$ leachate (solvent extraction of $NiSO_4$ leachate, $NiSO_4$ production from other leaching processes), and crystallisation from a purified $NiSO_4$ leachate (crystallisation from a purified $NiSO_4$ leachate, $NiSO_4$ production from nickel matte).

2.3 Downstream uses of nickel sulphate

The Nickel Institute provided, from internal consultations, the following estimation of the used volumes for five main industrial applications of $NiSO_4$ (see table 8).

Table 8. Used volumes of $NiSO_4$ by main application (source: Nickel Institute)

Use	Volume used (t/y)
Production of other nickel salts used for catalysts and catalyst precursors	< 3,000
Production of other nickel salts (dinitrate, dichloride and hydroxycarbonate)	2,400
Production of nickel metal powder	2,400
Surface treatment	12,000
Total (without batteries)	**19,800**
Batteries manufacturing	Confidential

The top user countries (all uses included) are the following: Germany (6,538 t/y), France (1,437 t/y), Italy (944 t/y) and Czech republic (799 t/y).

Table 9 provides the tonnages considered as to be intermediate and non-intermediate. According to the Nickel Institute, the production of other nickel compounds and nickel metal powder from $NiSO_4$ could logically be regarded as to be an intermediate use; however the detailed processes and chemical reactions involved have not been provided in order to confirm it. The main use of $NiSO_4$ in the batteries manufacturing is also considered as an intermediate use (see section 2.3.3). Nickel plating is considered by the nickel Industry as to be an intermediate use resulting in inclusion into or onto a matrix; however ECHA guidance document on intermediates explicitly states that surface treatment should not be considered an intermediate use because "the main aim of the process is to provide a specific physicochemical characteristic to a material (irrespective of whether the surface treating agent is consumed in a chemical reaction and which results in another substance)".

Table 9. Intermediate status and related volumes (t/y) of each reported use of $NiSO_4$

Use	Full tonnage	Tonnage non-intermediate	Tonnage intermediate
Treatment of metal surfaces	12,000	12,000	0
Production of nickel salts from $NiSO_4$ to be used for catalyst manufacturing, production of other salts (with other purpose than catalysts manufacturing) and production of nickel metal powder	7,800	0	7,800
Total (without batteries)	19,800	12,000	7,800
Production of batteries	Confidential	22	Confidential

In the following each reported use is explained. The information is aggregated and synthesized from data[13] provided by the Nickel Institute and collected from internal consultation of their members, especially for the purpose of the SEA exercises. **This information has not been peer-reviewed nor challenged and have thus to be considered as the Industry's point of view.** Nevertheless where possible, an appraisal of Anses on Industry's conclusions has been added. The intermediate status has to be considered as the Anses position , based on the description of uses given by industry. For each discussed application, the use description, volumes, intermediate status, main actors, analysis of alternatives and non-use scenario are provided when available.

2.3.1 Production of other nickel salts

Despite a distinction has been made by the Registrant in the CSR between production of nickel salts and production of nickel metal powder, this chapter only covers the manufacture of other nickel salts. This use refers to GES 6 of the registration dossier. In the CSR, GES 6 is described as "production of nickel salts from $NiSO_4$" and/or as "production of nickel salts to be used in production of catalysts" without additional explanation.

Several nickel salts (especially hydroxycarbonate, dinitrate and dichloride salts, potentially hydroxide and ammonium) are produced from $NiSO_4$. $NiSO_4$ is considered as to be an intermediate in the involved chemical reactions but the detailed processes and

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[13] documents dated 2011 to 2013

chemical reactions involved have not been provided in order to confirm it. Usually processes are enclosed with automation.

Nickel hydroxide is prepared by treating a $NiSO_4$ solution with sodium hydroxide to yield a gelatinous nickel hydroxide which forms a fine precipitate when neutralized.

Commercial basic nickel carbonate or hydroxycarbonate is produced by precipitation from a nickel solution, i.e. usually the sulphate or chloride, with sodium carbonate; the obtained nickel hydroxycarbonate is precipitated out of solution (as crude nickel hydroxycarbonate) then recovered and washed.

Nickel chloride is produced from other nickel containing compounds by dissolution in hydrochloric acid. This includes metallic nickel scrap, nickel sulphate, nickel hydroxycarbonates or other basic nickel compounds.

No specific alternatives analysis has been provided by the registrants. However it is assumed that nickel salts can easily be produced by other means than using $NiSO_4$ and that no nickel salt relies only on the use of $NiSO_4$.

Switching the production of a nickel compound from another nickel salt than $NiSO_4$ will not reduce the level of risk for workers as all nickel salts are classified as CMRs under the CLP Regulation.

2.3.2 Treatment of metal surfaces

Metal surface treatment (including nickel electroplating, nickel electroforming and electroless nickel plating) is a major end use of $NiSO_4$. Surface treatment (sometimes referred to as surface engineering or coating) involves altering/covering the surface of an engineered material in order to give it superior properties. These include corrosion and tarnish resistance, improved strength of the material, improved durability-wear-chemical resistance, altering properties such as conductivity-friction-reflectiveness-resistivity, altering the appearance such as the shine, texture/smoothness and colour, enabling lightweight recyclable materials (e.g. plastic and aluminium) to be coated without affecting the longevity of the product. The main material substrates which are nickel plated include steel and stainless steel (most common), copper and copper alloys (e.g. brass), zinc and zinc alloys, aluminium and aluminium alloys, magnesium and magnesium alloys, plastic (in particular acrylonitrile butadiene styrene - ABS plastic), glass and ceramics.

The following provides an overall description of the surface treatment sector and the currently used plating technologies and a description per main activity sector.

2.3.2.1 Description of the surface treatment sector and tonnages

The RAR stated in 2008 that from the total amount of $NiSO_4$ used (i.e. 15,000 t/y), 88.9% are applied in surface treatment (i.e. 13,335 t/y). This estimate is consistent with the information provided by the Nickel Institute in 2013 (i.e. 12,000 t/y).

Each of the available plating chemistries is used in several market sectors, especially aerospace, automotive and electronics. Nickel dichloride and sulphate are widely used across all sectors, although their primary use is for decorative coatings in the automotive sector. Nickel acetate and hydroxycarbonate are both used in electroless nickel plating, and therefore more widely used in the electronics industry. Nickel dinitrate is only used in passivates, primarily in the automotive industry.

The figure below estimates the distribution of nickel chemicals across market sectors (Distribution in % of the uses of nickel compounds across market sectors; source: Nickel Institute from Rowan technology Group, 2013)

	aerospace	**automotive**	**consumer products**	**electronics**	**industrial equipments**	**other**
Ni acetate	5	30	3	27	22	13
Ni dichloride	5	44	16	5	15	15
Ni dinitrate	9	75	12	1		2
Ni hydroxy-carbonate	20	30	2	19	19	12
Ni sulphamate	11	28	2	34	13	14
Ni sulphate	**21**	**39**	**9**	**4**	**13**	**15**

The nickel plating sector is dominated by small and medium-sized enterprises (SMEs). The Nickel Institute estimates that in 2010, the EU nickel plating industry accounted some 2,000 companies, standing for 59,000 jobs across Europe. The nickel plating sector is mainly concentrated in following countries:

- Germany: around 500 companies (mostly SMEs, more than 1,000 manufacturing companies have their own in-house plating plant; Germany is by far the biggest metal finishing chemicals market in Europe),
- Italy: around 250 companies (the vast majority of which are SMEs),
- UK: nearly 250 specialist UK surface engineering companies, all are SMEs,
- France: nearly 200 specialist FR surface engineering companies, all are SMEs,
- In the last decade, some new Member States such as the Czech Republic have emerged as significant nickel chemicals users for plating due to their developing car industry

2.3.2.2 Description of the surface treatment technologies/processes

From all existing electroplates (including nickel, chromium, zinc, gold, etc), zinc is the most widely used (in term of tonnages) for galvanizing but nickel is considered as the basis for a very large number of other secondary coatings. Nickel sulphate and nickel chloride are the most used nickel compounds in nickel plating.

The three most common techniques in surface treatments involving nickel are nickel electroplating (without topcoat, with chromium topcoat or with other topcoats such as gold, silver or brass, plus composite electroplating such as nickel with silicon carbide), nickel electroforming and nickel electroless plating. Within these categories, there are two basic processes by which nickel metal can be deposited from aqueous solutions containing Ni^{2+} cations: electrolytic deposition via a direct electrical current and electroless deposition where the Ni^{2+} ions are reduced to the zero valent metallic state by chemical agents added to the solution. In addition to these processes, nickel is also used in surface treatment through composites and alloys, such as with cadmium or zinc.

Nickel electroplating

Nickel electroplating involves the deposition of nickel using a direct electrical current flowing between the anode (e.g. a sacrificial nickel metal plates or slabs that is dissolved in a electrolyte) and the cathode (article to be plated) which are immersed in an electrolyte solution (bath) containing dissolved nickel salts in addition to the nickel coming from the anode. There are three water-soluble salts used predominantly in electrolytic (and also electroless nickel plating, see below) that account for probably

95%, or more, of the nickel compounds employed: nickel sulphate, nickel chloride and nickel sulphamate. Nickel sulphate is the most used salt; it is the less expensive nickel source and the related sulphate anion has little effect on the deposit properties contrary to anions from other salts. The less soluble nickel carbonate is also used sometimes. There are four main types of nickel-sulphate-containing solutions used in electroplating: watts solution (240-300 g/L nickel sulphate, 40-60 g/L, nickel chloride and 25-40 g/L boric acid), hard nickel solution (180 g/L nickel sulphate, 30 g/L nickel chloride, 30 g/L boric acid), high chloride solution (200 g/L nickel sulphate, 560 g/L nickel chloride, 25-30 g/L boric acid) and high throwing power solution (30 g/L nickel sulphate, 38 g/L nickel chloride, 25 g/L boric acid). A chromium topcoat is commonly applied over the nickel layer to enhance corrosion-resistance.

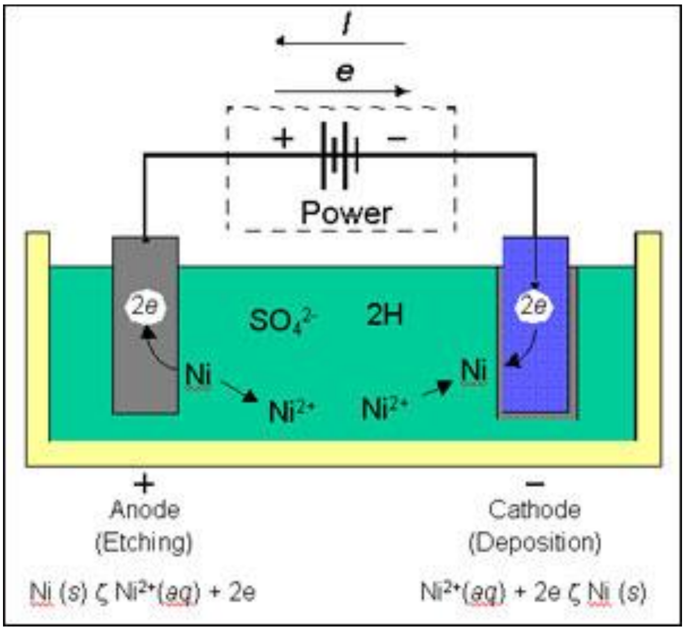


Illustration source: Sunder Sham Industries website

Nickel electroforming

Electroforming is a basic metal forming process producing or reproducing articles by electro-deposition upon a ‘mandrel’ or mould that is subsequently separated from the metal deposit. The process can reproduce fine surface detail with great accuracy. The coated layer is itself the product of the process. It is designed to be stripped from the substrate to make a nickel product. Advantages of this technique are the ability to make a product with intricate shapes (e.g., master moulds for disc and CD production) or with intricate patterns of holes (e.g., printing screens, sieves, electric shaver foils).

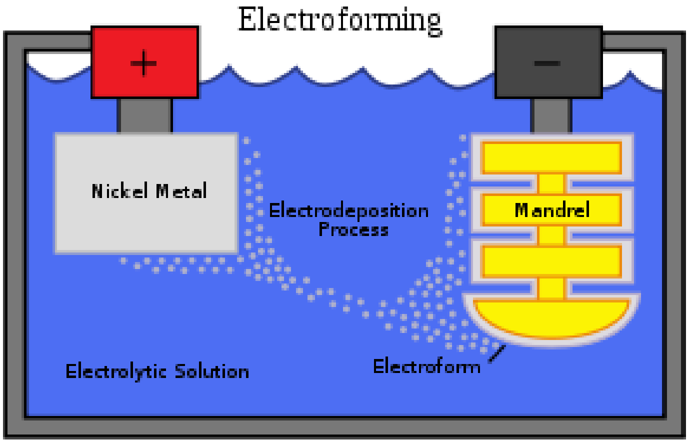


Illustration source: http://en.wikipedia.org/wiki/Electroforming

Electroless nickel plating

Electroless nickel plating (also called nickel autocatalytic plating or nickel deposition) is a process for depositing nickel metal from solutions containing nickel salts without the use of an electrical current. It includes the use of nickel strike solution for replacement coatings or for nickel flashing on steel that is to be porcelain enamelled. Items to be nickel-plated are catalytically prepared and immersed in a nickel-containing solution which is the source for nickel plating. Ni^{2+} ions in solution are reduced from the divalent ionic state to the zero-valent metallic state by the action of a chemical reducing agent, usually sodium hypophosphite. It is used to plate items that are non-conducting such as plastics, items with shapes that make uniform plating difficult and items with high specification engineering components. Other coatings (Ni, Cr, Au) can then be deposited on the nickel layer (substrate).

2.3.2.3 Description per application and/or per main activity sector

Nickel plating is used in a range of applications (electrical and electronics, printing applications, automotive, hygiene, currency/security applications - including hologram production, coinage and banknote production and also in decorative applications).

Global overview

The very common decorative nickel-chromium plating is extensively used for bathroom and kitchen fittings, furniture, the construction industry, the automotive industry and a host of applications in the electronics industry. With these applications, nickel plating provides users with attractive finishes, frequently complemented by improved wear and resistance to corrosion (typical examples include shower and bath fittings as well as decorative trim used in motor vehicles).

The automotive industry also uses zinc-nickel plating surface treatment on steel parts which have to be protected against corrosion. In the aeronautical industry, nickel surface treatments are used to resist high temperature corrosion and for large sections of aircraft wings.

In the electrical and electronics industry (including audio recording, CD/DVD production, computer hard drives and in shielding electronic equipment), nickel is precipitated onto aluminum or steel battery housings, connectors, transistor terminals and beds, semi-conductor components and in anti-corrosion base coatings on connectors.

In the textile industry, yarn guides, rollers and reel winders are nickel coated. In the printing industry a nickel layer is used to provide the necessary refinement and precision during screen printing. In the paper industry, rollers are nickel-coated too.

In the optical media industry (e.g. CDs, DVDs and Blu-ray discs), nickel (usually sulphamate) electroforming is used to the create "masters" that are used for mass replication/production.

It is expected that up to 2017, nickel plating will be dominated by two markets with more than 85% of the use of nickel plating: transport (automotive parts) and domestic and consumer applications. Around 70% of demand is predicted for "decorative" uses and the remaining 30% is predicted for "engineering" applications (with non-aesthetic properties).

Ni plating in electronics

One of the most important uses of nickel plating in the electronics industry is to create a diffusion barrier to prevent gold, tin and copper from diffusing into each other, leading to failure of chips, connections and circuit boards. Nickel sulphate is particularly used in electroless plating technology for chip assemblies, printed circuit boards and electrical connectors.

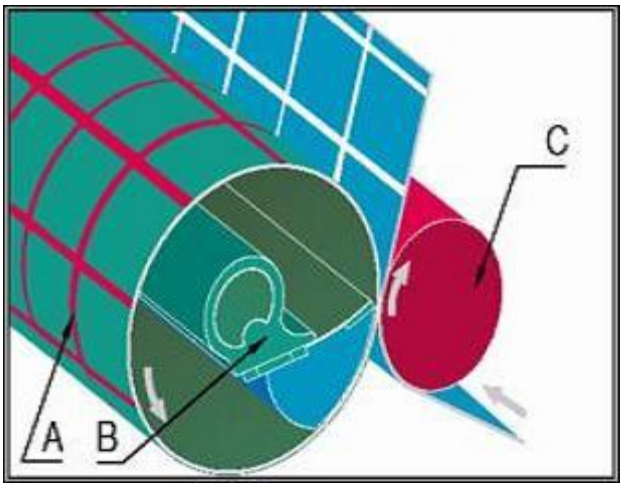
The electronics industry has been driven by the need to meet RoHS requirements, particularly the requirement for lead-free solder. According to Industry, it is still not clear that the available lead-free solders can meet the strict reliability and safety requirements of the aerospace and defense industries. The use of nickel diffusion barriers has grown with the advent of lead-free solders because the solders have higher melting points, which greatly increases inter-diffusion between copper and gold during wave soldering.

Nickel plating is also used in electrical connectors for critical applications such as aerospace and defence. Connectors are typically made of aluminum or steel, coated with a thin layer of nickel for corrosion resistance and adhesion, overcoated with cadmium plate for corrosion resistance and galvanic compatibility, and passivated with chromate. Some electrical connector companies are now attempting to eliminate the use of cadmium, and are replacing it with either electroless nickel-PTFE or with zinc-nickel electroplate.

Ni plating in machinery

Because industry is moving toward increasing automation and electronics, including networking and remote troubleshooting, there is increasing use of automatic systems with more sensors, most of which involve the use of electronic systems which require nickel coatings.

The production of printing rotary screen cylinders is the single largest application of nickel electroforming and is the main technology used to print textiles, wallpapers and carpets world-wide. The annual tonnage used is low. The only EU producer of rotary screen printing cylinders, [confidential] in the Netherlands, uses [confidential] tons of nickel and [confidential] tonnes of $NiSO_4$ per year (over the last three years); a similar demand for $NiSO_4$ is predicted in the future. Nickel screens lay thin layers of ink, or other materials and are extensively used to print textiles ([confidential] of endmarkets), graphics (e.g. product labels and packaging) ([confidential] of endmarkets) as well as other industrial products (e.g. printed electronics, antennae for RFID tags, solar cells and medical diagnostic strips). Rotary screen printing cylinders are manufactured from 100% nickel using an electroforming process involving the use of $NiSO_4$ (nickel chloride and nickel sulphamate are also reported in the SEA for such manufacturing).



A: screen plate, B: squeegee, C: Impression roller

Illustration source: http://www.rnp-automation.com

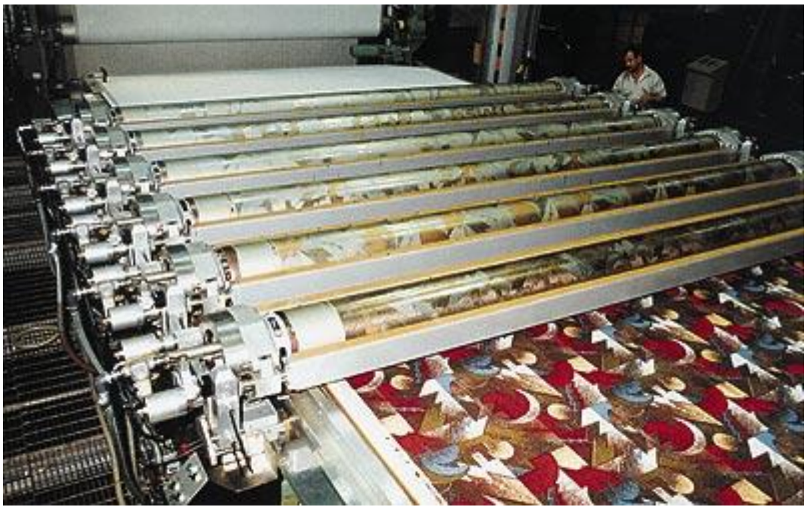


Illustration source: http://www.mitter-mmb.com/textile/rotary-screen-printing.html

This sector stands for about [confidential] jobs in the EU (around [confidential] direct and [confidential] indirect).

Ni plating in consumers goods

The consumer market has traditionally used decorative coatings such as electroplated nickel and bright chromium which uses a nickel underlay and also electroless nickel decorative plating on plastics and composite material.

In electroplating, nickel is rarely used on its own for decoration but typically used as a substrate for a top-layer of another metal, such as chromium or gold. The nickel under-layer is self leveling, with the result that a mirror like finish is achieved when the top layer of chromium is applied. However, without the chromium (or other) top-layer, nickel would tarnish and require frequent polishing; without the nickel base layer, the chromium top-layer wouldn't be able to provide the mirror effect.

In the bathroom fittings application (taps and showerheads mainly) which uses [confidential] tons per year of nickel in Europe, nickel surface treatment provides the following five key functions:

- decorative effects (nickel plating provides an aesthetically finish to the substrate, providing the characteristic colour and shine associated with bathroom fittings),
- corrosion protection (it protects the underlying substrate material - e.g. brass, steel and plastics with an even corrosion resistant coating),
- durability (resistance to scrub and UV radiation especially for plastic fittings),
- recycling of substrate materials,
- hygiene benefits (plated surfaces have anti-microbial properties that inhibit the growth of microorganisms such as bacteria and fungi).

According to the Nickel Institute, this sector accounts for 2,500 manufacturers in the EU and 154,740 jobs. However, it has to be noted that these figures might be overestimated since they cover all types of bathroom fittings (nickel-coated and others).

Ni plating in automotive industry

Nickel plating has always been used as a corrosion-resistant leveling layer (to make the top coat smooth and reflective) whenever a decorative coating such as bright chrome is used. It is used in automobile components such as gears, bearings, hydraulic brake pistons, thrust washers, heat sinks, and other areas that require good corrosion or wear resistance. For corrosion resistance on components such as screws, automotive industry uses electroplated Zn/Ni and metal-flake filled polymers.

With the development in the use of plastics to save weight and increase fuel efficiency and electroless nickel use is used as a "strike layer" for plastics.

Since the introduction of Directives End of Life Vehicles and RoHS the automotive industry has adopted compliant coatings for corrosion resistance on fasteners. The primary electroplate for this purpose is Zn/Ni which combines corrosion resistance with better wear and abrasion resistance. NiSO4 is used in this type of Zn-Ni alloy within an alkaline process.

Ni plating in aerospace

Nickel plating is used in the aerospace sector both for electronic equipments and structural pieces and fastenings, both in the aircrafts manufacture and maintenance. Processes involving $NiSO_4$ are the following: brightening of cadmium plating, electroforming, pre-nickel plating before electrolytic deposition on stainless steel, electrolytic plating (including fitting), zinc-nickel deposition, nickel plating-PTFE, nickel plating-phosphorus, nickel electroless plating, ionic nitriding.

A very large number of the aluminum struts and bulkheads that make up the frame of an aircraft are anodized to improve their corrosion resistance and prevent major structural failures initiated by corrosion of these high-strength aluminum alloys. Because of their porosity, these coatings are always protected with corrosion-resistant chromates (using chromium trioxide and sodium dichromate); but under current regulations such as REACH and RoHS, aircraft manufacturers and users are moving toward chromate-free alternatives i.e. nickel-based coatings (zinc-nickel, nickel-PTFE, nickel-phosphorus) using $NiSO_4$ but also nickel acetate or electroless nickel plus electroplated alkaline Zn/Ni with non-chromate passivation.

Regarding electronic equipments, aerospace industry declares to be dependent upon all of the uses of nickel salts. Electroless nickel-PTFE is used in place of cadmium on the many electrical connectors used throughout an aircraft. Industry is moving to composite connectors to save weight, but composites must be coated to prevent radio frequency interference: electroless nickel is required as the initial layer since composites are insulators.

Nickel plating is used for the maintenance of safety-critical aircraft components, which must be kept in good condition, with the correct dimensions and tolerances. Components that have suffered damage from corrosion or wear are rebuilt to initial specification with sulphamate nickel electroplate and hard chrome plate, to put them back into certified service condition. Nickel strike layers are widely used in order to ensure good adhesion of additional coatings to the many different materials used in aircrafts.

2.3.2.4 Analysis of alternatives

The analysis of alternatives reported below has been carried out by the Nickel Institute in the framework of a socioeconomic analysis (SEA) based on internal reviews and reports as well as available literature[14]. **Again this information has not been peer-reviewed or challenged and shall thus be considered as the Industry point of view; it has been aggregated, interpreted and summarized by Anses.** It would be similar or close to the information that would be provided in a formal application for authorisation.

In theory at least, several possible types of alternative can be envisaged

- ‘drop-in’ substances that directly replace $NiSO_4$ in the same production process without change (except minor changes),
- alternative substances (metals) or combinations of substances that would replace nickel (partially or totally) but would require some modifications of the process,
- alternative materials that would not use nickel in the manufacturing of the same end-product,
- the use of alternative processes/technologies.

Alternative materials (stainless steel, porcelain, plastics, etc.) are not developed further here since their relevancy can only be assessed on a case by case basis which is impossible in a RMOA.

The main technical properties which relate to the specific use of nickel and which would still be expected from a substitute are the following (amongst other specific properties for each application): hardness; resistance to wear and tear; levelling power; anti-diffusion barrier layer (no galvanic coupling); anti-corrosion; post-thermal shock corrosion resistance; hot use; electrical conductivity (essential in connection to technology to prevent electrical breakdown problems in the automobile and aeronautical industry);

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[14] Hart A. 2011. Substitution issues related to the use of nickel in electrolytic and electroless surface engineering processes. Transactions of the Institute of Metal Finishing 89 (4): 181-186

bonding; magnetic shielding; improved enamel adherence; penetration rate; ductility; colour stability; and faithful reproduction of fine details.

The main aesthetic properties which relate to the use of nickel are: brightness, colour and optical absorption. These properties refer to the nickel metal present in the finished product and synthesised by means of different nickel salts, more particularly, nickel sulphate, nickel chloride and nickel sulphamate.

'Drop-in' substances

Generally speaking, soluble nickel salts can be substituted for each other, but present the same hazard profile therefore without any risk reduction benefit. A number of other nickel salts have been used as intermediates in specialised electroless and electrolytic applications: nickel acetate, nickel fluoborate, nickel hypophosphite and nickel methanesulphonate. However this theoretical substitution is not always feasible in several processes.

When dissolved in water all of the seven soluble nickel compounds listed (the four listed above, plus nickel sulphate, nickel chloride and nickel sulphamate used predominantly in electrolytic and electroless plating) produce highly dissociated solution of the divalent nickel cation and the appropriate anion. Nickel acetate is also used in electroless nickel formulations since the acetate anions can also act as a complexing agent for Ni^{2+} ions.

However salts in which the Ni^{2+} ion is strongly complexed cannot be used in nickel plating. Nickel cyanide, for example, has an extremely low dissociation constant and is almost completely insoluble in water. Nickel nitrate, although highly soluble, is not used for nickel plating because of the undesirable reactions of the nitrate anion.

The nearest equivalent to the Watts bath that is used extensively in nickel electrodeposition is the nickel sulphamate solution where the $NiSO_4$ content of the solution is substituted by nickel sulphamate, usually in similar concentrations. Sulphamate-based solutions produce nickel deposits with a much lower internal stress than those deposited from the Watts bath and the electrical conductivity of the sulphamate bath is inherently higher than sulphate-based solutions. The main reason why these processes are not more widely used is that nickel sulphamate is more expensive than $NiSO_4$.

Other nickel salts used in surface treatments such as chloride could be substituted for $NiSO_4$ in some areas of the superabrasives industry, but $NiSO_4$ has no substitutes for the diamond adhesion phase.

Therefore the substitution between nickel salts would not be technically feasible in all situations.

Nickel may be potentially substituted with cobalt salts, cobalt alloys and chromates for plating using same processes. However cobalt and chromate salts are already listed as candidates for authorisation under REACH. As such these substitutions would not result in a reduction in the risk to human health and are not developed further.

Alternative substances or combinations of substances

Relatively few of the metallic elements in the periodic table can be electrodeposited from aqueous solutions and even fewer can be deposited by electroless processes. There are only five metals that are commonly electrodeposited commercially in large quantities: chromium, nickel, copper, zinc and tin. Of these only nickel and copper can be deposited by electroless processes. There are only about nine other metals that have been deposited on a commercial scale, albeit in much smaller quantities: cadmium, cobalt, iron, lead, manganese, indium, gold, silver and platinum.

Iron and tin can in certain specific cases be considered to be potential substitutes, but nickel is always necessary when the abovementioned technical characteristics, such as durability, hardness, high corrosion resistance and capability to withstand high temperatures are required. Alternatives such as cobalt or cadmium have been ruled out because of their similar hazard profile or their inferior technical properties. Lamellar zinc does not enable uniform treatment of small parts and irregular shapes respecting the hollows and spacing. This would furthermore lead to the use of less efficient processes associated to higher energy uses.

Many metals in common commercial use cannot be deposited from electrolytic or electroless processes including: aluminium, molybdenum, titanium, tungsten, vanadium and zirconium. There are some specialised techniques available for the deposition, for example of aluminium. However, these involve very complex materials, processes and equipment which mean that they cannot be used for general commercial metal deposition. An examination of the properties of those metals that can be readily deposited on an industrial scale reveals that none of them exhibit the combination of chemical and mechanical properties shown by nickel.

Stainless steel however may be an appropriate alternative to bright nickel plating of bathroom fittings, without exactly the same final aesthetic effect.

Alternative processes/technologies

Recent technological developments demonstrate a growing trend towards an exploration of new techniques like vacuum surface treatments (e.g. evaporation, spraying or chemical / physical vapour deposition - PVD). PVD has some applications in the automotive industry, for example in the manufacture of reflectors. However, these are enclosed and not directly exposed to wear or the weather because PVD coatings are by their nature very thin and do not provide adequate corrosion protection; they are not suitable for applications with a need for good wear resistance and durability. High temperatures may make it incompatible with some materials. At this stage, only big companies can afford to implement this type of surface treatment enabling the use of processes not involving nickel salts. The costs are considered prohibitive for SMEs. In addition, while these processes are considered to be safe in use, cleanup and maintenance must take place in extremely strict conditions because of the fume hazard. These processes are not always appropriate for parts with particularly sophisticated shapes.

Pigments are also used with metallic appearance and powder coating systems for polymers. Such pigments are used in the automotive industry, but have poor wear resistance compared to electroplated nickel. Hence they are only suitable for applications where there are no concerns about wear and durability.

Powder coating of metals is an already implemented technology and a suitable alternative for customers that want a finish that is different to bright chrome or equivalent finish, but without wear resistance requirements.

The “alternative to alternative” issue

Due to the progressive ban of cadmium and chromate plating under current environmental legislation, aircraft and vehicles manufacturers are now replacing the use of cadmium plating and chromates for corrosion resistant coatings by electroplated Zn/Ni and by electroless nickel composite coatings (electroless nickel with PTFE, SiC, diamond, etc.) as the only available drop-in cadmium alternative.

In order to maintain the safety of aircraft electrical systems, which have always depended on chromate converted cadmium to maintain electrical continuity under corrosive attack, several connector suppliers now supply connectors protected with electroless nickel-PTFE and connectors with Zn/Ni coatings. The entire connector industry is therefore moving toward electroless Ni-PTFE and Zn/Ni in order to meet the strict functional requirements for aircraft connectors without the use of Cd, but the benefit of hindsight is still lacking.

Chromium plating has always been used by the aircraft industry to protect flight-critical moving components such as landing gear and hydraulic actuators, as well as to refurbish them when they become scratched, corroded or worn. Because of the increasing restrictions on the use of chromate compounds under REACH (especially chromic acid), aircraft manufacturers and overhaul companies have begun to adopt electroless nickel for its combination of corrosion and wear resistance.

2.3.2.5 Analysis of alternatives per main activity sector or applications

Substitution in decorative applications

As regards plating for decorative purposes in particular, alternative metals could replace nickel: steel, copper, zinc, aluminium, white bronze and palladium.

Over stainless steel, the use of plating based on zinc alloy seems to be rather common to protect against corrosion but does not provide the same brightness as nickel plating in the long-term, due to technical difficulties to add a finishing topcoating. A difference in color is also observed with the use of white bronze alloy. Copper alloys are technically feasible but show a reduced resistance to corrosion and detergents use. This is particularly the case for bathroom and kitchen fittings (taps, showerheads, etc.). In such alloys, copper can be covered by white bronze but is not resistant to high temperature (above 400°C). Moreover, although white bronze is cheaper than nickel, plating based on copper/white bronze alloy might be in the end more costly due to the higher amount of chemicals need. Copper can also be topcoated by palladium which allows a very good protection but its use seems to be technically difficult and largely more expensive. Finally, over plastic, zinc (zamak) and aluminium, white bronze may also be an alternative but the corrosion resistance is weak, especially for outdoor uses. As a whole, for decorative applications, some alternatives seem to exist, at least for some treatment techniques and are not necessarily more costly. The nickel plating used for sanitary fittings seems to be the most difficult to substitute due to important constraints of use (corrosion, detergents, etc.).

As a whole, the replacement of nickel plating with plating made of alternative metals does not seem to meet the requirements searched for decorative applications. Some manufacturers seem to produce some coloured nickel-free sanitary fittings but the sales volumes are relatively low. Finally, other materials could be alternatives such as the use of plastic or porcelain but the final products and the end-use markets would be very different. According to industry, the present demand for that kind of products is much lower than the demand for nickel-chromium plated products. However, the argument of industry about consumers' preferences for nickel-chromium plated products (e.g. nickel-chromium plated bathroom taps) is not supported by any objective data or indicator in their analysis of alternatives. The assumptions that these products meet an exclusive market demand or that the demand would not be transferred to alternative products in case of $NiSO_4$ ban or limitation in use are thus questionable.

Substitution in the automotive sector

Nickel salts, and in particular $NiSO_4$ are already used as substitutes for chromium in automobile sector related applications.

Research is underway in order to use pure alkaline zinc instead of nickel-zinc in electroplating process. However, some significant technical problems, such as the necessary degree of corrosion prevention, have not yet been resolved. To reach the same degree of quality, a thicker layer of plating would be needed e.g. (30µm vs 8µm) which would make the process more difficult to achieve and increase the production cost. This research would require at least another three to four years work as well as validation to meet the required safety standards. Likewise, the plating based on Tin/Zn alloy could be efficient but only with a high share of tin, between 60% and 90%. The process would be made more difficult and although the prices of tin and $NiSO_4$ are similar, the production cost would be higher since a relatively larger proportion of tin would be needed. Other alternative alloys such as zinc/steel alloy, based on non-electrolytic plating techniques or sherardisation (projection of melted zinc powder), or treatments with phosphates, aluminium and dip-spin coatings are also presented by industry as potential substitutes but without further detail. The sherardisation does not seem to provide sufficient anti-corrosion property and non-electrolytic plating based on Zn could be applied without extra production cost but with a problem of thickness for some uses.

Regarding the Nikasil technology, it is used on automotive niche markets (mainly for aluminium pieces of powerful motors for race cars e.g.) and no alternative seems to be available for that specific use.

Finally, electroless nickel plating is being developed for the surface treatment of pieces with complex shades used to reduce cars weight, in replacement of nickel electroplating in automotive industry. This is not a chemical substitution since $NiSO_4$ is still used in the plating process but it shows the advantage of being totally automated. However, electroless plating for that application seems to be more costly and might reveal some anti-corrosion failures.

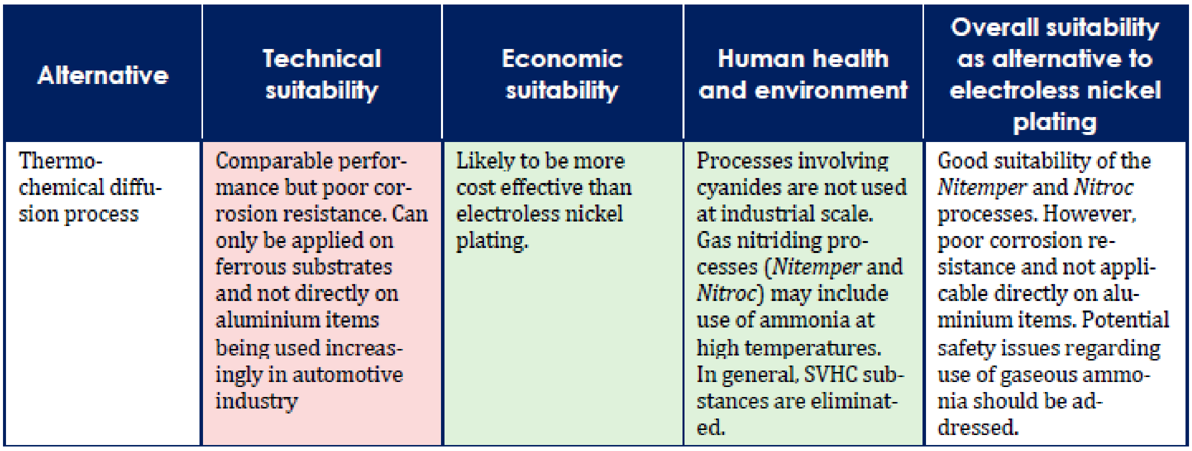
Tables 10 and 11 (from the Nickel Institute) provide an assessment of alternative technologies in the automotive sector. Note that the hazard of the alternative substances (based on the CLP classification) is dated 2013 and may have been updated recently.

Table 10. Assessment of alternative technologies relative to zinc-nickel plating within the automotive industry

Alternative	Technical suitability	Economic suitability	Human health and environment	Overall suitability as alternative to zinc-nickel plating
Zinc plating	Lower corrosion resistance. To compensate for this, increased layer thickness is required to achieve same corrosion resistance. The thickness may be a limitation for some uses.	Increased production costs as thicker layer and thus material and process time are needed. This reduces the capacity of the production equipment.	Less hazardous raw materials. SVHC substances eliminated.	Not suitable due to lower technical performance and increased costs of production.
Tin-zinc plating	Good corrosion resistance at high tin content. Process more difficult to operate.	Increased raw material costs as high tin content is needed.	Toxic potassium cyanide is used in some bath types. However cyanide free alternatives are available. SVHC substances are eliminated.	Less attractive from an economic point of view due to market prices of tin.
Non-electrolytic methods - zinc plating	Technically feasible at high thicknesses. Less adhesion than the electrolytic plating.	Cost effective at a thickness of 25-30 µm.	Less hazardous raw materials. SVHC substances eliminated.	Not technically suitable due to poorer adhesion.
Non-electrolytic methods - sherardizing	Lower corrosion resistance compared to zinc-nickel. Coating forms red corrosion products. Good adhesion and comparable durability.	Cost effective for thickness of 25-30 µm.	SVHC substances eliminated.	Corrosion resistance is lower than that of zinc-nickel plating.
Non-electrolytic methods - dip-spin technologies	Simple process with comparable performance. Not applicable for complex geometric shapes and small items. Less adhesion than the electrolytic plating.	Cost effective.	SVHC substances eliminated.	Not generally suitable due to poorer adhesion. Limitations regarding the geometry and size of the coated items.

Source: Nickel Institute

Table 11. Assessment of alternative technologies relative to electroless nickel plating within the automotive industry



Alternative	Technical suitability	Economic suitability	Human health and environment	Overall suitability as alternative to electroless nickel plating
Thermo-chemical diffusion process	Comparable performance but poor corrosion resistance. Can only be applied on ferrous substrates and not directly on aluminium items being used increasingly in automotive industry	Likely to be more cost effective than electroless nickel plating.	Processes involving cyanides are not used at industrial scale. Gas nitriding processes (*Nitemper* and *Nitroc*) may include use of ammonia at high temperatures. In general, SVHC substances are eliminated.	Good suitability of the *Nitemper* and *Nitroc* processes. However, poor corrosion resistance and not applicable directly on aluminium items. Potential safety issues regarding use of gaseous ammonia should be addressed.

Source: Nickel Institute

As a whole in the automotive industry, some alternatives seem to be available but according to the assessment provided by Industry, these alternatives fail to be efficient or affordable substitutes, particularly when security is required. However, some alternatives could be possible when security requirement is not at stake (such as zinc/steel alloys). Generally speaking, the substitution possibilities in this sector can thus be deemed low. Nonetheless, given the lack of details supporting this assessment and given that it has not been challenged, it is hard to draw a clear-cut conclusion on the alternatives for this sector.

Substitution in the aerospace sector

Within the aerospace sector, the use of nickel plating is increasing due to the need for substituting cadmium (replaced mainly by zinc-nickel alloys within electrolytic processes) and hard chromium (replaced by electroless nickel plating or nickel composite plating). This sector is subject to strict safety requirements; the implementation of new surface treatment techniques is thus time-consuming. Furthermore, nickel based surface treatments often remove the need to paint certain components such as reactors, while ensuring increased hardness and resistance.

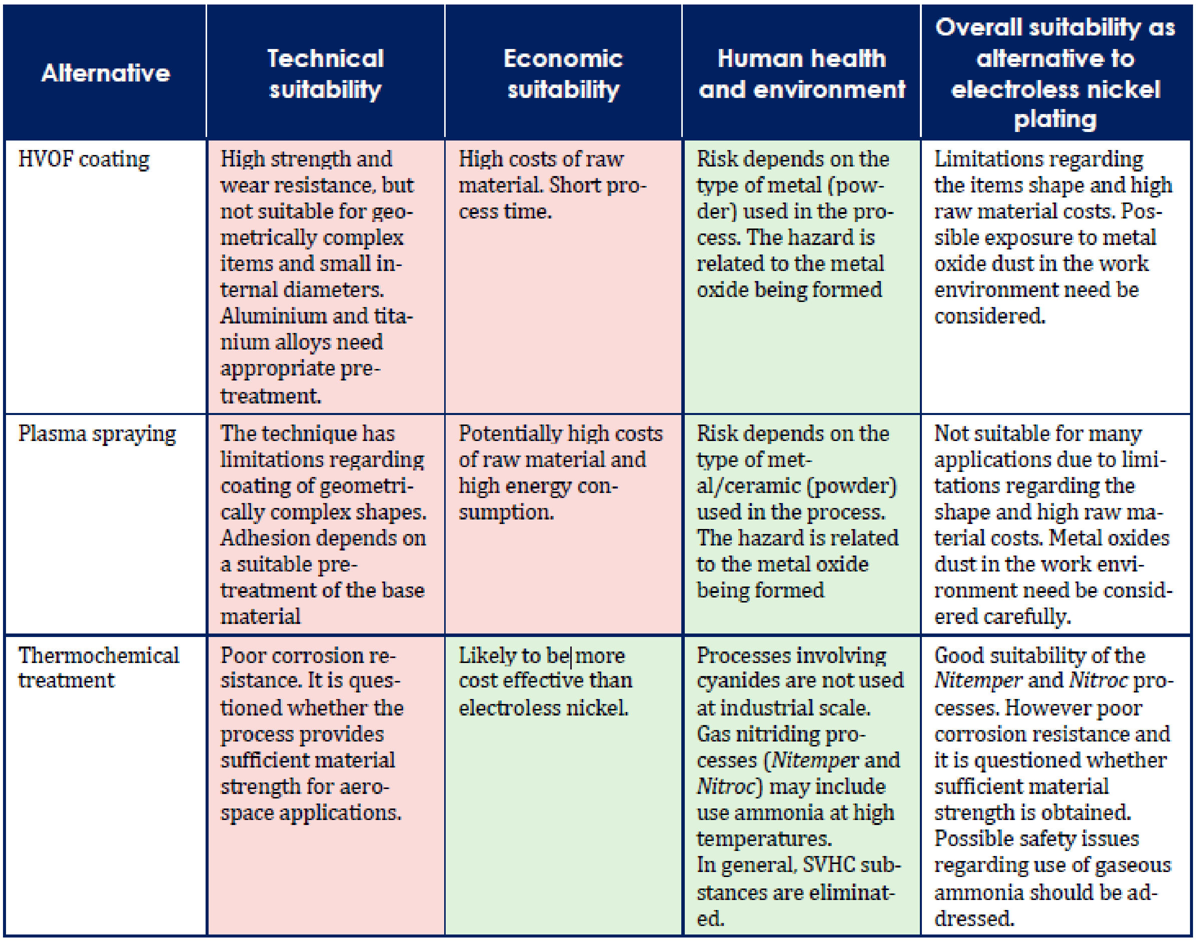
The electroless nickel plating is growingly used to replace hard chromium in order to get uniform layer over pieces of complex forms. Nickel sulphate is used in acid baths and nickel chloride in alkaline baths. The production sites are not fully automated to date but could be, according to industry. However, there does not seem to be available chemical substitution to replace nickel in a suitable way. The treatment based on HVOF, plasma spraying or thermo-chemical treatments do not seem to meet the properties required.

The electrolytic nickel plating based on zinc-nickel alloys is increasingly used to replace cadmium but the operations are not fully automated. No chemical substitution is yet available to replace nickel in a suitable way according to industry. Plating based on pure zinc encounters the same difficulties as for the automotive industry (problem of thickness, anti-corrosion and cost). In the US aerospace industry, electroplating based on aluminium seems to be used but this type of alloy has not been authorized in the EU so far. Moreover, treatments based on metallic ceramics can also be used to replace cadmium but they still contain some Chromium VI traces; some R&D programs are being developed to remove these traces.

Nickel electroforming is also used to plate some pieces but it seems to concern much more nickel sulphamate than $NiSO_4$. This use is marginal but regards key components which ought to be of very high quality.

Table 12 (from the Nickel Institute) provide an assessment of alternative technologies in the aerospace sector. Note that the hazard of the alternative substances (based on the CLP classification) is dated 2013 and may have been updated recently.

Table 12. Assessment of alternative technologies relative to electroless nickel plating within the aerospace industry



Alternative	Technical suitability	Economic suitability	Human health and environment	Overall suitability as alternative to electroless nickel plating
HVOF coating	High strength and wear resistance, but not suitable for geometrically complex items and small internal diameters. Aluminium and titanium alloys need appropriate pre-treatment.	High costs of raw material. Short process time.	Risk depends on the type of metal (powder) used in the process. The hazard is related to the metal oxide being formed	Limitations regarding the items shape and high raw material costs. Possible exposure to metal oxide dust in the work environment need be considered.
Plasma spraying	The technique has limitations regarding coating of geometrically complex shapes. Adhesion depends on a suitable pre-treatment of the base material	Potentially high costs of raw material and high energy consumption.	Risk depends on the type of metal/ceramic (powder) used in the process. The hazard is related to the metal oxide being formed	Not suitable for many applications due to limitations regarding the shape and high raw material costs. Metal oxides dust in the work environment need be considered carefully.
Thermochemical treatment	Poor corrosion resistance. It is questioned whether the process provides sufficient material strength for aerospace applications.	Likely to be more cost effective than electroless nickel.	Processes involving cyanides are not used at industrial scale. Gas nitriding processes (*Nitemper* and *Nitroc*) may include use ammonia at high temperatures. In general, SVHC substances are eliminated.	Good suitability of the *Nitemper* and *Nitroc* processes. However poor corrosion resistance and it is questioned whether sufficient material strength is obtained. Possible safety issues regarding use of gaseous ammonia should be addressed.

Source: Nickel Institute

As a whole, in the aerospace industry, some alternatives seem to be available but according to the assessment provided by industry, they all fail to be efficient or affordable substitutes. However, the possibility to reach a full automation process in the near future is a major step for reducing the occupational exposure. This implementation may nevertheless be questioned for SME that are subcontractors and/or main contractors for high quality or high specific platings (very low volumes). Today, in the aerospace sector, the substitution possibilities can thus be deemed very low.

The substitution in nickel-electroformed applications

As already mentioned, some applications are plated based on electroforming process. This is the case of the production of printing rotary screens for industrial uses. $NiSO_4$ is used in that particular case for high precision (microns holes), high surface quality, durability (wear protection), reliability (chemical resistance against staining) and speed of the printing process.

Regarding 'drop-in' substances, alternative technologies explored include the use of metals such as iron (Fe), copper (Cu) and zinc (Zn), either alone or in combination, [confidential] With the exception of nickel sulphamate, nickel chloride and nickel acetate it is questionable to what extent most of these alternatives can be considered true drop-in substances as the composition of the final product is significantly changed by their use. [additional text confidential]

Regarding the use of alternative printing processes, none of the available technologies are considered suitable by the Industry because they cannot produce prints of the quality and precision required, or the speed of processing is too slow; use of any radically different printing process would require the complete replacement of printing machinery.

In conclusion it appears that alternatives (nickel-free alloys) may exist but not considered feasible because of lower performances and technical barriers. Other technologies may already be available with some economic drawbacks.

Conclusion on the analysis of alternatives for metal treatment

The review on alternatives provided by the Industry show that few alternatives / substitutes already exist for limited uses or are in development and could be released at short or medium term, but Industry often highlights that durability issue and lack of corrosion resistance remain as the most important weaknesses.

The drop-in substitution between nickel salts or with other hazardous substances is not suitable given the similar hazard properties that would not allow a reduction in the human health risk.

The most promising options with alternative technologies are PVD and powder coating, but only for decorative purposes although the demand from consumers is low, especially in a market trend that is dominated by nickel-chrome plating because of customers' preferences and habits. In the bathroom fittings market, stainless steel is the most promising and already available alternative across the full range of technical and aesthetic functions provided by nickel-based plating; however manufacturers may not consider it economically feasible to change to production of goods based on stainless steel outside of their normal investment cycle, as this might in many cases require a complete change in manufacturing process.

Alternatives in activity sectors where security is a prerequisite (such as the aerospace and automobile sectors) are not available and may need extended R&D and then testing against specifications which may thus require several years. It is not known yet if the current R&D will be able to solve several tricky issues (especially corrosion protection for both electronic and structural elements) and if solutions will meet the expected standards. In parallel, Industry considers the possibility to reach a full automated process for electroplating which would represent a real improvement in reducing occupational exposure to nickel salts. This is however questioned if all contractors and especially SMEs would be able to support the costs of the automation considering that the electroplating market is highly price competitive; automation may thus cover the major part of the electroplating production but not all.

Where security is not the main issue, alternatives may already exist and may be implemented more easily and faster, once the remaining technical barriers are removed. Indeed, e.g. for bathroom fittings (corrosion treatment as well as decorative purposes), some technical barriers remain and provided that some compromise in the appearance of the final product is accepted, the substitution is to some extent possible. In the case of automobile sector (corrosion treatments), technical barriers also remain but when it comes to security-unrelated issues, substitution possibilities exist. However, although the security is not at stake, in the case of printing rotary screens (anti-corrosion as well as quality and precision properties), the substitution seems to be impossible.

As a whole, based on the reports and analysis of alternatives provided by Industry, an overview of the substitution possibilities can be drawn, such as abovementioned and presented in the table below.

Table 13. Substitution possibilities per activity sector according to Industry

$NiSO_4$ metal surface treatment	**Substitution possibility**
Aerospace sector	Very low possibility
Automotive sector	Low possibility (*very low* for security property and *possibility* for not security-related properties)
Decorative coatings sector	Possibility
Rotary screens sector	Impossibility

Regarding the economic issue often raised by Industry, it is assumed that the cost of the relevant alternatives will decrease once the technology is adopted and widely implemented by Industry.

Regarding the weight of the current customers' preferences for the nickel based aesthetic properties (mirror effect allowed by the nickel layer) in decorative applications, it is not clear if available substitutes (stainless steel bathroom fittings) may efficiently compete with imported nickel electroplated fittings.

2.3.3 Batteries manufacturing

The industrial battery market is a global market with over a hundred manufacturers located across the world. The vast majority of these manufacturers concentrate on the lead/acid technology which dominates the market with approximately 90% of the market share. Only a minority (approximately 20 legal entities worldwide) operate in the high performance industrial battery market (including, but not limited to Ni-based batteries).

The main types of batteries available on the current market of rechargeable battery are the following: lead-acid, nickel-cadmium (NiCd), nickel-metal hydride (NiMH), Lithium-ion (Li-ion), sodium-based and the lithium-polymer technology. Nickel is used in the nickel-cadmium (NiCd), nickel metal hydride (Ni-MH) and also lithium-nickel batteries (one of the available Li-ion technologies uses $LiNiO_2$ as raw material); Li-ion also uses zinc and cobalt oxides as raw material instead of nickel. The technologies that have disappeared so far are nickel-iron (Ni-Fe), nickel-zinc (Ni-Zn) and nickel-hydrogen ($Ni-H_2$).

In Europe $NiSO_4$ is only used for the manufacturing of one type of NiCd battery (pocket plate technology).

2.3.3.1 Battery technologies and related applications

Different manufacturers adopt somewhat different materials and procedures for making electrodes, but all of them share similar technologies for electrode manufacturing. Feed stocks used variously include nickel metal powder, black nickel oxide powder, nickel hydroxide particles, nickel nitrate crystals or solution, and nickel or stainless steel strips etc.

Lead-acid technology is an old, cheap, widely used and well experienced rechargeable battery technology. It is used in numerous industrial applications from back-up for uninterruptible power supplies and grid energy storage and for traction in battery electric vehicles. It is also used in the automotive battery market for starting, lighting and ignition (SLI) in conventional combustion engine vehicles (e.g. the familiar lead acid car battery).

Nickel cadmium (NiCd) batteries are essentially used for industrial standby (safety back-up) applications. The chemistry of NiCd is considered more complex than other Ni-based batteries and many years of development and continuous improvements lie behind the modern NiCd battery (much of this is empirical “company know-how” and is kept confidential). The segments in which NiCd batteries justify their much higher cost relative to lead acid are the critical uses in which valuable assets, processes or security/safety sectors and for cycling and rescue applications in severe environments with high stakes in reliability and security. These include back-up batteries for energy (electrical) and communication (IT and telecom) networks, as well as safety back up in the transportation sector (passenger aircraft manufacturers as well as high speed train manufacturers typically select Ni based batteries over lead/acid batteries, even with a much higher initial cost – by a factor of three or four).

Three types of NiCd batteries are distinguished based on the way electrodes are manufactured: pocket plate, sintered and plastic-bond / positive mousse electrodes.

In the pocket plate type, a perforated nickel-plated steel pocket is used to contain the active material, i.e. positive and negative electrodes that are produced from nickel sulfate[15]. [confidential] They are very versatile, can be designed both for energy and power as well as cycling and floating. The segments of choice for these batteries are stationary back-up for several industrial processes such as the oil and gas industry, as well back-up for several types of systems aboard passenger trains.

In the sintered type, a porous partially sintered nickel substrate is used. Electrodes are produced from nickel dinitrate [confidential]. Sintered negative electrode batteries are usually designed with high power characteristics with excellent cycling performance. This makes them a good choice for back-up of several types of systems aboard passenger trains as well as passenger aircraft. They are also used for back-up in several types of network. Costs are generally higher than pocket plate batteries.

Plastic-bond nickel electrode (PNE) and positive mousse electrode (PME) uses a plastic bonded structure manufactured from nickel hydroxide. In this instance nickel hydroxide is purchased directly from an external supplier, and neither nickel sulphate neither nickel nitrate is used in the process. [confidential] PME & PNE negative electrode batteries are often designed with excellent energy storage, floating and volumetric energy performance. This makes them a good fit for network back up in areas were the grid is of reasonable quality, such as base stations for telecom networks in many countries. Costs are generally higher than pocket plate batteries.

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[15] nickel hydroxide is the reactant material on the positive mass and is obtained by chemical reaction from nickel sulfate

All NiCd cells (i.e. battery element) are produced in Europe and then assembled into the final battery article either in Europe or worldwide. In Europe, $NiSO_4$ is only used to manufacture pocket plate NiCd batteries.

The technology of NiMH batteries is basically considered similar to NiCd batteries but the chemistry is technically less complex. NiMH use positive electrodes of nickel hydroxide similarly to NiCd electrodes, but the negative electrodes use a hydrogen-absorbing alloy instead of cadmium, being in essence a practical application of nickel–hydrogen battery chemistry. The rapid success of the NiMH technology is much due to its simple chemistry that made its adaptation into a battery technology rather straightforward. Energy density is higher than for NiCd batteries, but the cost of production is higher due to the rarity of the earth elements used for the metal hydride manufacturing and due to the need of electronic control. The operating temperature range is lower than NiCd batteries. NiMH batteries find applications in camcorders, mobile phones, computers and IT equipments.

Principles of Li-ion batteries are similar to NiMH cells but use lithium as energy carrier. In most commercial cell construction a lithiated cobalt oxide is used as electrode material corresponding to the nickel hydroxide in the NiMH cell. Other materials such as manganese oxide, nickel oxide or sulphur are also used. Despite a lower density, the Li-ion technology offers the highest energy densities by weight of all the commercial rechargeable battery technologies. Compared to NiMH the advantage is about 30%. Lithium-Ion (Li-Ion) is currently the dominant battery system for portable applications (e.g. laptop and mobile phone batteries). In other markets, lithium based batteries are essentially used in electric and hybrid vehicles, in grid energy storage as well as in satellite applications.

To avoid the liquid organic electrolyte, and to further increase the energy capacity, cells with polymer or gel type electrolytes, so called lithium polymer batteries, have been developed. This cell is also considered to be very competitive with the low-end-price batteries of today.

Sodium based batteries have a high energy density, long cycle life and can operate in harsh environments such as temperatures of -40°C to +60°C. For these reasons they are targeting applications such as energy grid storage, for the storing of energy from intermittent energy sources such as wind and solar-power.

2.3.3.2 European nickel-based battery manufacturers

The European production of NiMH and Li-ion batteries is not developed hereafter. Indeed $NiSO_4$ is not used for those batteries manufacturing and no information has been provided.

Within the EU, there are approximately 10 industrial battery manufacturers; two are subsidiaries of US corporations focusing on the lead/acid technology [confidential], five are essentially family owned by German/Austrian or Italian corporations [confidential] (not focused technology) and three have a significant presence in the high performance industrial battery market with non Pb/acid technologies (pocket plate and Ni-based included): [confidential]. [additional text confidential]. Several start-ups (approximately half a dozen) have also been established in the EU over the past few years but are not focusing on the industrial market.

[additional text confidential]. NiCd cells are produced for the industrial market only and are not produced anymore for "portable" batteries intended for the use in cordless power tools for which all NiCd batteries are imported, mainly from Asia. [additional text confidential].

[additional text confidential].

All [confidential] NiCd electrodes manufactured either from nickel sulphate, nitrate or dihydroxyde that are manufactured in Europe are assembled into the final article (i.e. the battery) either in Europe ([confidential]) or outside Europe where the market is on demand (especially in India and China where the rail sector is booming).

2.3.3.3 NiCd technology using nickel sulphate and used volumes

NiCd rechargeable batteries comprise cadmium (cathode) and nickel (anode) electrodes packed in an alkaline electrolyte. The surface of the nickel electrode which takes part in the electrochemical charge/discharge reactions is hydrated nickel oxide $Ni(OH)_2$, which is reduced to nickel(II)hydroxide (NiOOH). The hydrated nickel oxide at the anode is usually in powder form and is held in pocket plates or suspended gel or paste and placed in sintered or fibre electrodes. Depending of this form, nickel dihydroxyde is either purchased as such for electrode production (for PNE and PME electrodes) either produced by chemical reaction from nickel sulphate or nickel nitrate that are thus intermediates in the process. Nickel sulphate and nickel nitrate are produced on-site by leaching nickel matte with sulphuric or nitric acid.

[additional text confidential].

The selection of $NiSO_4$ for use in the negative electrode reflects many years of research into battery design; it is introduced in the negative electrode of pocket plate batteries to enhance several key parameters, with the following advantages:

- the addition of nickel cations and sulphate anions improves battery capacity by enhancing the conductivity of the negative electrode;
- $NiSO_4$ enhances battery capacity by increasing the surface area of the “grains” of the active material in the negative electrode; surface area is the key parameter affecting the amount of oxidation/reduction reactions that will occur upon charging and discharging the battery;
- $NiSO_4$ extends battery life by limiting crystal growth within the active material;
- use of $NiSO_4$ limits airborne dust release; by having the proper geometry of the grains, the amount of dust released during the process is greatly limited, thus ensuring a better quality workplace.

The manufacture of pocket plate batteries uses $NiSO_4$ in three processes (see table 11).

- Use 1: [confidential] of $NiSO_4$ ([confidential]) is used for surface treatment/electroplating of the current collector and various mechanical parts to prevent corrosion of positive and negative electrodes. Nickel sulphate is purchased from external supplier (because of the specifications on purity requirements) and used to prepare the Watts baths (together with nickel chloride and boric acid) for electroplating of connectors and other mechanical parts.
- Use 2: [confidential] (most of the total tonnage) of $NiSO_4$ ([confidential] t/y) is used as an intermediate in the manufacture of nickel hydroxide, the active material which is used in pocket plate positive electrode (cathode).
- Use 3: [confidential] of $NiSO_4$ ([confidential] t/y) is used as a reactant during the production of pocket plate negative electrode (anode).

The most relevant process step for the use of $NiSO_4$ is the active mass (positive electrode) production (uses 2) that uses over [confidential] of $NiSO_4$ produced on site. At later stages in the process [confidential] $NiSO_4$ is transformed into nickel hydroxide which is the final reactive nickel substance of the battery.

According to the provided data on the manufacturing processes, FR MSCA would consider the following intermediate status:

- Use 1 (surface treatment from $NiSO_4$) has to be considered as non-intermediate use according to ECHA guidance on intermediates use.
- Use 2 (nickel hydroxide production on the cathode from $NiSO_4$) has to be considered as an intermediate use.
- Use 3 (reactant substance for the production of pocket plate anode from $NiSO_4$) has to be considered as a non-intermediate use.

Table 14. $NiSO_4$ volumes used in battery manufacturing and intermediate status

Use	Tonnage used per year	Intermediate status
Use 1: surface treatment	[confidential][16]	no
Use 2: Ni(OH)2 production for cathode manufacturing	[confidential]	yes
Use 3: anode manufacturing	[confidential]	no
Total tonnage	[confidential]	

For some applications, representing less than [confidential] of the EU use of $NiSO_4$ for batteries, the transformation of nickel sulphate to nickel dihydroxide takes place during a later stage of the manufacture; in this case $NiSO_4$ would be considered as an on-site isolated intermediate or as a transported isolated intermediate if the transformation would end in another plant. No more information is available.

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[16] Information gathered in the framework of an SEA exercise from the two European battery producers stipulates that [confidential] kg of NiSO4 are used each year for electroplating with conventional Watts solution bath. The value of [confidential] t/y provided by the Nickel Institute has been retained.

2.3.3.4 Market description for NiCd batteries.

In this section, information provided by the European manufacturers has been completed and reviewed with another external data[17].

Typical uses of NiCd batteries are emergency lighting, alarm systems, medical devices, various power tools and power supply in the rail transport sector. Worldwide in the electronic sector, NiCd batteries are progressively superseded by NiMH and Li-ion technology except in specific industrial applications.

Industrial batteries differ significantly in size from the consumer batteries (which, due to progressive loss of EU competitiveness between the 80's and the late 90's, are now exclusively imported into the EU from Asia) that are commonly used in consumer electrical products. Industrial batteries and battery systems are typically built up from multiple battery units and when combined can occupy large spaces (e.g. a whole room).

Pocket plate technology is especially used for the stationary and railway market (trains, metros, trams, etc.) where batteries are used in the event of grid failure or where access to the grid is not available (e.g. in sections of the railway where there is no access to grid electricity). The market for stationary and non-stationary applications is global, with competing products that use different technologies and raw materials. These products vary with respect to technical performance are it appears that pocket plate nickel batteries are the preferred choice in certain applications. According to [confidential], the main reasons for this preference are the technical reliability and robustness, with a long service life, the ability to operate over a broad range of temperatures, the minimal maintenance needs, the fast and simple charging, the ability to be charged/discharged (cycles) over 1,000 times if properly maintained, the ability to provide instant backup, avoiding any service interruption, the ease of storage and transport, the economical cost. As regards [confidential], they produce batteries primarily for stationary end uses and to a lesser extent for railways end uses. These batteries are sold in the EU as well as all around the world.

Pocket-plate Ni-based batteries are also used as stand-by batteries (rescue batteries in the event of a power grid failure) particularly in the oil and gas industry, as emergency back-up batteries for the power generation and electricity distribution sector, in commercial and military aviation to provide power back-up for critical safety functions (emergency systems), avionics and for engine-starting and also in motive power for highly specialist vehicles (however this sector uses preferentially common lead/acid batteries).

Competition between technologies per activity sector

The main market drivers for choosing a battery are the following: use profile in which the battery is going to operate (standby mode or cycling mode), power or energy (is the battery going to be used to give a high powerful current over a short span of time, or to supply a lower current over a much longer period of time), life span, mechanical and electrical sturdiness, operating temperature range, ageing pattern (does the battery ageing process lead to a progressive loss of functionality which allows flexibility in the maintenance schedule, or to a sudden death syndrome which requires mandatory advanced replacement for fear of a sudden loss of functionality), cost.

In the standby sector (including telecommunications), lead-acid and NiCd are the most often used technologies. NiCd batteries provide the highest performances and guarantee

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[17] Dag Noreus (2000). Substitution of rechargeable NiCd batteries; a background document to evaluate the possibilities of finding alternatives to NiCd batteries. Stockholm University.

back-up power in the event of a power grid failure, particularly in the oil and gas industry which represents nearly 50% of [confidential] turnover in the standby market. Other uses include emergency back-up for the power generation and electricity distribution sector, as well as railway signaling systems and hospitals (i.e. operating theatres).

Illustration of NiCd batteries used for the stand-by sector

In the aeronautic sector, both NiCd (sintered batteries only) and NiMh technologies are well established but are being replaced by the Li-ion technology in the most recent aircrafts such as Airbus A380 and the military A400M.

Illustration of NiCd batteries used for the aeronautic sector

The traditional automotive sector uses especially led acid batteries which is the less costly technology implemented for a long time. The lead-acid battery, being the starter battery for almost all vehicles, makes it by far the largest market for rechargeable batteries both by value and volume. Large production volumes and relative low material costs make lead acid batteries significantly cheaper. The other battery technologies are only able to compete by having a better performance in more demanding applications. NiCd batteries may be used, for specialist vehicles such as forklift trucks; the End Of Life Vehicle Directive now bans the use of cadmium in vehicles. NiMH and Li-ion batteries are exclusively used in the new hybrid electric vehicles (HEV); NiMH was the former technology chosen by Toyota for HEV manufacturing but this technology is being replaced by Li-ion batteries.

In the railway sector (electric and diesel trains, trams, light rail vehicles, metros), NiCd pocket plate batteries are used for back-up power for communication, lighting and air conditioning systems, as well as safety critical applications such as emergency braking and door-opening systems.

Illustration of NiCd batteries used for the railway sector

In the power tool sector (cordless power tool), NiMH production has already superseded the NiCd technology.

Illustration of NiMH batteries used for the cordless power tool sector

Market trends

The specific industrial market is covered by three battery technologies: lead-acid, NiCd and Li-ion. The lead-acid technology covers 80% of the market (forklift and stationary rescue). The NiCd technology covers 10% of the market (stationary rescue where high performance is required). The Li-ion technology covers less than 1% of the market (satellites, energy storage and electrical mobility). According to [confidential], each technology will continue to serve different market segments with a moderate overlapping range.

The industrial market of NiCd and NiMH are competitive to a certain extent, except for niche markets; the industrial market of NiCd and Li-ion are less competitive and both technologies appear to be complementary. Indeed Li-ion technology has not established a significant presence in the industrial market due to several factors; amongst which is the lack of benefit in using Li-ion batteries in stand-by (power back-up) applications (Li-ion is excellent in cycling applications), the lower intrinsic mechanical and electrical sturdiness which requires the development of several layers (mechanical, electrical and electronic) of protection, the low value placed on low weight in industrial uses which are for the most part stand-by applications, and the difficulty of justifying the development costs of the necessary electronics which needs to be customised for each use in the context of the short production runs typically found in industrial uses.

The importance of the NiCd battery has been reduced by the development of the new battery technologies, which all have superior storage capacities and are replacing NiCd batteries in an increasing number of common applications. On the contrary NiCd batteries offer a number of advantages, being more physically and chemically robust and providing a greater charge density compared to NiMh and Li-ion technologies; this explains that NiCd batteries are often the preferred choice for the industrial sector.

A direct substitution into existing batteries is usually not possible. The different batteries need different charging algorithms. They also perform differently with respect to temperature and temperature gradients, which needs to be considered when designing the battery application in order to obtain the best performance at an optimum cost. The specific needs of the industrial customers drive the selection of the type of battery, together with the cost.

The constant new developments from R&D in combination with an increased demand for improved batteries from the growing electronic industry, lead to an important change on the global market scene and to a lesser extent on the industrial market: the NIMH, Li-ion and Li-polymer batteries are more and more used worldwide and cover the major part of the global market. In comparison, the industrial NiCd battery market appears to be rather marginal but remains stable.

Recycling issues may also impact the market trends. NiMH recycling is different and much simpler than NiCd recycling. The absence of cadmium and other hazardous metals makes it possible to recover spent NiMH batteries together with steel scrap. This means that no special recovery system needs to be established, as in the case of NiCd which has to be kept separate from other recovery systems due to handling precautions with cadmium. Recollected NiCd cells have to be recycled in a separate process which increases handling costs.

It is interesting to note that the observed expanding volumes of the global battery market are covered by the new technologies whereas the NiCd production remains fairly constant since the mid-nineties (niche market from the industrial sector). The global new market is essentially driven by demand for high capacity batteries. Lower NiMH prices with a performance similar or better than NiCd in areas such as power tool and emergency lighting systems, where NiCd are dominating and where most of the NiCd cells are used, may however accelerate the substitution.

2.3.3.5 Analysis of alternatives for pocket plate batteries (AoA)

The analysis of alternatives reported below has been carried out by [confidential] in the framework of an SEA (socioeconomic analysis). The AoA focuses on the use of $NiSO_4$ in the production of [confidential] batteries and is based on information from historic and on-going research and development activities undertaken [confidential]. This information has not been peer-reviewed and shall be considered as the Industry point of view. It would be similar or close to the information that would be provided in an application for authorisation.

The purpose of this AoA is to determine if there are any 'suitable' alternatives to the use of $NiSO_4$ rather than a comprehensive assessment of each alternative. The AoA has been framed by four main criteria that are the technical feasibility of alternatives, their availability, their economic feasibility and the human health and environmental implications of alternatives.

In theory at least, several possible types of alternative can be envisaged

- 'drop-in' substances that directly replace $NiSO_4$ in the same production process without change (except minor changes),
- alternative substances or combinations of substances that would replace nickel (partially or totally) but would require some modifications of the process,
- alternative materials that would not use nickel in the manufacturing of the same end-product,
- the use of alternative processes/technologies.

'Drop-in' alternatives

Other nickel salts (nitrate, hydroxide, acetate and diformate) have been assessed for the manufacture of pocket plate batteries but none are considered to be technically feasible by Industry. No more information is available but the main issue may be the production of nickel dihydroxide from the raw nickel salt used. Anyway, those alternatives are based on other nickel compounds which present identical or similar hazard properties (classified as CMR substances under Annex VI of the CLP) and wouldn't bring any health benefit. As a result, they cannot be considered as suitable alternative to $NiSO_4$.

Alternative substances and materials

The registrant also provided an assessment of possible alternative batteries to nickel batteries for the markets that it supplies. Those are lead acid, NiMH, Li-ion, sodium sulphur (Na/S) and zinc-carbon and zinc-bromide batteries.

Lead acid batteries are widely used on the market but several technical issues don't make them suitable alternatives to replace nickel based batteries (insufficient performance, insufficient service-life 3-5 years vs. 8-15 years, insufficient reliability in extreme temperatures, sudden death vs. aging progressively and predictably, high weight and high volumes not fitted for several sectors as avionic). Those issues also explain why more efficient batteries (nickel based batteries, lithium-ion batteries, etc.) have been further developed within the past years. Moreover, lead compounds used to manufacture such batteries are also hazardous substances and most of them are already included in the candidate list.

NiMH batteries have beneficiated from an extensive R&D [confidential] at the end of the eighties for application in the industrial sector but without customer interest. Today the market of NiMH in this sector is very low and still declining. Therefore NiMH batteries are not a suitable alternative to NiCd in the industrial sector.

Lithium-ion batteries show lot of advantages such as good cycling performance, higher energy and power as well as superior ability to cycle many thousands of times than nickel based batteries. However and contrary to Ni-based batteries, they need to be driven and monitored with advanced electronic system specific to each use, which is costly. They are currently specifically targeted for technologies in which the electronics development costs can be spread over large quantities. Lithium-ion batteries may also suit market sectors where weight limitations is important, volumes are high, and the intrinsic price difference of this technology along with the cost of the required battery management system can be justified. However, regarding potential replacement of NiCd batteries by Lithium-ion, Li-ion batteries cannot fit in an electrical system which is designed around a Ni-based pocket plate battery (batteries are not interchangeable "plug and play" devices): standard operating voltage, charging system and general behaviour are such that a whole electrical system redesign and replacement needs to be developed and implemented, making such a change, in the case of a Li-ion being a replacement battery, beyond the reach of normal and even enhanced maintenance. Lifespan of current engines equipped with batteries may reach up to 30 years (trains, planes, etc.) and will probably still need Ni-based batteries for maintenance over such a period of time. This particular issue would however not be a limitation in the case of a lithium ion battery replacing a Ni-based battery at the time of the design of new equipment. According to [confidential], Li-ion batteries are not a good candidate for industrial floating uses.

Sodium-sulphur (Na/S) batteries are a relatively new technology currently mostly used in Japan. Their high energy density makes them suitable for grid storage (e.g. linked to wind and solar power); they are suitable for some stationary applications. Application in the fields of transport and space has been explored, but there seems limited interest in these fields. One technical issue regarding their potential alternative status to Ni-based batteries is that they operate at high temperatures around 350°C (requiring bulky insulation) and the corrosive nature of the sodium polysulfide gives rise to limited shelf life. Significant R&D would firstly have to go into the feasibility of batteries for each market application and to ensure the safety/secure use in each application.

Zinc-carbon and zinc bromide batteries are the cheapest non-industrial batteries and are often incorporated into products (e.g. flash lights, remote controls and other portable devices). This type of battery is not rechargeable, has low energy density and a short shelf life. It is therefore not a technically feasible alternative.

If technically efficient, the performance characteristics and price of these batteries (roughly twice the cost) rules them out for the applications that could continue to be supplied by pocket plate batteries.

Alternative processes/technologies

Fuel cells could be technically feasible for some applications but may not operate well relative to Ni-based batteries in temperature extremes e.g. freezing water can damage the stack and therefore requires careful temperature maintenance. Excessive heat can also cause damage. Start times can be slow, typically around 30 seconds to reach full power and so requiring further back-up where systems are sensitive to supply interruption. Controlling the operating temperatures as well as supplying enough oxygen requires compressors, pumps and other accessories that consume about 30 percent of the energy generate. Therefore fuel-cells are not considered as a suitable alternative yet. In the long term the use of fuel cells is likely to become much more widespread than now, though costs need to fall and some technical barriers remain.

Compressed air systems could provide a technically feasible alternative for backup systems as they can store and discharge all energy rapidly with low losses. They can also operate in extreme temperatures and have a long lifespan. Issues with patents are expected. It is unlikely in the short/medium term that there would be sufficient supply to replace the nickel battery market as there are not many global producers.

Flywheel energy storage (FES)[18] could provide a technically feasible alternative to batteries as they can store and discharge all energy rapidly without being damaged, meaning they can charge up to full capacity within minutes. They can also operate in extreme temperatures and have a long lifespan. A major constraint is the time over which flywheels can produce output, typically only around 30 seconds. In some applications this is not a problem as back-up generators are typically online within 5-20 seconds. However, it is clearly incompatible with systems where back-up is designed to last several minutes or longer. FES is therefore an alternative technology that is considered not technically nor economically feasible and suitable for the time being.

Super-capacitors - double-layer capacitor (DLR) is ideal for energy storage that undergoes frequent charge and discharge cycles at high current and short duration. Maintenance requirements are low. However, the duration of power provision is very short, currently around 10 seconds and extensive research is ongoing to improve it up to around 30 seconds at the maximum. It does not have the energy density to be currently used in industrial applications. This makes them unsuited to the applications of interest where Ni-based batteries are used. DLR is therefore an alternative technology that is considered not technically nor economically feasible and suitable for the time being.

Conclusion of the analysis of alternatives

The AoA conducted indicates that there are a number of possible alternatives to NiCd PP batteries, however considered by the registrants to be not currently suitable for all applications when considering technical and economic feasibility.

The use of other nickel compounds or lead compounds as ‘drop-in’ alternative to nickel is not suitable given the similar hazard properties that would not allow a reduction in the human health risk, neither technically efficient nor possible.

In the replacement battery market, preference would indeed be given to Ni-based cells for the reason that it is not practicable to fit other batteries either on grounds of space, or compatibility with supporting circuitry. Lifespan of current engines equipped with batteries may reach up to 30 years (trains, planes, etc...) and will probably still need Ni-based batteries for maintenance over such a period of time. However, without cost consideration, a switch to available alternatives the Li-ion alternative is considered technically possible when designing new equipments.

From all the other potential alternatives, the Li-ion technology appears as the most promising alternative in the near future. Some existing segments using Pb/acid batteries or Ni-based batteries may switch to Li-ion in the near future, but such changes are expected to be minor in scale from the time being according to the registrants without more explanation however. Other technologies (e.g. fuel cells, flywheels, zinc-bromide batteries) could in principle be technically feasible for some applications but there are likely to be issues over supply to the market in the short/medium term.

Existing plants would not be able to switch production to alternative batteries or products without complete redevelopment and significant costs (e.g. R&D, marketing, production, training, etc).

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[18] Flywheel energy storage (FES) works by accelerating a rotor to a very high speed and maintaining the energy in the system as rotational energy. When energy is extracted from the system, the flywheel's rotational speed is reduced as a consequence of the principle of conservation of energy; adding energy to the system correspondingly results in an increase in the speed of the flywheel.

3 RISK ASSESSMENT AND OBJECTIVES FOR FURTHER RISK MANAGEMENT

3.1 Hazard identification

Nickel sulphate is classified under Annex VI of the CLP Regulation EC No.1272/2008 (see Table 15).

Table 15. Harmonised classification of $NiSO_4$ according to CLP Regulation EC No.1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
028-009-00-5	Nickel sulphate	232-104-9	7786-81-4	Acute tox. 4	H302	Skin Sens. 1; H317: C ≥ 0,01% STOT RE 1; H373: C ≥ 1% STOT RE 2; H373: 0,1% ≤ C < 1% Skin Irrit. 2; H315: C ≥ 20% M=1	none
				Skin Irrit. 2	H315		
				Skin Sens. 1	H317		
				Acute Tox. 4	H332		
				Resp Sens. 1	H334		
				Muta. 2	H341		
				Carc. 1A	H350i		
				Repr. 1B	H360D		
				STOT RE 1	H372		
				Aquatic acute 1	H400		
				Aquatic chronic 1	H410		

Such classification has been reviewed based on the new available hazard information provided in the last registration dossiers update and is considered to be still up to date and relevant.

3.2 Risk assessment based on the registration dossiers under REACH

The available RAR on nickel and nickel compounds carried out under the framework of the Existing Substance Regulation (ESR) program (Directive 93/67/EEC and Regulation N° 1488/94 on Risk Assessment for New and Existing substances) is dated 2008-2009 and built on data collected in or around the year 2000 with respect to exposure, emissions, operational conditions (OCs) and RMMs from industrial sites located in the EU-15 countries.

The REACH registrants of $NiSO_4$ have used part of this information and additional information that was gathered by the Nickel Consortia during 2008-2010 via internal consultations of producers and downstream users of $NiSO_4$ located in the EU-27 countries and Norway. Indeed since the year 2000, some nickel substances producers and users have developed new best available technologies, adapted and improved operations and processes, and upgraded their RMMs. In parallel information on exposure, production processes and RMMs has been gathered through sites visits. Such updated information has been used to develop the Generic Exposure Scenarios (GES) provided in the registration dossiers.

A new risk assessment has therefore been carried out by Anses in the frame of this RMOA on the information provided in the last registration dossiers update (May 2013). Risk Characterization Ratios (RCRs) have been re-calculated with the DNEL for long term inhalation exposure proposed by Anses (DNEL of 0,01 mg Ni/m3, i.e. inhalable OEL proposed by SCOEL, see below). When monitoring exposure data were available, they were used for the risk characterization. On the other hand, the Tier I model MEASE was used when exposure measurements were not available. Based on the former risk assessment conclusions (i.e. risk identified for workers, no risk for consumer except from exposure to food, water and food supplement), this assessment has been targeted on the worker population only. In the RAR, inhalation and dermal routes were the main exposure paths to $NiSO_4$ considered for workers.

Indeed the REACH registration dossiers confirm that consumers are not exposed to $NiSO_4$. Moreover human health risk arising from exposure to food and water is not covered by REACH. According to article 2 of the REACH regulation, provisions of titles II (registration), V (downstream users), VI (evaluation) and VII (authorisation) shall not apply to the extent that a substance is used in food and feedingstuffs in accordance with Regulation EC n° 178/2002 including use as food additive in foodstuffs, as a flavouring in foodstuffs, as an additive in feedingstuffs, etc. The use in food supplement is excluded from REACH and falls under the Food Supplement Directive (2002/46/EC) of the European Food Safety Authority. The RMO analysis focuses only on the occupational human health.

Note however that the registrants have raised another possible consumer use of $NiSO_4$ that may lead to exposure: use of $NiSO_4$ in Do-It-Yourself (DIY)[19] nickel electroplating hobby kits. The use of $NiSO_4$ in Do-It-Yourself (DIY) nickel electroplating hobby kits available either in hobby shops either on the Internet is however mentioned under the section of "uses advised against" in the CSR and falls now under Annex XVII of REACH (restrictions concerning substances classified Carc. 1A/1B, Muta. 1A/1B and/or repr. 1A/1B under Annex VI of the CLP which shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public). Therefore the risk is considered managed and has not been investigated further in this document.

3.3 Health hazard related to nickel sulphate

3.3.1 Toxicokinetics

3.3.1.1 Absorption

Inhalation

The available data on $NiSO_4$ and nickel chloride indicate that the absorption of nickel following inhalation of these nickel compounds might be as high as up to 97-99%; it should be noted that the fraction absorbed apparently depends on the concentration of the nickel compound in the inhaled air as well as on the duration of exposure. For the purpose of risk characterisation, a value of 100% is taken forward to the risk characterisation for the absorbed fraction of nickel from the respiratory tract following

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[19] http://www.nickelinstitute.org/~/media/Files/HealthEnvironmentSafeUse/AdvisoryNotes/EN/AdvisoryNotesDIYPlatingA409rev.ashx

exposure by inhalation of $NiSO_4$ for particulates with an aerodynamic diameter below 5 µm (respirable fraction). For nickel particulates with aerodynamic diameters above 5 µm (non-respirable fraction), the absorption of nickel from the respiratory tract is considered to be negligible as these particles predominantly will be cleared from the respiratory tract by mucociliary action and translocated into the gastrointestinal tract and absorbed. Hence, for the non-respirable fraction, 100% clearance from the respiratory tract by mucociliary action and translocation into the gastrointestinal tract is assumed and the oral absorption figures can be taken.

Oral

The available data indicate that the absorption of nickel following administration in the drinking water to fasting individuals might be as high as up to about 25-27% and about 1-6% when administered to non-fasting individuals and/or together with (or in close proximity to) a meal. For the purpose of risk characterisation, a value of 30% is taken forward to the risk characterisation for the absorbed fraction of nickel from the gastrointestinal tract following oral exposure to $NiSO_4$ in the exposure scenarios where fasting individuals might be exposed to $NiSO_4$. In all the other exposure scenarios, a value of 5% is used for the absorbed fraction of nickel from the gastrointestinal tract.

Dermal

The available data indicate that absorption of nickel following dermal contact to various nickel compounds can take place, but to a limited extent with a large part of the applied dose remaining on the skin surface or in the stratum corneum. The data are too limited for an evaluation of the absorbed fraction of nickel following dermal contact to $NiSO_4$. The *in vitro* study of soluble nickel compounds (nickel sulphate, nickel chloride, nickel nitrate, and nickel acetate) using human skin (Tanojo *et al*. 2001) showed about 98% of the dose remained in the donor solution, whereas 1% or less was found in the receptor fluid and less than 1% was retained in the stratum corneum. According to the revised TGD, the amount absorbed into the skin, but not passed into the receptor fluid, should also be included in the estimate of dermal absorption. For the purpose of risk characterisation, a value of 2% is taken forward to the risk characterisation for the absorbed fraction of nickel following dermal contact to $NiSO_4$.

3.3.1.2 Distribution and elimination

Two inhalation studies in rats (Benson *et al*. 1988, NTP 1996) indicate that lung nickel burdens increase with increasing concentrations of $NiSO_4$ (at least up to around 0.8 mg Ni/m^3) in the inhaled air as well as with duration of exposure. The study by Benson *et al.* (1988) indicates that the lung nickel burden may rise to a steady state level as the lung nickel burdens were almost similar in rats exposed to 15 or 30 mg/m^3. A third study (Dunnick *et al*. 1989) found similar concentrations of nickel in the lungs of rats and mice after 4, 9, and 13 weeks of inhalation to $NiSO_4$ (0.02 to 0.4 mg Ni/m^3). Of nickel remaining in the body after 96 hours following a single dose of $NiSO_4$ administered by intratracheal administration, over 50% was in the lungs. The deposition of nickel in the lungs of rats is apparently greater than in the lungs of mice. No human data have been located.

Generally, nickel tends to deposit in the lungs of workers occupationally exposed to nickel compounds and in experimental animals following inhalation or intratracheal instillation of nickel compounds. The tissue distribution of nickel in experimental animals does not appear to depend significantly on the route of exposure (inhalation/intratracheal instillation or oral administration) although some differences have been observed. Low levels of accumulation in tissues are observed (generally below 1 ppm). A primary site of elevated tissue levels is the kidney. In addition, elevated concentrations of nickel are often found in the lung, also after oral dosing, and in the liver. Elevated nickel levels are less often found in other tissues. Limited information exists on tissue distribution in humans.

Absorbed nickel is excreted in the urine, regardless of the route of exposure. Most ingested nickel is excreted via faeces due to the relatively low gastrointestinal absorption. In humans, nickel excreted in the urine following oral intake of $NiSO_4$ accounts for 20-30% of the dose administered in drinking water to fasting subjects compared with 1-5% when administered together with food or in close proximity to a meal.

From biological monitoring in small groups of electroplaters exposed to $NiSO_4$ and nickel chloride, the half-life for urinary elimination of nickel has been estimated to range from 17 to 39 hours.

Inhaled nickel particles can be eliminated from the respiratory tract either by exhalation, by absorption from the respiratory tract, or by removal due to mucociliary elimination.

3.3.2 Acute toxicity

Oral

Since the publication of the European Union Risk assessment Report on Nickel (2008), a newly conducted GLP OECD guideline compliant study reported an LD50 =361 mg/kg for $NiSO_4$ hexahydrate, which confirms classification for acute oral toxicity under the 1st ATP to the CLP Regulation (EPSL, 2009a). Indeed, the current classification of nickel sulfate is (i) under the Directive 67/548/EEC as Harmful with Xn; R22 (Harmful if swallowed) and (ii) under the CPL regulation as Acute Tox. 4: H302 (Harmful if swallowed).

Inhalation

As data were not available at the time of the European Union Risk Assessment (2008), the classification for acute inhalation toxicity was based on read-across from the oral data. However, a newly conducted GLP OECD guideline compliant study reported an LC50 =2.48 mg/L for $NiSO_4$ hexahydrate, which confirms the classification for acute inhalation toxicity under the 1st ATP to the CLP Regulation (EPSL, 2009b). Indeed, the current classification for acute inhalation toxicity of $NiSO_4$ as Acute Tox. 4 H332, under the 1st ATP to the CLP Regulation

Dermal

No proper acute dermal studies with $NiSO_4$ have been found. No risk characterization will be conducted for acute dermal toxicity, following the approach taken in the EU RAR (2008-2009). Acute systemic effects are not relevant due to the very low dermal absorption of nickel (2%) from $NiSO_4$ hexahydrate. Acute local effects are covered by risk reduction measures (i.e., protective equipment) associated with its classification as “irritant” (Xi; R38 at concentrations above 20%; Skin Irrit. 2:H315 in the 1st ATP to the CLP Regulation) and by the long term DNEL based on prevention of dermal sensitization.

3.3.3 Irritation

Skin

In an OECD guideline test in rabbits, $NiSO_4$ was not a skin irritant. However, human data indicate that $NiSO_4$ in concentrations above 20% can induce skin irritation. Based on this human data, $NiSO_4$ is classified as Xi; R38 with a specific concentration limit of 20% in the 30th ATP. [$NiSO_4$ is classified as Xi; R38 and Skin Irrit. 2:H315 in the 1st ATP to the CLP Regulation.]

Eye

Nickel sulphate is not an eye irritant in experimental animals (OECD guideline test in rabbit). The TC C&L has agreed not to classify $NiSO_4$ for eye irritation.

Respiratory tract

The available data do not allow any conclusion on respiratory irritation. The criteria for classification for respiratory irritation are mainly based on human experience, which is lacking. There is a concern for respiratory irritation. However, this concern is considered to be more appropriately covered by the proposed classification for chronic effects (T; R48/23) with a specific concentration limit lower than the general limit in the Preparations Directive (EC, 1999).

3.3.4 Sensitisation

Skin sensitization

A number of studies using different protocols showed that $NiSO_4$ is a skin sensitiser in guinea pigs and mice.

In addition to these animal data, copious information on human dermal sensitization is documented in the European Union Risk Assessment (2008). Compared to the RAR, additional studies are summarized in the $NiSO_4$ CSR. One of these studies, a meta-analysis of published patch test studies by Fischer *et al.* (2005) has been used as the basis for the derivation of a DNEL for dermal elicitation/sensitization with $NiSO_4$. The aim of the study by Fischer *et al*. (2005) was to assess thresholds of response by making a statistical analysis of available dose-response studies with a single occluded exposure and comparing the results to thresholds from other modes of exposure. Eight occluded Ni dose-response studies were selected based on statistical considerations. The statistical analysis showed that 5% of a sensitized population reacts to 0.44 µg Ni/cm^2 and 10% react to 1.04 µg Ni/cm^2. In another study with a single open application, 7.8% of sensitized persons responded to a dose 6x higher than the dose to which 10% reacted in occluded exposure. The NOAEL of 0.00044 mg Ni/cm^2 from the Fischer et al. (2005) study is carried forward as the basis for the derivation of DNEL for dermal elicitation/sensitization.

In conclusion, data demonstrate that $NiSO_4$ is a skin sensitiser in humans and in experimental animals. $NiSO_4$ is classified as R43 and Skin Sens. 1; H317 in the 1st ATP to the CLP Regulation.

Respiratory sensitization

Based on a recent literature review, the available data for $NiSO_4$ may not be sufficient for classification as a respiratory sensitizer.

Nickel sulfate is classified as R42 and Resp. Sens. 1; H334 in the 1st ATP to the CLP Regulation. A comprehensive review of the available literature regarding the potential of soluble Ni compounds to induce respiratory sensitization has been submitted by the applicant in the CSR. In summary, criteria associated with classification of a given compound as a respiratory sensitizer are not yet well defined. However, the peer-reviewed literature generally indicate that soluble nickel compounds meet the common criteria shared between respiratory and contact allergens as these compounds can both act as haptens, gain access to the target tissue, and engage an immune response via cytokines and chemokines. Regarding criteria that set the respiratory and contact sensitization apart, which are generally accepted to be associated with the type of immunological responses that they induce, soluble nickel compounds have been associated with Type I reactions involving IgE in case studies of workers with occupational asthma. This is the response pathway associated with respiratory hypersensitivity.

3.3.5 Repeated dose toxicity

There are several studies that have investigated the repeated toxicity of $NiSO_4$ via oral and inhalation routes of exposure. Only one set of studies investigating the effects of repeated exposure via the dermal route was identified. The target organ for toxicity caused by repeated exposure to $NiSO_4$ depends on the route of exposure.

Inhalation exposure

There are several inhalation studies ranging from 12 days to 24 months of exposure that have examined the effects of repeated exposure to $NiSO_4$ in rats and mice. These studies identified the target organ for toxicity effects of inhalation exposure to $NiSO_4$ as the respiratory tract, with effects seen in the nose and the lungs.

Following inhalation of $NiSO_4$ the most serious toxicity effects observed in the respiratory tract are chronic inflammation and fibrosis. The most relevant and sensitive studies to assess chronic effects are the 2-year rat inhalation studies with $NiSO_4$ hexahydrate conducted by NTP (1996a). Rats appeared to be more sensitive to the toxicity effects of $NiSO_4$ by inhalation than mice. Chronic lung inflammation in rats including lung fibrosis was observed at a concentration of 0.056 mg Ni/m3 or 0.25 mg $NiSO_4$ hexahydrate/m3, with a NOAEC of 0.027 mg Ni/m3 identified for these effects. Although macrophage hyperplasia was detected at the exposure level of 0.027 mg Ni/ m3, this effect was considered an adaptive effect and not an adverse toxicity effect. The LOAEC for repeated dose toxicity via inhalation of 0.056 mg Ni/m3 and the NOAEC of 0.027 mg Ni/m3 are used in the risk characterization of $NiSO_4$.

Nickel sulphate fulfils the criteria for classification for repeated dose toxicity via inhalation since chronic lung inflammation including lung fibrosis results from long-term exposure via inhalation to a concentration of 0.056 mg/Ni/m^3 or 0.25 mg $NiSO_4$ hexahydrate/m^3. $NiSO_4$ was classified as T: R48/23 and STOT RE 1; H372 in the 1st ATP to the CLP.

Oral Exposure

In a 3-6-month drinking water study by Vyskocil *et al*. (1994a), increased urinary albumin was detected in female rats exposed to 6.8 mg Ni/kg bw/day. In a 13-week study conducted by Obone *et al.* (1999), a LOAEL of 11 mg Ni/kg bw/day was identified for $NiSO_4$ hexahydrate given in drinking water. At this exposure level, a 4% reduction in body weight and increases in relative organ weights were observed. The NOAEL for these effects was 4.5 mg Ni/kg bw/day. A more recent 90-day study, by gavage, showed 8% body weight reduction at 7-11 mg Ni/kg bw/day (Benson *et al.,* 2002). A 2-year chronic rat study conducted by Ambrose *et al.* (1976) examined the effects of $NiSO_4$ hexahydrate administered to rats in the diet. Effects on body weights were also observed in this study, with a NOAEL of 10 mg Ni/kg bw/day and a LOAEL of 100 mg Ni/kg bw/day identified for these effects. The same researchers conducted a 2-year study in dogs (Ambrose *et al*., 1976), and identified a NOAEL of 75 mg Ni/kg bw/day and a LOAEL of 188 mg Ni/kg bw/day for decreased body weight, lung granulomas, and bone marrow hyperplasia.

However, because of the small group size (3 dogs/sex) it is possible that this study missed effects at the lower dose exposure levels.

A more recent 2-year OECD 451 carcinogenicity study found decreased body weight gains ranging from 4% to 12% in rats (males and females combined) following oral gavage administration of 2.2 to 11 mg Ni/kg bw/day. Survival was reduced in a dose-related manner, achieving statistical significance at the two highest dose levels in females (Heim *et al.,* 2007).

The kidney has been identified as a target organ for oral toxicity of nickel (e.g., albuminuria) although marked histopathological kidney damage after oral exposure has not been observed (TERA, 1999). A mouse study showed mild tubular nephropathy but at higher dose levels. The increases in urinary albumin were observed at approximately the same dose level as the reduction in body weight. Various effects on the immune system have also been reported after oral exposure to $NiSO_4$. The immune effects have been observed at dose levels above those causing body weight loss. Therefore, a LOAEL of 6.7 mg Ni/kg bw/day based on reduced body weight and increased mortality together and a NOAEL of 2.2 mg Ni/kg bw/day was identified from the chronic Heim et *al.(*2007) study.

Dermal exposure

One set of studies describing toxicity effects after repeated exposure through the skin has been identified (Mathur *et al*. 1977; 1991; 1992; 1993; 1994) A NOAEL of 40 mg Ni/kg was identified in the Mathur *et al.* (1977) study for local effects on skin and systemic effects in testis and liver. However, due to the methodological limitations of this study, a NOAEL for toxicity effects via the dermal route is not carried forward to the risk characterisation.

3.3.6 Mutagenicity

Based on the available data, there is clear evidence indicating that $NiSO_4$ is genotoxic *in vitro*, and in particular, is clastogenic. There are a number of *in vivo* studies in both animals and human. The study by Benson *et al*. (2002) is the most comprehensive part of the database on *in vivo* genotoxicity of Ni compounds and shows that $NiSO_4$ given by inhalation seems to induce inflammation and genotoxicity in lung cells at approximately the same concentrations. The results from some of the other animal studies are conflicting. Results of two recent micronucleus studies, one after oral and one after intraperitoneal administration are negative. Evidence from human studies is limited.

There are no definitive studies on germ cells, and little evidence concerning hereditable effects. Whilst there is evidence that the nickel ion reaches the testes, no effect on spermatogonial cells was seen in the Mathur *et al*. (1978) study. The effects seen in the Sobti & Gill (1989) study may reflect toxic effects on germ cells rather than chromosomal damage.

The opinion of the Specialised Experts has been sought with regard to the classification of $NiSO_4$ as Muta. Cat. 3; R68 at their meeting in April 2004. The Specialised Experts concluded that $NiSO_4$, nickel chloride and nickel nitrate should be classified as Muta. Cat. 3; R68. [$NiSO_4$ is classified as Muta. Cat. 3; R68 and Muta. 2: H341 in the 1st ATP to the CLP Regulation.]

This conclusion is based on evidence of *in vivo* genotoxicity in somatic cells, after systemic exposure. Hence the possibility that the germ cells are affected cannot be excluded. The Specialised Experts did not consider that further testing of effects on germ cells was practicable (European Commission, 2004).

Recently, there has been some recognition that $NiSO_4$ may be a genotoxic carcinogen with a practical threshold (SCOEL report, 2011)

3.3.7 Carcinogenicity

3.3.7.1 Animal Data

Inhalation studies with $NiSO_4$ hexahydrate (MMAD = 2.1-2.5 µm; GSD ~ 2) have been performed in rats and mice (NTP 1996a). No exposure related neoplasms were observed in rats (F344/N) or in mice (B6C3F1) after exposure for two years at concentrations up to 0.11 mg Ni/m^3 or 0.22 mg Ni/m^3, respectively.

These results are in contrast to those obtained with crystalline nickel subsulphide and green (high calcining temperature) nickel oxide. Inhalation studies with nickel oxide (NTP, 1996b) and nickel subsulphide (NTP, 1996c) showed some evidence and clear evidence, respectively, for carcinogenic activity following inhalation exposure in rats, and there was equivocal evidence for nickel oxide in female mice.

The different results obtained with $NiSO_4$, nickel oxide, and nickel subsulphide raise questions as to whether these compounds differ in their mode of action or carcinogenic potency. The role of respiratory toxicity on carcinogenicity is also an important consideration. Water soluble nickel compounds are some of the most toxic of the nickel compounds for the respiratory tract but induced no tumors even at exposure levels corresponding to the maximum tolerated dose. A possible model for tumor initiation based on the Ni bioavailability at critical intracellular sites has been described to help reconcile all these possibilities (Oller *et al*., 2008; Goodman *et al*., 2009). It is postulated that there are many factors that can affect the bioavailability of nickel at key intracellular sites and that if these factors preclude Ni to be available at nuclear sites in sufficient amounts, no tumors will be induced. This could be the case for soluble nickel compounds that are very toxic to the lungs, and this toxicity limits the exposure levels that can be tolerated. In addition, these compounds are cleared from the lungs very quickly, and the Ni ion released extracellularly is very poorly taken up by the cells.

The possibility that exposure to soluble nickel compounds may enhance the development of tumors initiated by other carcinogens cannot be excluded based on the data from animals experiments with single exposures.

The carcinogenicity of $NiSO_4$ following oral administration has been studied in rats and dogs and no neoplasms were observed in either of these two animal species (see Ambrose *et al.,* 1976).

However, these studies were old and not guideline compliant; therefore some uncertainties remained. A recent 2-year carcinogenicity study in rats by oral gavage has been completed (Heim *et al.,* 2007). This study was performed according to OECD 451 guidance and it did not show a carcinogenic potential for exposure to $NiSO_4$ following oral administration. In conclusion, there is sufficient oral carcinogenicity data to show that $NiSO_4$ does not show a carcinogenic potential in experimental animals following oral administration.

The negative results from the oral study are consistent with the negative results from the inhalation study in rats and provide supporting evidence for the low intracellular uptake and rapid excretion of water soluble nickel compound.

No data regarding carcinogenicity following dermal contact to $NiSO_4$ in experimental animals have been located. In conclusion, the available data are too limited for an evaluation of the carcinogenic potential in experimental animals following dermal contact to water soluble nickel compounds. As oral exposure does not show carcinogenicity, it seems reasonable to assume that cancer is not a relevant endpoint for dermal exposure.

Studies on the carcinogenicity of $NiSO_4$ following intramuscular or intraperitoneal injections have been performed in rats. The results have either been negative (e.g., Kasprzak *et al.,* 1983) or have shown low incidence of injection site tumors at very high exposure levels (e.g., Pott *et al*., 1989). It should be noted that these routes of administration are irrelevant for human beings who will only be exposed via inhalation, oral intake or dermal contact to $NiSO_4$.

Three studies with $NiSO_4$ in experimental animals suggest a promoter effect of $NiSO_4$, if applied locally to the nasopharynx or the oral cavity, or by the feed to pups from initiated dams; however, the indications are rather weak. Goodman *et al.* (2009) considered these data and concluded that although several possible non-genotoxic effects of the nickel ion have been described, it is not clear whether soluble nickel compounds can elicit these effects in vivo or whether these effects, if elicited, would result in tumor promotion.

3.3.7.2 Epidemiology Data

As discussed in the European Union Risk Assessment for $NiSO_4$ (2008-2009) and in the SCOEL recommendation report (SCOEL, 2011), epidemiological studies from at least three nickel refineries processing sulphidic nickel ores have demonstrated elevated risk of lung and nasal cancer in workers exposed to dust containing $NiSO_4$ in the presence of variable amounts of water insoluble nickel compounds. These refineries were: the Clydach refinery in Wales, UK; the Kristiansand refinery in Norway; and the Harjavalta refinery in Finland. Among electrolysis workers at the Port Colborne refinery in Canada the association between respiratory cancer and exposure to $NiSO_4$ was not observed.

Clydach, South Wales (Easton et al. 1992)

In Clydach, elevated risk for death from lung or nasal cancer was found in workers employed in the hydrometallurgy department where $NiSO_4$ was the dominating form of nickel in the exposures. Exposure to $NiSO_4$ also took place in other departments, and there was evidence of a dose-response relationship with cancer risk, in workers with high oxidic and/or sulfidic exposure when the data were cross-tabulated. Regression analyses offering adjustment for exposure to other types of nickel or adjustment for work in other high-risk departments also showed a dose response.

No exposure measurements existed, but the high risks left no doubt as to their occupational origin. In the nickel refinery groups exposed mainly to $NiSO_4$ for more than 5 years, the lung cancer risk was 3 times higher than expected from national data. Nickel chloride was not used in the production. It was not possible to adjust for tobacco smoking, but the increase in lung cancer risk was far too high to be explained by confounding from smoking. The risk of nasal cancer in the same group was reported to be more than 100 times the expected rates in the general population. The nasal cancer risk is only slightly affected by smoking habits.

Kristiansand, Norway

The Kristiansand workers were employed in the processing of sulphidic nickel matte, which included work areas such as roasting and smelting, with relatively high insoluble nickel exposures (>5 mg Ni/m^3, or >11.5 mg Ni/m^3 as inhalable) and lower levels of soluble nickel exposure, as well as electrolytic nickel refining using sulphuric acid and were exposed mainly to high concentrations (> 1 mg/m^3 or >1.6 mg Ni/m^3 as inhalable) of $NiSO_4$ and much lower concentrations of other, poorly soluble nickel compounds. The highest lung cancer risks occurred in electrolysis workers and the highest nasal cancer risks appeared to be in roasting and smelting workers (Doll, 1990). A recent evaluation of the relation between nickel compounds and respiratory tumours in an extended group of persons who had worked in the nickel refinery in Kristiansand from 1916–1983 substantiated the indications of a carcinogenic effect of soluble nickel (Andersen *et al.* 1996). A total of 1979 mortalities, 32 new cases of nasal cancer (standardised incidence ratio (SIR) 18.0; 95% confidence interval (CI) 12.3–25.4) and 203 new cases of lung cancer (SIR 3.0; 95% CI 2.6– 3.4) were observed. The authors also indicated that there was an interaction for lung cancer between smoking and exposure to total nickel. The lung cancer risk of Kristiansand workers has been further analysed in a case control study with diagnoses occurring 1952-1995 (Grimsrud *et al.,* 2002). This study indicated that lung cancer risk appeared more strongly associated with soluble nickel exposure than with exposure to other nickel compounds, although soluble and insoluble nickel exposures were highly correlated. In the past, particularly high exposures to soluble nickel occurred in the electrolysis department (Doll, 1990). The data suggesting a role for soluble nickel in the carcinogenic process still seem to be convincing, but effects due to exposures to other forms of nickel and sulphuric acid cannot be completely ruled out for this plant either.

An update (Grimsrud *et al.,* 2003) confirmed the main findings in earlier reports of the increased lung cancer risk among Norwegian workers. The analyses demonstrated an association between risk and length of employment or duration of nickel exposure. For the Norwegian cohort a strong association was observed for cumulative exposure to water soluble nickel and lung cancer risk, when nickel exposure, historical exposure to arsenic, cobalt, asbestos and acid mists were considered (Grimsrud *et al.,* 2005).

Harjavalta, Finland

The refinery in Harjavalta also treated a sulphidic nickel concentrate, as did the two refineries in Clydach and Kristiansand. Elevated risk for lung and nasal cancers was demonstrated in the group of workers where $NiSO_4$ was the dominating form of nickel in the working atmosphere. The historical nickel exposures were well documented. No adjustment for smoking could be performed in the analyses of lung cancer risk. No dose-response was found, but the number of cancer cases was low.

Briefly, there was an increase in cancer incidence in a cohort of 369 workers with a total of 8794 person years in the electrolytic nickel refinery department between 1960 and 1995. Two cases of nasal cancer (SIR 41.1; 95% CI 4.97–148) were observed in the group of refinery workers exposed primarily towards soluble nickel at mean exposure levels in the order of 0.25 mg Ni/m^3. An increased risk of stomach cancer (3 cases; SIR 4.98; 95% CI 1.62–11.6) and lung cancer (6 cases; SIR 2.61; 95% CI 0.96–5.67) was also found. Smelter workers in the same plant with exposure to poorly soluble nickel compounds exerted an increase lung cancer incidence (Antilla *et al.,* 1998).

Port Colborne, Canada

The electrolysis workers at the Port Colborne refinery were exposed mainly to $NiSO_4$ until 1942 and from that year exposures contained a mixture of sulphate and chloride. In contrast to the three cohorts described above, lung cancer mortality risks were not elevated among the electrolysis workers with no exposure in leaching, calcining or sintering plant (Roberts *et al*., 1989a,b; Doll *et al.,* 1990). In addition, there were no nasal cancer cases among these workers. The level of exposure to soluble nickel was estimated to be relatively low, i.e. 0.25 mg/m^3 (or 0.4 mg/m^3 as inhalable) (compared to ≥ 1mg/m^3 or > 1.6 mg/m^3 as inhalable in the Kristiansand electrolysis workers).

Discussion on cancer epidemiology

Altogether, epidemiological evidence points towards a dose-related carcinogenic potential of water soluble nickel compounds, especially evident also after quantitative reevaluation of the Kristiansand cohort (Norway) (Grimsrud *et al*., 2002, 2003, 2005), the Clydach cohort (South Wales) (Easton *et al.,* 1992) and the Harjavalta cohort (Finland) (Antilla *et al.,* 1998). A general contribution, albeit not dose dependent, of sulphidic and oxidic nickel species to cancer risk was also seen in the reevaluation of the Kristiansand cohort.

It has to be emphasized, however, that the epidemiological evaluation of the carcinogenic risk for different nickel species has some limitations. Thus, there are no cohorts available exclusively exposed to a single nickel species. Furthermore, assessments of the relative contribution of the diverse nickel species far back in time depend largely on exposure estimates such as job history, which introduces uncertainty, and comparatively minor differences may have a high impact on dose-response relationships. This is especially true since high exposures with clearly elevated cancer risks were found for workers first employed before 1930 for example in the Clydach refinery (Grimsrud and Peto, 2006).

Finally, combination effect either with confounding factors (smoking, sulphuric acid in case of Kristiansand) or between water soluble and water insoluble nickel species cannot be excluded.

Conclusion on cancer epidemiology

Carcinogenic effects of nickel have long been recognized. The main target is the respiratory system and tumours involve primarily the lungs and nasal cavities.

The epidemiological evidence (without the animal data) was reviewed by the Specialised Experts at their in April, 2004. The Specialised Experts concluded that the epidemiological evidence was sufficient to classify $NiSO_4$ in Category 1, known to be carcinogenic to man. The Specialised Experts considered the data to be sufficient to establish a causal association between the human exposure to the substances and the development of lung cancer and they considered that there was supporting evidence for this conclusion from more limited data on nasal cancer (European Union Risk Assessment for Nickel Sulphate, 2008-2009).

In addition, nickel compounds have been classified by IARC as group 1 carcinogens (IARC, 1990).

3.3.7.3 Mode of action

An integrating consideration of the relevant cellular and biochemical findings allows the conclusion that the presence of nickel ions at target cellular sites is responsible for the inflammatory, genotoxic and/or carcinogenic effects of nickel compounds.

According to mechanistic studies, nickel ions are the ultimate genotoxic forms of nickel. Soluble nickel salts are non-mutagenic in almost all bacterial mutagenicity tests and only weakly mutagenic in tests with mammalian cells. Nickel ions cause chromosome aberrations, sister chromatid exchange, DNA breaks and DNA–protein cross links in mammalian cells only in higher concentrations (mmol/l range) (IARC 1990).

Based on cellular investigations, at low concentrations nickel ions do not directly interact with DNA but rather exert indirect genotoxic effects such as interference with DNA repair systems and DNA methylation patterns, which lead to clastogenicity and an increased genomic instability. These effects are mediated by nickel ions, even though it cannot be excluded that on conditions of particle overload chronic inflammation may contribute to the carcinogenicity (SCOEL, 2011).

The SCOEL (2011) concluded that since mechanistic data indicate an indirect genotoxic mode of action, nickel is considered a carcinogen group C (carcinogen with a practical threshold).

A background document summarizing the potential of Ni compounds to cause cancer via the oral route of exposure was submitted by the applicant. In summary, absence of oral carcinogenicity of the nickel (II) ion demonstrates that the possible carcinogenic effects of nickel-containing substances in humans are limited to the inhalation route of exposure and the associated organ of entry (i. e., the respiratory tract). After inhalation, respiratory toxicity limits the systemic absorption of Ni (II) ion to levels below those that can be achieved via oral exposure.

3.3.8 Toxicity for reproduction

3.3.8.1 Effects on fertility

Two oral multi-generation reproduction studies and a range-finding one-generation study of nickel sulphate are available (Ambrose et al. 1976, SLI 2000a, SLI 2000b). No effects on fertility have been found in these studies following oral administration. The study by Ambrose et al. (1976) and the one-generation range-finding study (SLI 2000a) indicate NOAELs of 52-80 mg Ni/kg bw/day and 16.8 mg Ni/kg bw/day, respectively. However, the Ambrose et al. study has a limited reporting of data and the range-finding study uses only a limited number of animals (8 per group). Therefore, the most reliable NOAEL is from the OECD TG 416 two-generation study (SLI 2000b) where the NOAEL is the highest dose investigated, i. e. 2.2 mg Ni/kg bw/day.

No effects on sperm morphology or motility, or on vaginal cytology, were observed in rats or mice exposed to concentrations up to 0.45 mg Ni/m^3 (2.0 mg $NiSO_4$ hexahydrate/m^3) for 6 h/day, 5 days/week for 13 weeks (Dunnick *et al.,* 1989; NTP, 1996a). In addition, no histopathological effects on reproductive tissue were observed in the chronic studies, with exposures at concentrations up to 0.11 mg Ni/m^3 (rats) or 0.22 mg Ni/m^3 (mice) for 6 h/day, 5 days/week for 2 years. Degeneration of the germinal epithelium of the testes was observed only at the much higher concentration of 1.6 mg Ni/m^3 in male rats exposed for 6 h/day for 12 days over a 16-day period (Benson *et al.,* 1988) (Haber *et al.* 2000).

3.3.8.2 Developmental toxicity

<u>Human data</u>

In several studies the reproductive health of a large group of female nickel refinery workers exposed to water-soluble nickel species was investigated. There was no increased risk for newborns with genital malformations or undescendend testis (Vaktskjold *et al.*, 2006), for newborns small-for-gestational-age (Vaktskjold *et al.*, 2007) or for newborns with musculoskeletal defects (22,965 births; Vaktskjold *et al.*, 2008a). In a case-control study, the adjusted odds ratio for spontaneous abortions was slightly but statistically non significantly increased (OR 1.14; 95% confidence interval 0.95-1.37; Vaktskjold *et al.*, 2008b). The geometric means of the workers' exposures in this study ranged from 0.03-0.084 mg Ni/m^3 in the low exposure group to 0.15-0.33 mg Ni/m^3 in the high exposure group.

Animal data

No standard prenatal developmental toxicity studies with $NiSO_4$ are available.

According to an abstract from Morvai *et al*. (1982), the group has previously reported that $NiSO_4$ is embryotoxic and teratogenic in mice and rats, and it is embryotoxic and induces spontaneous abortion in rabbits. These studies have, however, not been located in published literature. The abstract describes a study where groups of nonpregnant and pregnant rats were treated daily for 10 days or between the 6th and 15th days of the organogenesis with 100 mg $NiSO_4$ /kg bw/day (22 mg Ni/kg bw/day) by gavage. Authors concluded that nickel caused embryotoxic and teratogenic effects. The results reported from this study indicate that a dose level of 100 mg/kg bw/day (22 mg Ni/kg bw/day) may cause malformations. However, the study is only reported in an abstract and the findings can therefore not be properly evaluated (EU-RAR 2008).

In the range-finding one-generation study in Sprague-Dawley rats given $NiSO_4$ hexahydrate at doses of 0, 10, 20, 30, 50, 75 mg/kg bw/day by gavage (EU-RAR 2008), evaluation of postimplantation/perinatal lethality among the offspring of treated parental rats (i.e. number of pups conceived minus the number of live pups at birth) showed statistically significant increases at the 30, 50, and 75 mg/kg bw/day exposures. The values were also increased at the 10 and 20 mg/kg bw/day levels. However, the difference was not statistically significant. The mean live litter size was significantly decreased at 75 mg/kg bw/day. The number of dead offspring on lactation day 0 (stillbirth) was significantly increased in all exposure groups except the 50 mg/kg bw/day group. The results of this range-finding study indicate a LOAEL for neonatal death of 10 mg/kg bw/day (2.2 mg Ni/kg bw/day) and a NOAEL was not found.

In the 2-generation reproduction study in Sprague-Dawley rats administered $NiSO_4$ hexahydrate at dose levels of 1, 2.5, 5.0, and 10 mg/kg bw/day by gavage (EURAR 2008), the postimplantation/perinatal lethality until postnatal day 0 among the F1 offspring (i.e. number of pups conceived minus the number of live pups at birth) was higher at 10 mg/kg bw/day, however, the difference was not statistically significant (2.1 at 10 mg/kg bw/day vs. 0.9 in the control group, p = 8.6% in Mann-Whitney test). In F2 offspring, the value for postimplantation/perinatal lethality was similar to the F2 control value. The authors state that the results indicate that the highest dose of 10 mg/kg bw/day (2.2 mg Ni/kg bw/day) was a NOAEL for the developmental end points studied, including the variable of post implantation/perinatal lethality. Based on supplementary statistics using the litter as the statistical unit and showing that the increase in postimplantation/perinatal lethality in F1 is statistically significant as well as the above consideration concerning the finding of effects in F1 but not in F2, 10 mg/kg bw/day (2.2 mg Ni/kg bw/day) cannot be regarded as a clear NOAEL. Consequently, the NOAEL is set to 5 mg/kg bw/day (1.1 mg Ni/kg bw/day) in this study (EU-RAR 2008).

In the 3-generation reproduction study Wistar rats were administered 0, 250, 500, or 1000 ppm nickel ($NiSO_4$ hexahydrate) in the diet (EU-RAR 2008)**.** The number of pups born dead was increased at all nickel doses in the F1a generation and at 500 ppm and 1000 ppm in the F1b generation, but there was no effect on pup mortality in later generations. There was a clear and consistent decrease averaging 27% in mean weanling body weight at 1000 ppm in all generations. The study authors state that there was no evidence of teratogenicity, based on gross examinations, and no histopathologic effects on the F3b generation. Evaluation of this study is complicated by the lack of statistical analyses and the reporting of results using pups rather than litters as the unit. Statistical analysis of the number of pups born dead show that the increased numbers at all doses levels in F1a and at 500 and 1000 ppm in F1b is statistically significant. Consequently the LOAEL in the study is set to the lowest dose level investigated, i.e. 250 ppm (13-20 mg Ni/kg bw/day).

Conclusion on reproduction toxicity

There is consistent evidence of developmental toxicity (stillbirth, postimplantation/perinatal lethality) in rats at dose levels not causing maternal toxicity. The TC C&L has agreed to classify $NiSO_4$ as Repr. Cat. 2; R61. [$NiSO_4$ is classified as Cat 2: R61 and Repr. 1B; H360D in the 1st ATP to the CLP Regulation.] This classification is included in the Annex I entry in the 30th ATP.

There is a lack of standard prenatal developmental toxicity studies (OECD 414) and therefore the minimum data requirement in the revised TGD is not fulfilled. However, the minimum data requirement in the prior TGD is more than fulfilled as the multi-generation studies is more extensive than the OECD screening test for reproductive toxicity.

Based on the findings of peri-/postnatal death in the multi-generation studies there is not considered to be urgent need for further testing for developmental toxicity if $NiSO_4$ is classified in Category 2 for developmental toxicity. The potential for effects of $NiSO_4$ on fertility have not been sufficiently investigated, since the highest dose level in the recent OECD TG 416 two-generation study did not induce any signs of toxicity in the adult animals. Therefore, to be able to draw clear conclusions regarding the potential for effects of $NiSO_4$ on fertility further studies using higher dose levels would be relevant. However, there is no reason to expect that such testing would lead to lower NOAELs than the ones already determined for fertility and developmental effects.

3.4 Derivation of Reference Values

3.4.1 Derivation of workers-DNEL

Occupational exposure to $NiSO_4$ occurs primarily by inhalation and by dermal exposure. Direct oral exposure is considered to be negligible and is ignored in this risk characterization.

3.4.1.1 Acute exposure

Inhalation exposure

The Registrant proposed to derive two acute DNEL after inhalation:

- DNEL =16 mg Ni/m3 for acute systemic effects.

This value is based on a NOAEL of 120 mg Ni/m^3 observed in a 4-h single dose inhalation study (EPSL, 2009). In this study the LC50 (50% mortality) was reported at 561 mg Ni/m^3 (equivalent to 2.43 mg NiSO4/m^3). The Registrant proposed to add an assessment factors (AF) to the NOAEL to taking into account interspecies and intraspecies differences in susceptibility and exposure duration.

- DNEL = 0.7 mg Ni/m3 for local respiratory effects.

This value is based on a LOAEL of 0.7 mg Ni/m^3 (toxicity in respiratory tract) observed in rat after an exposure inhalation of 16 days (NTP, 1996). The Registrant proposed to add assessment factors (AF) considering interspecies and intraspecies differences in susceptibility, conversion of LOAEC to NOAEC, and exposure duration.

The risk characterization for acute inhalation (RCR local and systemic) has not been presented in this RMOA. The Registrant has derived the acute exposure estimates by multiplying by 3 the estimate values for long-term exposure and then compared them with either acute local DNEL or acute systemic DNEL. Both acute DNEL are largely higher (more than a factor 3) than the DNEL for long-term inhalation exposure. Thus, the risk characterization for an acute exposure of worker to $NiSO_4$ should be cover by the risk characterization made for the long-term exposure.

Dermal exposure

In the Chemical Safety report (CSR) submitted, no DNEL has been derived for systemic or local effects by dermal route.

3.4.1.2 Chronic exposure

Inhalation exposure

Long –term systemic effects are relevant to long-term worker’s exposure defined as 8 hours/day and 5 days per week for a working life.

The final DNEL for long term effects for workers should be selected on based on a weight of evidence approach and should be protective against carcinogenicity affects as well as possible systemic effects.

SCOEL approach

Nickel compounds have been evaluated in 2011 by the Scientific Committee on Occupational Exposure Limits (SCOEL). The SCOEL has recommended the following proposal:

- An inhalable aerosol fraction indicative OEL of 0.01 mg Ni/m^3 for nickel compounds (excluding nickel metal), based on human epidemiological respiratory cancer data.
- A respirable aerosol fraction indicative OEL of 0.005 mg Ni/m^3 for nickel metal and all nickel compounds, based on respiratory toxicity effects observed in rats exposed to aerosols of MMAD ~ 2 µm and GSD ~ 2.

The SCOEL-proposed indicative inhalable OEL of 0.01 mg/m^3 was derived recognizing that, although nickel compounds may be genotoxic carcinogens, their effects are indirect and there is a practical threshold for tumor induction by nickel. Besides SCOEL, the indirect effects of nickel are broadly accepted in the scientific community (Bal *et al*. 2011; report from 2010 TERA workshop).

Registrant (NiPERA[20]) approach

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[20] Nickel Producers Environmental Research Association (NiPERA)

The Registrant proposed to use an inhalable DNEL of 0.05 mg Ni/m^3 as the DNEL for workers in the "long term- local and systemic effects – inhalation" risk characterization for nickel substances.

This value is based on the approach followed by the SCOEL in recommending indicative nickel OEL (inhalable and respirable) for nickel compounds with further adjustments for differences in particle size distributions between animal experiments and workplace exposures and differences in sampling efficiency between 37-mm and inhalable samplers. The entire NiPERA reasoning is provided in the CSR of the registration dossier (appendix C), besides to the NiPERA comments on the SCOEL approach. As a given exposure level in animals will not necessarily result in the same deposited or retained dose (at a particularly respiratory tract region) in humans, NiPERA used the MPPD model in order to adjust this exposure (based on knowledge of particle size, distribution of the aerosol and breathing rates, etc.) before the DNELs can be compared to the workplaces exposure. The Multiple-Path Particle Dosimetry (MPPD) model was originally developed jointly by the Chemical Industry Institute of Toxicology (CIIT, currently The Hamner Institutes for Health Sciences) and the Dutch National Institute for Public Health and the Environment (RIVM)[21]. MPPD[22] is a computational model that can be used for estimating human and rat airway particle dosimetry which calculates the deposition and clearance of monodisperse and polydisperse aerosols in the respiratory tracts of rats and human (deposition only) for particles ranging in size from ultrafine (0.01 µm) to coarse (20 µm).

The SCOEL value was based on epidemiological data on cancer effects. The registrant-derived inhalable value of 0.05 mg Ni/m^3 is based on toxicity local effects observed in the lungs of rats after inhalation and carcinogenicity effects in the respiratory tract observed in human studies.

Anses approach

The DNEL worker proposed by the registrant in the $NiSO_4$ CSR cannot be endorsed for the following complementary reasons:

- No clear data have been presented by the NiPERA supporting the use of the MPPD model as a validated tool for the nickel particles. Some MPPD models exist that are validated for few particle compounds; MPPD models are specific to compounds and shall be validated from field data; it is not acceptable to apply a generic model to a specific compound without considering the physico-chemical parameters of the considered particle compound.

- MPPD model was originally developed/validated for particles with aerodynamic diameter up to 10 µm and its application to particles up to 61 µm (if this assumption is correct) with important standard deviation (SD) cannot be performed without an extensive validation step. Moreover other important physical properties of the particles as density for instance, are not taken into account in this model. Additionally, because elevated risk of lung and nasal sinus cancer among nickel workers has been demonstrated it does not seem correct to ignore the toxic effect of the fraction of particles not reaching the pulmonary tract. At the end, the proposed mathematic equations to add a clearance function to this model are disproportionately simplistic to describe the clearance mechanisms both in humans and rats, and their differences between species. At least all these

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[21] Anjilvel, S. and Asgharian, B. (1995). A multiple-path model of particle deposition in the rat lung. Fundam. Appl. Toxicol. 28, 41-50 ; National Institute for Public Health and the Environment (RIVM) (2002). Multiple Path Particle Dosimetry Model (MPPD v 1.0): A Model for Human and Rat Airway Particle Dosimetry. Bilthoven, The Netherlands. RIVA Report 650010030

[22] The MPPD software is available for download at http://www.ara.com/products/mppd.htm

reasons/doubts should support the use of an additional assessment factor for interspecies extrapolation based on MPPD model.

- The granulometry data included in the MPPD model are not considered as generalizable (coming from a limited number of working sites/jobs with a questionable methodology, non-publicly available report from Vincent JH 1996 for instance),
- The possible toxicodynamic differences between human and rat should be taken into account by a specific assessment factor (different from 1) due to the fact that MPPD extrapolation only takes into account possible toxicokinetic differences,
- The assumption that retained pulmonary doses, are more relevant for chronic, long-term toxicity/pulmonary effects of nickel particles should be more supported by scientific evidence and mechanism of toxicity. Independently of retained dose, possible heterogeneity of the particles deposition in lung of rats/humans (hotspots) and its influence on cancer development should be discussed.

In conclusion, the DNEL of 0.05 mg Ni/m^3 proposed by registrants is not considered relevant.

As noted previously, limits for nickel and inorganic nickel compounds was set in the recommendation from the SCOEL of June 2011:

- OEL = 0.005 mg Ni/m^3 for the respirable fraction based on chronic lung inflammation and fibrosis in rats observed with $NiSO_4$ (NTP, 1996);
- OEL = 0.01 mg Ni/m^3 for the inhalable fraction based on epidemiological data on cancer effects (lung and nasal cavity).

Respirable and inhalable fractions are described as follows by (Nieboer *et al*., 2005):

- *Respirable aerosol fraction* (or alveolar fraction) is the sub-fraction of the inhaled particles, with an aerodynamic diameter < 10µm, that penetrates into the alveolar region of the lung (i.e., includes the respiratory bronchioles, the alveolar ducts and sacs) and is pertinent to development of such chronic diseases as pneumoconiosis and emphysema.
- *Inhalable aerosol fraction* is the fraction of total airborne particles that enters the body through nose and/or mouth during breathing. This fraction corresponds to particles with aerodynamic diameter ≤ 100 µm and is relevant to health effects anywhere in the respiratory tract such as rhinitis, nasal, bronchial effects, and lung cancer.

In a conservative approach, the lowest OEL proposed by the SCOEL would be used for the risk characterization. However, this value of 0.005 mg Ni/m^3 is based on animal studies with inhalation exposure to respirable aerosols which are of small particle size and of great homogeneity. At the workplace, particles are not limited to the respirable fraction, and workers are usually exposed to coarser and more heterogeneous aerosols. Therefore an OEL based on animal aerosols of MMAD < 10 µm is not directly comparable to the workplace exposures and may overestimate the risk associated with the coarser workplace nickel exposures.

On this basis, the OEL of 0.01 mg Ni/m^3 set by the SCOEL for the inhalable fraction is considered as more relevant for the risk characterization. This value is based on a significant increase in cancer incidence in a refinery workers cohort (Grimsrud *et al*., 2002) and is therefore directly comparable to exposure estimates that are presented by the registrants in the dossiers.

However, it has to be noted that this value covers the risk of cancer incidence, and also the reproductive effect, but it does not take into account the respiratory chronic inflammations observed at lower doses in animal exposed to respirable fraction of nickel compounds (NTP, 1996).

3.4.1.3 Dermal exposure

As the absorption by the dermal route is low (2% see point 3.1.1.1), systemic effects from this route has not been considered to be of concern.

Thus, the Registrant only considered local effects as relevant, taking into account the sensitizing potential of $NiSO_4$.

However, sensitization is more often considered as a non-threshold effect, and available data cannot permit to assess quantitatively the risk, thus no DNEL can be derived. A qualitative risk assessment is therefore considered as relevant for this effect, with appropriate risk management measures and operating conditions.

3.5 Exposure data and risk characterization

3.5.1 Data description

Inhalation and dermal routes are the main exposure paths to $NiSO_4$ considered for workers.

Exposure data presented below are from the CSR provided by Registrant. Risk Characterization Ratios (RCRs) have been re-calculated with the new DNEL for long term inhalation exposure proposed by ANSES.

The risk characterization for acute inhalation (RCR local and systemic) has not been presented in this RMOA. The Registrant has derived the acute exposure estimates by multiplying by 3 the estimate values for long-term exposure and then compared them with either acute local DNEL or acute systemic DNEL. Both acute DNEL are largely higher (more than a factor 3) than the DNEL for long-term inhalation exposure (see point 3.1.1.2.2). Thus, the risk characterization for an acute exposure of worker to $NiSO_4$ should be cover by the risk characterization made for the long-term exposure.

3.5.1.1 Overview of the available information

According to the CSR, descriptive information on uses and processes in addition to human health exposure data presented in this chapter and related annex are based on data collected for the EU $NiSO_4$ producers and Downstream Users (DUs) under the framework of the Existing Substance Regulation (ESR) program (Directive 93/67/EEC and Regulation N° 1488/94 on Risk Assessment for New and Existing substances) for the development of the EU RAR for Nickel and Nickel Compounds (2008-2009). The EU RAR (2008-2009) contains valuable information collected in or around the year 2000 with respect to exposure, emissions, Operational Conditions (OCs) and RMMs from industrial sites located in the EU-15 countries.

Since the year 2000, some nickel substance producers and users have developed new best available technologies, adapted and improved operations and processes, and upgraded their RMMs. In addition, the EU has expanded to 27 Member States. Therefore, updated and new information was gathered by the Nickel Consortia during 2008-2010 via questionnaire for REACH from producers and DUs of $NiSO_4$ located in the EU-27 countries and Norway. The REACH questionnaire focused on general exposure and contextual information, in particular:

- Production facility details, tonnage of raw materials, general description of use, manufacturing processes, RMMs, detailed environmental emission information (*e.g.* emission data, ambient monitoring data, dilution factor and bioavailability parameters) and occupational exposure information (*e.g.* particle size information, efficiency information of exhaust equipment and Personal Protective Equipment (PPE)).

In parallel to the questionnaires, The Institute of Occupational Medicine (IOM) conducted site visits (IOM report, 2009) at five nickel and nickel substance producing companies, to assist in the collection and the evaluation of nickel occupational exposure data. During the site visits, IOM gathered information on exposure, production processes and RMMs.

Information and exposure data from all these sources were used to develop the Generic Exposure Scenarios (GES).

For $NiSO_4$ producers, inhalation exposure data were provided by 5 or 6 sites, with monitoring records going back as far as the late 1990s. Most exposure measurement data were reported as (or assumed to be) measurement of the inhalable fraction. When respirable dust measurements were reported, values were multiplied by an arbitrary correction factor of 2 to convert them into an inhalable exposure level for comparison with DNEL.

Limited inhalation and dermal exposure measurements have been published in the literature and these are reports based on IOM studies (Hughson, 2004). In the case of NiSO4, such exposure data were available for one site only (Company 3). These data have been used as read across for estimating exposure in analogous packing operations.

For downstream users (DU), only a small number of them, using $NiSO_4$, provided exposure concentration measurements and data are only available for electroplating. In addition, small number of DU using other nickel salts for electroplating also provided exposure data that were considered relevant to assessing $NiSO_4$ exposures. The quantity and quality of data provided by the DU was very variable and there are significant uncertainties in their interpretation. The process descriptions and descriptions of RMM in place provided by DU generally lacked details. The extent of process automation and enclosure that is typically in place is difficult to assess for most exposure scenarios. Moreover, with the exception of some of the data reviewed by the EU RAR (2008-2009) and data published more recently by Hughson (2010), most measurements of nickel exposure in downstream user industries, including measurements reported in the recent DU survey, have not distinguished between soluble and insoluble nickel.

3.5.1.2 Exposure and risk assessment

Information of the personal protective equipments (PPEs) and risk management measures (RMMs) that are implemented by Industry are provided either in the following sections either in appendix 4 depending of the GES.

For the GES 1, 2, 3, 4, 6 and 9, data on PPEs and other RMMs are provided in the summary tables in appendix 4 because of the large quantity of information. Those tables are extracted from the CSR[23] and include the process summary, operating conditions, risk management measures, exposure data description, etc.

For the GES 5, 7, 8, 10 and 11, data on PPEs and other RMMs have been revised in the registration dossier updates of 2012 and 2013 and have been preferred to the former data provided in appendix 4 (some are indeed non consistent with the old ones). Those updated data are thus provided as summary tables in the following document in each concerned GES.

3.5.2 Risk characterization per GES

A summary table is presented in appendix 5.

Regarding nickel sulphate production in Europe

Four companies (Companies 1 to 4) at six sites manufacture $NiSO_4$ hexahydrate ($NiSO_46H_2O$) as a crystalline powder, from $NiSO_4$ solution. Nickel sulphate is produced as a by-product of production of copper and other metals and via the refining of nickel matte and nickel intermediates produced during the recyling of a variety of secondary materials (*e.g.* spent nickel catalysts, nickel/cobalt residues, copper-nickel alloys and drosses).

Based on the information provided by the companies, the registrant has developed three GES:

- $NiSO_4$ production from copper refining (GES 1)
- Solvent extraction of $NiSO_4$ leachate (GES 2)
- Crystallisation from purified $NiSO_4$ leachate (GES 3)

Regarding the downstream uses of nickel sulphate

The potential exposure to $NiSO_4$ is described from the occupational standpoints for the downstream uses made known to the Nickel Consortia. The exposure assessment and risk characterisation covered by the current DUs GES are likely to be refined over time due to the iterative process of the exposure scenarios communication in the supply chain.

The actual identified downstream uses of $NiSO_4$ cover the following sectors:

- Metal surface treatment – nickel electroplating, nickel electroforming and electroless nickel plating (GES 4),
- Production of batteries using positive nickel electrodes (GES 5),
- Production of nickel salts from $NiSO_4$ (GES 6),
- Use of $NiSO_4$ in the manufacturing of micronutrient additives for biogas production (GES 7)
- Production of nickel-containing pigments from $NiSO_4$ (GES 8),
- Selective plating (GES 9),
- Formulation of products for surface treatment of anodized aluminum sheets (GES 10)

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[23] Pages 245 to 347

3.5.2.1 GES 1: Nickel sulphate production from copper refining

Contributing Exposure Scenarios

Companies 1 and 2 operate this manufacturing process both at two different sites. The spent electrolyte, obtained during the electro-refining of copper, is purified by precipitation of copper sulphate and by electrowinning copper. Processing of the purified $NiSO_4$ solution involves converting the $NiSO_4$ solution into the final product, $NiSO_4 6H_2O$ or $NiSO_4 6H_2O$, for recovery.

Table 16 summarizes the Contributing Exposure Scenarios (CES) developed from the contextual data reported on the process and, to a lesser extent, from the sampling records attached to the exposure measurements.

Table 16. CES developed for GES 1 $NiSO_4$ production from copper refining from industry

CES title	**Description**
1.1: Electrolyte Reception	Reception of spent (Cu-Ni) electrolyte obtained from electrolysis (of Ni-containing Cu anode to give Cu cathode) from the copper refinery
1.2: De-copperisation / electrolysis	Purification by de-copperisation of spent electrolyte to give a $NiSO_4$ solution
1.3: Solution concentration & NiSO4.2H2O or $NiSO_4 6H_2O$ crystallisation	Concentration of the $NiSO_4$ solution by volume reduction and precipitation/crystallisation of $NiSO_4 6H_2O$ or $NiSO_4 6H_2O$ from the NiSO4 solution.
1.4: Packaging	Packaging of moist $NiSO_4 6H_2O$ or $NiSO_4 6H_2O$ crystals
1.5: Cleaning & Maintenance	Cleaning and Maintenance are reported as examples of regular and service maintenance routines for plant and premises

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in the Table 17.

Table 17. CES developed for GES 1: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m^3	**Methods for calculation**	**mg Ni/m^3**	**Tier 1**	**Tier 2**	
CES 1.1 Electrolyte reception	0.52	**MEASE modeling (tier1 model):** - PROC2. - Medium dustiness - Non-direct handling - Closed system without breaches.	0.01	**52**	**1.3****	🟥 RCR> 1 (MEASE modelling, RPE 40)
CES 1.2 De-copperisation	0.006	**Exposure data measurements:**	0.01	**0.6**	**-**	N° measure: 2 GSD: not specified

CES (Contributing Exposure Scenario)	Inhalation Exposure estimation		DNEL	RCR	RCR	Confidence in the RCR
	mg Ni/m^3	Methods for calculation	mg Ni/m^3	Tier 1	Tier 2	
/electrolysis		Highest of 2 personal, inhalable exposure measurements for evaporator and filter Operator				**Insufficient**
CES 1.3 Solution concentration & $NiSO_46H_2O$ or $NiSO_46H_2O$ crystallisation	0.006	**Exposure data measurements:** Single personal, inhalable exposure measurement for 'evaporator and filter' operator	0.01	**0.6**	**-**	N° measure: 1 GSD: not specified **Insufficient**
CES 1.4 Packaging	0.02	**Exposure data measurements:** 2 personal respirable measurements taken during filling and loading to containers. Inhalable value estimated as twice the respirable exposure level.	0.01	**2**	**0.1***	N° measure: 2 GSD: not specified **Insufficient**
CES 1.5 Cleaning & Maintenance	0.08	**Exposure data measurements:** Inhalable value estimated as twice the respirable exposure level (personal, respirable value was the maximum result of 4 measurement ranges for evaporators and crystalliser service)	0.01	**8**	**0.4***	N° measure: not specified only 4 ranges (min and max values) available GSD: not specified **Insufficient**

Legend:

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

Tier 2: *: considering a protection factor of 20 for RPE . **: considering a protection factor of 40 for RPE

- CES 1.1:

For the CES 1.1, no inhalation exposure monitoring data were available for the reception of the purified electrolyte in raw materials handling. Thus, inhalation exposure concentrations were estimated using the Tier 1 model, MEASE.

MEASE is a simple metal-specific Microsoft Excel tool that calculates the long-term exposure concentrations based on generic PROC codes, properties of the substance being handled, the type of the use (e.g. industrial) and finally any common risk management measures (RMMs) in place.

According to the MEASE model using the parameters summarized in table 2, the inhalation exposure was estimated at 0.52mg Ni m^{-3}, RCR for long term inhalation exposure are above 1 even considering PPE with an APF of 40. This level of protection is consistent with the RPE (APF 40) proposed by the Registrant for this task. Indeed, the registrant provided some information on the available Risk Management Measures (RMM) and PPE for the GES 1 which is presented in the Annex 3 Table 1.

However even considering RPE (APF 40), as RCR is > to 1, the risk for workers is unacceptable for CES 1.1.

- CES 1.2; CES 1.3; CES 1.4 and CES 1.5

For all other CES (CES 1.2; CES 1.3; CES 1.4 and CES 1.5) included in the GES 1, only a few personal or static inhalation measurements have been reported for three of the four sites: 7 as individual and 5 as a range). These measurements for inhalation were obtained from two companies (1 and 2) by questionnaire (see details in CSR).

Due to the limited number of measurements recorded for GES 1 operations or because the full data set was not available it was not feasible to use the 75th percentile of the exposure distributions as the exposure estimates (cf. Table 14). For CES 1.2, CES 1.3, CES 1.4, the number of exposure is ≤ 2 and for CES 1.5, only a range (minimum and maximum values) is available. In this context, the registrant proposed to use the maximum value for each CES for the inhalation exposure estimation.

For CES 1.2 and CES 1.3, the calculated RCR for long term exposure are below 1 considering no RPE.

For CES 1.4 and CES 1.5, the calculated RCR for long term exposure are below 1 considering RPE with an APF of 20. This recommendation is consistent with the RPE (APF 20 or 40) proposed by the Registrant which is presented in the Annex 3 Table 1.

However, the small number of measurements combined with the lack of monitoring details and contextual information reported for these measurements means there is high level of uncertainty associated with the exposure estimates and their associated RCR. Indeed, according to the REACh guidance on occupational exposure estimation[24] a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5.

Thus, no definite conclusion can be made on the risk for the CES 1.2, CES 1.3, CES 1.4 and CES 1.5.

Dermal route: Exposure estimates

According to the Registrant, dermal exposure during $NiSO_4$ production from copper refining from industry was modeled using the 90th percentile from MEASE modeling for CES 1.1 and CES 1.2.

For CES 1.4 and CES 1.5, dermal exposure estimation was based on a qualitative assessment using the 75th percentile (full body exposure) based on packaging data from an analogous operation (packaging of $NiSO_4 6H_2O$).

For CES 1.3, the registrant assumed that dermal exposure is likely to be sufficiently controlled by prevention of acid burns.

Table 18. CES developed for GES 1: dermal exposure estimates and RCR

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[24] Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupationnal exposure estimation, version2.1, November 2012.

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 1.1	2	- Solid, medium dustiness- Content in preparation: > 25% - Duration exposure: > 240 min - Incidental exposure- NDH-NDU - Closed system without breaches - Area of skin (cm^2): 240 - PPE: yes.	0.00005	0.011
CES 1.2	22	- Solid, medium dustiness- Content in preparation: > 25% - Duration exposure: > 240 min - Incidental exposure- NDH-NDU - Closed system without breaches - Area of skin (cm^2): 1980 - PPE: yes.	0.00005	0.011
CES 1.3	-	-	Not reported	< 1 *
CES 1.4	-	-	0.00067	1.5 without PPE < 1 with gloves *
CES 1.5	-	-	0.00067	1.5 without PPE < 1 with gloves *

*Qualitative assessment

NDH Non- direct handling

NDU Non- dispersive use

WDU Wide dispersive use

GV General ventilation

LEV Local exhaust ventilation

Enc Enclosure

Ext LEV Exterior LEV

RCR are below unity (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during these tasks.

According to registrant (see Table 1 in Annex 3), gloves is required for all task of GES 1.

3.5.2.2 GES 2: Nickel sulphate production from solvent extraction of nickel sulphate leachate

Contributing Exposure Scenarios

Only one company in Europe (Company 3) operates this production process. Only two CES were developed in GES 2, namely CES 2.1 which consolidates all process steps, including raw materials handling and packaging final product, and CES 2.2 covering cleaning and maintenance. Table 16 also presents the breakdown of CES 2.1 into the four process steps (as underpinning CES) which effectively define CES 2.1.

Table 19. CES developed for GES 2 $NiSO_4$ production from solvent extraction of $NiSO_4$ solution from industry

CES	**Underpinning CES**	**Description of underpinning CES**
2.1: Production	1: Crude $NiSO_46H_2O$	Impure (recrystallised as crude) $NiSO_46H_2O$ (and/or crude $NiSO_4$

	and $NiCO_3$ reception &leaching	solution) and nickel carbonate are charged into a reactor and dissolved in sulphuric acid to give an impure $NiSO_4$ leachate solution
	2: Purification of leachate to make $NiSO_4$ solution	Purification of the impure (crude) $NiSO_4$ leachate solution by precipitation and separation of iron and copper from solution.
	3: Further solution purification, concentration & $NiSO_46H_2O$ crystallisation	Removal of cobalt by solvent extraction from the purified $NiSO_4$ solution and recrystallisation (from the raffinate), separation and drying of $NiSO_46H_2O$.
	4: Packaging	Packaging of dried $NiSO_46H_2O$ into bags
2.2: Cleaning & Maintenance	5: Cleaning & Maintenance	Cleaning and Maintenance are reported as examples of regular and service maintenance routines for plant and premises

<u>Inhalation route: Exposure estimates and calculated RCR</u>

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in Table 20.

Table 20. CES developed for GES 2: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Confidence in the RCR**
	mg Ni/m^3	**Methods for calculation**				
CES 2.1: Charging *Crude $NiSO_46H_2O$ and $NiCO_3$ reception & leaching*	1.32	**MEASE modeling (tier1 model):** - PROC 4. - solid, Medium dustiness - Non-direct handling - LEV assumed.	0.01	**132**	**3.3****	RCR >1 (MEASE modeling, RPE = 40)
CES 2.2: Purification of leachate to make $NiSO_4$ solution	0.02	**MEASE modeling (tier1 model):** - PROC 2. - solution - Non-direct handling - LEV assumed.	0.01	**2**	**0.1***	RCR <1 (MEASE modeling, RPE 20)
CES 2.3: solvent extraction *Further solution purification, concentration & $NiSO_46H_2O$ crystallisation*	0.12	**MEASE modeling (tier1 model):** - PROC 2. - solid, Medium dustiness - Non-direct handling - LEV assumed.	0.01	**12**	**0.6***	RCR < 1 (MEASE modeling, RPE 20)

CES (Contributing Exposure Scenario)	Inhalation Exposure estimation		DNEL	RCR	RCR	Confidence in the RCR
	mg Ni/m3	Methods for calculation	mg Ni/m^3	Tier 1	Tier 2	
CES 2.4: Packaging of $NiSO_4 6H_2O$ into bags	0.01	**Exposure data measurements:** 75th percentile value of personal exposure measurements (n=12) aggregated over all activities	0.01	**1**	**0.05***	N° measure: 12 GSD: not specified
CES 2.5: Cleaning & Maintenance	0.66	**MEASE modeling (tier1 model):** - PROC 10. - solid, Medium dustiness - Non-direct handling - <240 min - LEV assumed.	0.01	**66**	**3.3*** **1.65****	RCR > 1 (MEASE modeling, RPE 40)

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

* RPE = 20 (RCR tier 2)

**RPE = 40 (RCR tier 2).

For CES 2.1, 2.2, 2.3 and 2.5 where measurement data was not available, inhalation exposure concentrations were estimated using the Tier 1 model, MEASE.

- CES 2.1, CES 2.5

For both CES 2.1 and CES 2.5, according to the MEASE model using the parameters summarized in Table 5, RCR for long term inhalation exposure are above one, even considering RPE with the maximum protection factor of 40 (APF 40). Based on the information on the available Risk Management Measures (RMM) and PPE submitted by the Registrant (see Annex 3 Table 2), it seems that only RPE with an APF of 20 was reported for these tasks.

Considering RPE (APF 40), as RCR is above one, the risk for workers is unacceptable for both scenario CES 2.1 and CES 2.5.

- CES 2.2, CES 2.3

For CES 2.2 and CES 2.3, inhalation exposures were estimated with the MEASE model using the parameters summarized in Table 17. Calculated RCR for long term inhalation exposure are below 1 only considering workers wearing RPE with a protection factor of 20 (APF 20). This level of protection is coherent with the PPE (APF 40) proposed by the Registrant (see Annex 3 Table 2).

Thus, considering RPE (APF 40) proposed by registrant, RCR are below the unit leading to an acceptable risk for CES 2.2 and CES 2.

- CES 2.4

According to the registrant, one summary inhalation exposure concentration was obtained from the industry data aggregated all process steps of GES 2 (including packing and excluding cleaning and maintenance). A long term exposure estimate of 0.01 mg Ni m^3 was proposed based on the 75th percentile value of 12 personal exposure measurements. No available inhalation measurement was available for CES 2.4 alone.

Calculated RCR for CES 2.4 is below 1 only considering workers wearing RPE with a protection factor of 20 (Table 17). This level of protection is consistent with the RPE (APF 40) proposed by the Registrant (see Table on information on the available Risk Management Measures (RMM) and PPE for the GES 2).

According to the REACh guidance on occupational exposure estimation, the number of measurements could be sufficient (n=12) but no information was provided on the distribution of the data (GSD not specified). Moreover, these measurements were aggregated from several different steps and are not specific to CES 2.4 alone.

Thus, although RCR is below the unit leading to an acceptable risk with the wear of RPE, no definite conclusion can be made for CES 2.4.

Dermal route: Exposure estimates

According to the Registrant, dermal exposure during $NiSO_4$ production during solvent extraction of $NiSO_4$ leachate was modeled using the 90th percentile from MEASE modeling for CES 2.1 CES 2.2, CES 2.3 and CES 2.5.

For CES 2.4, dermal exposure estimation was based on a qualitative assessment using the 75th percentile (full body exposure) based on packaging data from an analogous operation (packaging of $NiSO_46H_2O$).

Table 21. CES developed for GES 2: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 2.1	4	Solid, medium dustiness- Content in preparation: > 25% - Duration exposure: > 240 min - Incidental exposure- NDH-NDU - Area of skin (cm^2) : 960 - PPE: yes.	0.00005	0.113
CES 2.2	2	Solution Ni -Content in preparation: > 25% - Duration exposure: > 240 min - Incidental exposure- NDH-NDU - Area of skin (cm^2) :240 - PPE: yes.	0.00005	0.113
CES 1.3	2	Solid, medium dustiness- Content in preparation: > 25% - Duration exposure: > 240 min - Incidental exposure- NDH-NDU - Area of skin (cm^2) : 240 - PPE: yes.	0.00005	0.11
CES 2.4	-	-	0.00067	1.5 without PPE < 1 with gloves *
CES 1.5	10	Solid, medium dustiness- Content in preparation: > 25% - Duration exposure: < 240 min - Incidental	0.00003	0.068

		exposure- NDH-NDU - Area of skin (cm^2) : 960 - PPE: yes.		

*Qualitative assessment

NDH Non- direct handling	GV General ventilation	Enc Enclosure
NDU Non- dispersive use	LEV Local exhaust ventilation	ExtLEV Exterior LEV
WDU Wide dispersive use		

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during these tasks.

According to registrant (see Table 2 on Annex 3), gloves is required for all task of GES 2.

3.5.2.3 GES 3: Crystallisation of nickel sulphate hexahydrate from a purified nickel sulphate leachate

Contributing Exposure Scenarios

Only one company in Europe (Company 4) operates this production process on a multipurpose site where the matte is also produced by smelting. The raw material stream comes into the plant as a purified $NiSO_4$ leachate which is then processed to recover the $NiSO_46H_2O$. Table 22 provides a description of the five contributing exposure scenarios.

Table 22. CES developed for GES 3 $NiSO_4$ production by crystallisation of $NiSO_4$ from a purified $NiSO_4$ leachate

CES title	**Description**
3.1: Purified leachate reception & charge into reactor	A purified (excluding recrystallisation) $NiSO_4$ leachate solution is obtained ready for processing
3.2: Solution concentration, $NiSO_46H_2O$crystallisation & separation	Crystallisation and separation of $NiSO_46H_2O$from this $NiSO_4$ solution
3.3: Drying	Drying of $NiSO_46H_2O$
3.4: Packaging	Packaging of dried $NiSO_46H_2O$into bags
3.5: Cleaning & Maintenance	Cleaning and Maintenance are reported as examples of regular and service maintenance routines for plant and premises

The drying and packaging steps were recorded in the questionnaire as one step. However, the Registrant was decided to separate these into distinct CES as the drying and packing steps are likely to be carried out in separate parts of the plant. No information was provided on the type of drying plant used after centrifugal separation; however it is likely to be an enclosed and automated process. The packaging was described as a highly automated and enclosed process but is likely to involve more routine manual interventions during operation than a closed drying plant.

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in Table 23.

Table 23. CES developed for GES 3: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	Confidence in the RCR
	mg Ni/m3	**Methods for calculation**	**mg Ni/m3**	**Tier 1**	**Tier 2**	
CES 3.1 Purified leachate reception & charge into reactor	0.02	**MEASE modeling (tier1 model):** - PROC 1 -medium dustiness solid, - > 25% concentration, - non-direct use, - intermittent exposure for more than 4h - LEV	0.01	**2**	**0.1***	RCR < 1 (MEASE modeling)
CES 3.2 solution concentration, $NiSO_46H_2O$ crystallisation & separation	0.006	**Exposure data measurements:** single measurement taken during 'operating evaporator and filter' during an analogous activity	0.01	**0.6**	**-**	N° measure: 1 GSD: not specified **Insufficient**
CES 3.3 drying	0.11	**MEASE modeling (tier1 model):** - PROC 2 -medium dustiness solid, - > 25% concentration, - non-direct use, - intermittent exposure for more than 4h. - LEV	0.01	**11**	**0.55***	RCR < 1 (MEASE modeling, RPE 20)
CES 3.4 packaging	0.023	**Exposure data measurements:** 75th percentile of personal, inhalable measurements (n=7) for packaging. . Packaging value includes $NiSO_4$ and nickel hydroxycarbonate, as the packaging was carried out in same area and the operators rotate between both.	**0.01**	**2.3**	**0.11***	N° measure: 7 GSD: not specified

CES 3.5 cleaning & maintenance	0.3	**MEASE modeling (tier1 model):** - PROC 10 - low dustiness solid, - > 25% concentration, - non-direct handling, - non dispersive - intermittent exposure for ≤ 4h. - LEV	0.01	**30**	**1.5*** **0.07****	RCR < 1 MEASE modeling RPE 40

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

* RPE = 20 (RCR tier 2)

**RPE = 40 (RCR tier 2)

Personal inhalation exposure measurements are only available for the packaging operation (CES 3.4). No exposure data were available for the other contributing exposure scenarios.

- CES 3.4

Seven personal inhalation samples were collected for packaging in the $NiSO_4$and hydroxycarbonate packaging area in 2004 with a minimum sampling duration of six hours. The results of the measurements ranged from 0.011 to 0.101 mg Ni m^{-3}. Thus, for CES 3.4, packaging, a 75th percentile inhalation exposure value of 0.023 mg Ni m^{-3} was derived from these seven personal exposure measurements.

Table 8 shows that RCR is below 1 only when workers used RPE with an APF of 20. It was reported by the registrant that the operators wore air assisted filtering visors with P3 filter (APF =20) and 'rigger' type gloves during packaging. In addition, based on reasonably comprehensive/informative contextual information, the exposure measurements were assigned with some certainty to an automated bag packing and (full bag) stacking and wrapping system (Annex 3 Table 3).

However, the small number of measurements means there is high level of uncertainty associated with the exposure estimates and the associated RCR. Indeed, according to the REACh guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5.

Thus, no definite conclusion can be made on the risk for the CES 3.4.

- CES 3.1, CES 3.3 and CES 3.5

For CES 3.1, 3.3, and 3.5 as measurement data were not available, inhalation exposure concentrations were estimated using the Tier 1 model MEASE.

For CES 3.1 and CES 3.3, RCR for long term inhalation exposure are below 1 considering RPE with an APF of 20. This level of protection is consistent with the RPE (FFP3 mask) proposed by the Registrant for these tasks (see information on the available Risk Management Measures (RMM) and PPE for the GES 3 in Annex 3Table 3).

For CES 3.5, RCR for long term inhalation exposure are below 1 only when considering RPE with an APF of 40.

This level of protection is not consistent with the RPE (FFP3 mask) proposed by the Registrant for this task (see information on the available Risk Management Measures (RMM) and PPE for the GES 3 in Annex 3 Table 3).

In conclusion considering RPE (APF 20), RCR are below the unit leading to acceptable risk for CES 3.1, CES 3.3. For CES 3.5, RCR are above the unit leading to an unacceptable risk, considering RPE (APF 20) proposed by the Registrant.

- CES 3.2

For CES 3.2 an exposure estimate was assigned by read across from an analogous process step represented by CES 1.3. A single personal inhalable exposure measurement taken during operating evaporator and filter was available.

The calculated RCR for long term exposure are below 1 considering no RPE. The RCR can be reduced by using RPE recommended by the Registrant (APF 20) which is presented in the Annex 3 Table 3.

However, the small number of measurements means there is high level of uncertainty associated with the exposure estimates and the associated RCR. Indeed, according to the REACh guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5.

Thus, no definite conclusion can be made on the risk for the CES 3.2.

Dermal route: Exposure estimates

According to the Registrant, dermal exposure measurements are only available for the packaging operation for this site (CES 3.4). Packaging value includes $NiSO_4$ and nickel hydroxycarbonate, as the packaging was carried out in same area and the operators rotate between both. Dermal exposure measurements from various body parts were collected from 8 workers. The measurements were carried out using a wipe method.

The results of the dermal samples across all body parts ranged from 0.00001 to 0.00153 mg Ni cm^{-2}. A 75th percentile dermal exposure value of 0.00054 mg Ni cm^{-1} for hands and arms and 0.00067 mg Ni cm^{-1} for full body was derived from eight personal exposure measurement. The latter was used to determine the RCR.

For this CES, It was reported that the operators wore 'rigger' type gloves (Hughson, 2004) during packaging and according to registrant dermal exposure is likely to be sufficiently controlled by use of rigger gloves.

For CES 3.1, 3.2, 3.3 and 3.5 where measurement data was not available, dermal exposure concentrations were estimated using the Tier 1 model MEASE.

Table 24. CES developed for GES 3: dermal exposure estimates and RCR

CES	PROC code	MEASE modeling parameters	Exposure estimation (mg(Ni) cm^{-2} d^{-1})	RCR
CES 3.1	1	- Solid, medium dustiness- Content in preparation: > 25% - NDH-NDU - Intermittent exposure for more	0.00005	0.114

		than 4h - Area of skin (cm^2): 960 - PPE: yes.		
CES 3.2	2	- Solid, medium dustiness- Content in preparation: > 25% - NDH-NDU - Intermittent exposure for more than 4h - Area of skin (cm^2): 240 - PPE: yes.	0.00005	0.113
CES 3.3	2	- Solid, medium dustiness- Content in preparation: > 25% - NDH-NDU - Intermittent exposure for more than 4h - Area of skin (cm^2): 240 - PPE: yes.	0.00005	0.113
CES 3.4	-	-	0.00067	1.5 without PPE[1] < 1 with gloves[2]
CES 3.5	10	- Solid, medium dustiness- Content in preparation: > 25% - NDH-NDU - Intermittent exposure for more than 4h - Area of skin (cm^2): 960 - PPE: yes.	0.00003	0.068

[1] Estimated exposure exceed the DNEL (dermal), suitable gloves and clothing should be worn to minimize skin contact with Ni species and the associated risk of sensitization.

[2] Qualitative assessment.

NDH Non- direct handling

NDU Non- dispersive use

WDU Wide dispersive use

GV General ventilation

LEV Local exhaust ventilation

Enc Enclosure

ExtLEV Exterior LEV

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during these tasks.

According to registrant (see Annex 3 Table 3), gloves is required for all task of GES 3.

3.5.2.4 GES 4: Metal surface treatment: nickel electroplating, nickel electroforming and electrodes nickel plating

The exposure assessment for GES 4 is based on a redrafted version of the CSR (2013 updates) including new information on processes and exposure data provided to the nickel Consortia.

This exposure assessment chapter describes the use of hydrated $NiSO_4$ and $NiSO_4$ solution in surface finishing and electroforming.

Introduction and Contributing Exposure Scenarios

Ten companies submitted information on this use to the Registrant (Nickel Consortia) in 2008-09 using Questionnaire. Twelve (non-battery producing) companies submitted information on this use in a second survey which was carried out during 2011 and 2012 as part of the 2013 update. Two battery producing companies were reported during the update as using $NiSO_4$ (Companies 3 and 11) but only one of these was identified as performing $NiSO_4$-based electroplating (Company 3).

Surface finishing operations can be carried out using manual, mechanized or fully automated processes together with the application of different levels of risk management measures. Some companies operate as job shops taking in orders for surface finishing from a range of external production companies. Others are operated as in house or captive shops where they get their items for surface finishing from production departments within the same company. This means there is a wide range of operating conditions (OC) and risk management measures (RMM) in use in the surface finishing industry. Therefore one CES was developed as CES 4.1 to consolidate all process steps including:

- Raw materials handling,
- Preparation of $NiSO_4$ plating solution from a $NiSO_4$ purchased stock solution
- Addition of $NiSO_4$ to working tank solution during replenishment (dosing or topping-up),
- Dipping items with surfaces to be cleaned, prepared and coated into solutions,
- Rinsing treated and coated items,
- Removal of coated items from jigs or barrels,
- Removal and treatment of working and spent solutions and dirty rinse water from tanks,
- Testing working solution composition.

CES 4.2 represents the cleaning and maintenance of plant and premises and is considered to include solution maintenance tasks such as 'addition $NiSO_4 6H_2O$ to working tank solution during replenishment', 'preparation of $NiSO_4$ solution from $NiSO_4 6H_2O$ and solution filtering. Packaging is not covered in CES 4.1 because the Ni present at this stage would be Ni metal, deposited over the item's surfaces during finishing or comprising the item manufactured during electroforming. This Ni metal coating or surface would be washed free of $NiSO_4$ solution and then dried in the final step of the finishing process.

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in the Table 25a.

Table 25a. CES developed for GES 4: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m^3	**Methods for calculation**	**mg Ni/m^3**	**Tier 1**	**Tier 2**	
CES 4.1 Nickel electroplating, nickel electroforming & electroless nickel plating	0.0083	**Exposure data measurements:** 75th percentile value from 20 personal exposure measurements ranging from 0.0009-0.0235 mg m^3	0.01	**0.85**	**-**	N° measure: 20 GSD: 2.7 RCR < 1 (no RPE)
CES 4.2 Cleaning and Maintenance	0.342	**MEASE modeling (tier1 model):** - PROC 10 - medium dustiness solid,	0.01	**34.2**	**3.4°** **1.7*** **0.17****	RCR < 1 (MEASE modeling, RPE 40)

CES (Contributing Exposure Scenario)	Inhalation Exposure estimation		DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Confidence in the RCR
	mg Ni/m^3	Methods for calculation				
		-5-25% concentration - non-direct handling, -non dispersive -1h duration exposure - GV				🟥

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

° RPE = 10

* RPE = 20

** RPE= 40

- CES 4.1

Inhalation exposure measurements were available only for CES 4.1.The summary exposure estimate for CES 4.1 has been calculated as a 75th percentile value of 0.0083 mg m^{-3} from 20 individual personal exposure measurements ranging from 0.0009-0.0235 mg m^{-3} (table 22a). The 20 measurements were taken in 5 different companies using $NiSO_4$ as the only electrolyte (Company 7, Company 10, Company 14, Company 17 and Company 18) and in 3 companies using $NiSO_4$ together with $NiCl_2$ (Company 4, Company 16 and Company 20)

Calculated RCR is below 1 for CES 4.1. The data has a GSD of 2.7 (determined from 20 measurements) and has a RCR which lies in the range <0.5-0.1. ECHA classifies a GSD of 2.7 as moderate (2-3.5), requiring between 20 and 30 measurements to be sure that the actual value of the RCR is less than one. This means that there is sufficient number of measurements for CES 4.1 to be confident that the RCR value is below 1 (RCR < 1).

For CES 4.1, the risk for the worker is acceptable without wearing RPE.

The RCR can be reduced by using RPE. Indeed, the registrant provided information on the available PPE and RMM which can differ between Companies (see Annex 3 Table 4).

- CES 4.2

For CES 4.2, the long-term estimate was modeled as the 90th percentile value (mg Ni m^{-3}) for inhalable nickel using the MEASE model. Table 22 shows that RCR is below 1 (RCR <1) only when workers used RPE with an APF of 40. Based on the questionnaire submitted to the downstream user companies, it seems that only RPE with an APF of 10 or 20 (FFP2 or FPP3) was reported for these tasks (see Annex 3 Table 4).

In conclusion, considering the RPE proposed by registrants, RCR for long term inhalation exposure is above 1 for CES 4.2 leading to an unacceptable risk for this scenario.

Dermal route: Exposure estimates

Table 25b shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures. As no dermal exposure measurements were available for GES 4, the long-term estimates were modeled with the MEASE model as the 90th percentile value (mg Ni cm^{-2} day^{-1}) for dermal (soluble) nickel.

Table 25b. CES developed for GES 4: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 4.1	4, 5, 8b, 9, 13 & 15	- Aqueous solution- Content in preparation: 5-25% - Inclusion into matrix-NDH - Incidental – duration exposure: 8h - Area of skin (cm^2): 480 (proc 4, 5, 8b, 9, 13 & 15) / 240 (PROC 3) - LEV-PPE: yes.	0.00003	0.0682
	8a	- Solid, medium dustiness- Content in preparation: 5-25% - Inclusion into matrix- NDH - Incidental – duration exposure: 8h - Area of skin (cm2): 960 - LEV-PPE: yes.		
CES 4.2	10	- Solution- Content in preparation: 5-25% - NDU-NDH - Incidental – duration exposure: 1h - Area of skin (cm^2): 960 - GV-PPE: yes.	6 x 10-6	0.014
		- Solid, medium dustiness - Content in preparation: 5-25% - NDH-NDU - Incidental – duration exposure: 1h - Area of skin (cm^2): 960 - GV- PPE: yes.		

NDH-NDU

RCR are below unity (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during these tasks.

According to registrant (see table 10b), gloves is required for all task of GES 4.

3.5.2.5 GES 5: Production of batteries using positive nickel electrodes

The exposure assessment for GES 5 is based on a redrafted version of the CSR (2011 updates) including new information on processes and exposure data provided to the nickel Consortia.

In summary, the $NiSO_46H_2O$ is used to top up the (Watts nickel) plating solutions for nickel plating iron or steel strips used in (pocket plate and plastic bound) electrode production. The $NiSO_4$ solution is also used for making the nickel hydroxide, $Ni(OH)_2$. The $Ni(OH)_2$ and $NiSO_4$ solution are used to make active mass in the electrode production.

Contributing Exposure Scenarios

Three companies (Company 1, Company 2a and Company 2c) submitted information on the use of $NiSO_4$ to make 'positive' active mass, one company (Company 2a) submitted information on the use of $NiSO_4$ to make 'negative' active mass and one company (Company 2a) submitted information on nickel plating strips for electrode production from NiSO4 solution to the Registrant (Nickel Consortia).

Table 26a summarizes the Contributing Exposure Scenarios (CES) developed from the contextual data reported on the processes in the Nickel Institute's Questionnaires and from subsequent communication with Company 2.

Table 26a. CES developed for use of NiSO4 in electrode and battery manufacture

CES 5.1	PROC 4 & PROC 8b	Raw materials handling – i) nickel briquettes and ii) $NiSO_46H_2O$ powder
CES 5.2	PROC 4 & PROC 8b	Manufacture of the NiSO4 solution The NiSO4solution is made by reacting nickel briquettes with sulphuric acid.
CES 5.3	PROC 4, PROC 8b, PROC 14 & PROC 26 PROC 9	Manufacture of positive {Ni(OH)2 based} active mass Ni(OH)2 is precipitated out of and separated from the NiSO4 solution, loaded into the reactor and mixed with other ingredients e.g. glue, graphite and water to make the 'positive' active mass.
CES 5.4	PROC 4, PROC 8b & PROC 26 PROC 9	Manufacture of negative {Cd(OH)2/Ni(OH)2 based} active mass NiSO4 solution is piped into a reactor and mixed with 'Cd(OH)2', made from CdO, and other ingredients. This is treated to make the 'negative' active mass which contains Ni as Ni(OH)2.
CES 5.5	PROC 4 & PROC 21	Manufacture of electrodes as pocket plate electrodes
CES 5.6	PROC 4, PROC 8b & PROC 26	Nickel electroplating {maintenance of NiSO4 electroplating solution & manufacture of electrode strip by nickel plating a steel strip} The Ni levels in the plating solution are topping up the with NiSO4 powder. The nickel pellets are the anode, the NiSO4 solution is the electrolyte and the steel strip is the cathode in the electroplating cell.
CES 5.7	PROC 0 & PROC 10	Cleaning and Maintenance

▨ A shaded entry indicates that there is likely no NiSO4 exposure for that operation/CES

The RMM reported are presented in Table 23b

The strip electroplating is automated and there is limited operator intervention. Jig electroplating was reported as being used and this usually involves the manual hooking or wiring of items to be plated onto the jig and their manual removal from the jig. The plating of the items may be mechanized or fully automated.

Routine manufacture of positive actives mass from $Ni\ (OH)_2$ and negative active mass from $NiSO_4$ solution is considered automated with the process being operated from a control room (Table 26b).

Table 26b. Company reported RMMs by CES for NiSO4 use in battery manufacture

CES	**RMM**		
	Engineering controls		**PPE**
	Company 2	**Company 1**	
5.1	LEV	LEV	RPE not required No response to wearing of gloves but assume gloves
5.2	Enclosed during dissolution/mixing. LEV to remove H_2 gas.	LEV	RPE not required Gloves worn voluntarily
5.3	Enclosed during reaction & $Ni(OH)_2$ precipitation and during transfer {$Ni(OH)_2$ as slurry}. Not reported for filtration, washing & drying (as $Ni(OH)_2$ powder) Active mass production segregated (workers in a control room). No response to use of LEV in Questionnaire	Process step not reported in Questionnaire	No response to wearing of gloves or RPE in Questionnaire
5.4	Active mass production segregated (workers in a control room).	Process step not reported in Questionnaire	Not reported
5.5	Not relevant (No $NiSO_4$ exposure)	Not relevant (No $NiSO_4$ exposure)	Not Relevant (No $NiSO_4$ exposure)
5.6	Enclosed and LEV	LEV	Visor for face protection in Co 2 – not clear if this is powered for respiratory protection but RPE is worn in Co 1. Gloves worn
5.7	Assumed no LEV No response to use of PPE in Questionnaire but assume gloves and masks are used		No response to use of PPE in Questionnaire but assume gloves and masks are used

▨ A shaded area indicates no information is available

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in the Table 27.

Table 27. CES developed for GES 5: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m^3	**Method calculation**	**mg Ni/m^3**	**Tier 1**	**Tier 2**	
CES 5.1 $NiSO_4 6H_2O$& Ni briquettes reception (raw material handling)	Not applicable	**Exposure data measurements:** The higher of 2 static exposure values for the unbagging of $NiSO_4 6H_2O$ (=0.082). LEV is assumed to be in Place For calculation of acute systemic exposure inhalation only	0.01	Not applicable	-	Not applicable
CES 5.2 Manufacture of the $NiSO_4$ solution	[confidential]	**Exposure data measurements:** The highest of 7 personal inhalable nickel exposure measurements	0.01	**>1**	**<1***	N° measure: 3 GSD: not specified insufficient
CES 5.3 Manufacture of positive ($Ni(OH)_2$ based) active mass	[confidential]	**Exposure data measurements:** The highest of 3 personal inhalable nickel exposure measurements	0.01	**>1**	**<1***	N° measure: 3 GSD: not specified insufficient
CES 5.4 Manufacture of negative ($Cd(OH)_2/Ni(OH)_2$ based) active mass	[confidential]	**Exposure data measurements:** The highest of 2 personal inhalable nickel exposure measurements	0.01	**<1**	**-**	N° measure: 3 GSD: not specified insufficient
CES 5.5 Manufacture of electrodes as pocket plate electrodes	Not applicable	Exposure to $NiSO_4$ is not relevant for this process/activity. Ni is only in the form of Ni dihydroxide	0.01	Not applicable		Not applicable
CES 5.6 Nickel electroplating (strips)	[confidential]	**Exposure data measurements:** The highest of 5 static exposure measurements for nickel electroplating from a $NiSO_4$ rich solution	0.01	**>1**	**<1***	N° measure: 5 GSD: not specified insufficient
CES 5.7 Cleaning and maintenance	[confidential]	**Exposure data measurements:** 75th percentile personal, inhalable for raw materials handling in analogous process[1].	0.01	**>>1**	**>1** **<1****	N° measure: 3 GSD: not specified insufficient

		3 measurements.				🟪

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

- [1] Read across from an analogous operation: solution make up – measurements on NiCO3 in the catalyst industry

-* RPE = 20

- ** RPE= 40

- CES 5.1

For CES 5.1, the summary static inhalation exposure estimate was the higher of two measurement recorded for unbagging $NiSO_4 6H_2O$ of [confidential] mg Ni m^{-3}, based on LEV being present. This operation takes place about 4 times a month and lasts for up to 20 minutes.

Therefore this is considered by the registrant a short term exposure and no equivalent long term exposure is considered to exist.

No RCR for long term exposure was calculated.

- CES 5.2

For CES 5.2 exposure estimates have been derived for both the 'inhalable' and 'respirable' fractions. The maximum value of [confidential] mg (Ni) m^{-3} was used as the 'inhalable' summary exposure estimate for assessing long term exposure to Ni for briquetting. This was derived from 7 personal exposure measurements made for briquetting over the years 2011 and 2010. These measurements were presented as two measurement ranges of 3 (2010) and of 4 (2011) individual measurements quoted as 'inhalable nickel' but may in fact be for total inhalable dust.

The calculated RCR for long term exposure are below 1 (RCR < 1) considering RPE with an APF of 20 (Table 24).

Based on the questionnaire submitted to the downstream user companies, it seems that no RPE was reported for this task (see Table 23b). Moreover, according to the REACh guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5. For CES 5.2, only 7 individual measurements and no information on GSD were provided.

In conclusion, considering that no RPE is proposed by registrants, RCR for long term inhalation exposure is above 1 for CES 5.2 leading to an unacceptable risk for this scenario.

- CES 5.3

For CES 5.3 the 'inhalable' summary exposure estimate used was the maximum 'inhalable nickel' measurement of [confidential] mg (Ni) m^{-3} for positive active mass production which was recorded in 2010. This may in fact be the result for inhalable dust. This was the highest of 3 measurements recorded over 2010 and 2011.

The calculated RCR for long term exposure are below 1 (RCR < 1) considering RPE with an APF of 20 (table 24).

Based on the questionnaire submitted to the downstream user companies, it seems that no RPE was reported for this task (see Table 23b). Moreover, according to the REACh guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5. For CES 5.3, only 3 individual measurements and no information on GSD were provided.

In conclusion, considering that no RPE is proposed by registrants, RCR for long term inhalation exposure is above 1 for CES 5.3 leading to an unacceptable risk for this scenario.

- CES 5.4

For CES 5.4, the 'inhalable' summary exposure estimate used was the only 'inhalable nickel' measurement, [confidential] mg (Ni) m-3, recorded (in 2011).

The calculated RCR for long term exposure are below 1 (RCR < 1) considering no RPE (table 24).

No RPE was reported for this task by the downstream users in the questionnaire (Table 23b).

However, only 1 individual measurement was provided for CES 5.4. According to the REACH guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR.

Thus, no definite conclusion can be made on the risk for the CES 5.4

- CES 5.5

CES 5.5 represents the assembly of the pocket plate electrodes from the active mass (CES 5.3 and 5.4) and conducting substrate strips (CES 5.6). There is no exposure to NiSO4 at this point because the nickel is present as $Ni(OH)_2$ (separated and washed) which has been processed into in active mass and then contained within plated strips (electrode substrate).

- CES 5.6

For CES 5.6 the maximum measurement of a range of 5 static measurements, [confidential] mg (Ni) m^{-3}, was used as the summary exposure estimate for assessing long-term inhalation exposure to Ni. This was reported as 'inhalable nickel', and the RCR is calculated using the inhalable Ni DNEL, but the exposure may in fact be inhalable dust.

The calculated RCR for long term exposure are below 1 (RCR < 1) considering RPE with an APF of 20 (table 24).

Based on the questionnaire submitted to the downstream user companies, the level of protection (APF) for the RPE was not reported for this task (see Table 23b). Moreover, according to the REACh guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5. For CES 5.6, only 5 individual measurements and no information on GSD were provided.

In conclusion, no definite conclusion can be made on the risk for the CES 5.6.

- CES 5.7

In CES 5.7 no inhalation measurement data were available for Cleaning and Maintenance and this was read across from [confidential]. This involves handling dry powders during the preparation of solution and suspension used in [confidential] and represents a worst case situation.

The calculated RCR for long term exposure are below 1 (RCR < 1) considering RPE with an APF of 40 (table 24). However, based on the questionnaire submitted to the downstream user companies, the level of protection (APF) for the RPE was not reported for this task (see Table 23b). In addition, only 3 individual measurements were provided. According to REAcH guidance, a minimum of 12 is required to validate the RCR.

In conclusion, considering that no RPE is proposed by registrants, RCR for long term inhalation exposure is above 1 for CES 5.7 leading to an unacceptable risk for this scenario.

Dermal route: Exposure estimates

Table 28 shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures. As no dermal exposure measurements were available for GES 5, the long-term estimates were modeled with the MEASE model as the 90th percentile value (mg Ni cm^{-2} day^{-1}) for dermal (soluble) nickel.

Table 28. CES developed for GES 5: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 5.1	4 &8b	- Solid medium dustiness- Content in preparation: 5-25% - Non-direct handling- non dispersive use - Incidental – duration exposure: < 15 min - Area of skin (cm^2) : 480 - LEV / PPE: yes.	0.000003	7×10^{-3}
CES 5.2	4 &8b	- Solid, medium dustiness- Content in preparation: 5-25% - Non-direct handling- non dispersive use - Incidental – duration exposure: 8h - Area of skin (cm^2) : 480 - LEV /enclosure- PPE: yes.	0.00003	0.07
CES 5.3	4, 8b, 9, 14 & 26	- Solid, medium dustiness - Content in preparation: 1-5% - Non-direct handling-Non disperse use - Incidental – duration exposure: 8h - Area of skin (cm^2) : 480 - Enclosure/ Segregation - PPE: yes.	0.00001	0.023
CES 5.4	4, 8b, 9 & 14	- Solid, medium dustiness - Content in preparation: 1-5%	0.00001	0.023

		- Non-direct handling-Non disperse use - Incidental – duration exposure: 8h - Area of skin (cm^2) : 480 - Enclosure/ Segregation- PPE: yes.		
CES 5.5	Not relevant			
CES 5.6	4, 8b & 26	- Solid, medium dustiness -Content in preparation: 5-25% - Non-direct handling-Non disperse use - Incidental – duration exposure: 8h - Area of skin (cm^2) : 480 - LEV / Enclosure - PPE: yes.	0.00003	0.07
CE 5.7	10	- Solid, medium dustiness -Content in preparation: 5-25% - Non-direct handling-Non disperse use - Incidental – duration exposure: 4h - Area of skin (cm^2) : 960 - GV / PPE: yes.	0.000018	4.1×10^{-2}

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during these tasks.

According to registrant (see Annex 3 Table 5), gloves is required for all task of GES 5.

3.5.2.6 GES 6: Production of nickel salts from nickel sulphate

There are no recent exposure data concerning the GES 6. There is no information on process. No contributing scenario was developed.

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in Table 29.

Table 29. CES developed for GES 6: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Confidence in the RCR**
	mg Ni/m^3	**Method calculation**				

Production of Ni salts from Ni sulphate	**0.1**	**Exposure data measurements:** Reasonable worst case shift mean concentration based on expert judgement and experience in other industrial settings where powders are handled. LEV is assumed rather than enclosure and automation. Exposures would be 10 x lower for entirely automated and enclosed handling of powders	**0.01**	**10**[1] **1**[2]	**0.5***[1] 0.05*[2]	**RCR < 1** **With RPE 20**

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

-*RPE=20

-**RPE=40

Exposures would be 10 x lower for entirely automated and enclosed handling of powders:

[1] Without enclosure and automation

[2] With enclosure and automation

Data information from UE RAR

During the production of $NiSO_4$ from impure $NiSO_4$, the EU RAR for $NiSO_4$ considered that typical exposures to inhalable Ni were 0.12 mg m^{-3} of which 0.07 mg m-3 was in the form of $NiSO_4$ with a worst-case estimate of 1 mg m^{-3} (8-hour TWA) and short term exposure concentration of 2 mg m^{-3}. The RAR considered that typical exposures to inhalable Ni during chemicals production using $NiSO_4$ were about 0.006-0.45 mg m^{-3} of which 0.004 to 0.27 mg m^{-3} was in the form of $NiSO_4$ as an 8 hour TWA. The worst case exposure was estimated as about 7.0 mg m^{-3} as $NiSO_4$ with a short term peak concentration of 14 mg m^{-3}.

The RAR for $NiSO_4$ considered that typical dermal exposure to Ni during the production of $NiSO_4$ from impure $NiSO_4$ or during chemicals production using $NiSO_4$ is 1.2 mg Ni day^{-1} of which 0.8 mg Ni day^{-1} is in the form of $NiSO_4$. The worst-case estimate was 2.0 mg day^{-1} as total Ni of which 1.4 mg day^{-1} is in the form of $NiSO_4$.

Data Gaps

There are no recent measurement data and according to the Registrant, it unclear whether the historical data described in the EU RAR are relevant to the modern chemical industry. Modern chemical plants are typically highly automated with most processes taking place within enclosed systems. This includes automation and enclosure of potentially dusty processes such as the packing of dry powders. Operators spend a large proportion of their working day within control rooms, remote from the actual production process. The exposure levels described for $NiSO_4$ in the EU RAR seem very high in comparison to exposures to other chemicals elsewhere in the modern chemicals industry.

Derivation of Exposure estimates for Risk Assessment

In the absence of substantive measurement data, the Registrant proposed an exposure estimate value of 0.1 mg Ni m^{3}. This value corresponds to the estimated shift mean exposure to airborne $NiSO_4$ (0.1 mg Ni m^3) and was largely based on expert judgement and took account of experience in other industrial settings where powders are handled.

In the absence of process information, it was assumed that $NiSO_4$ is handled as a dry powder and that effective LEV is employed where processes are not entirely automated and enclosed. The exposure estimate was informed by the limited data reviewed in the EU RAR.

Some of the measurement data reviewed by the EU RAR and the estimated worst case exposure seem high for modern plants where processes are largely automated and enclosed and where effective LEV is likely to be used where enclosure is not practicable.

Table 26 shows that the calculated RCR is below 1 only when worker used RPE with an APF of 20. A corrective factor of 10 was also added in order to taking into account that the processes are entirely automated and enclosed. The RCR are as follows for long-term inhalation exposure:

- RCR=10 excluding RPE, without enclosure or automation and 1 including enclosure and automation;
- RCR=0.5 including RPE 20, without enclosure or automation and 0.05 with enclosure and automation.

According to registrant, RPE is required for cleaning and maintenance operations and where exposure to dry powders and/or dust and/or spray solution is possible. No information on the level of protection of this RPE (APF) is available.

As the exposure estimation of 0.1 mg Ni m^3 proposed by the registrant for this scenario are not referenced and as no information is available concerning the process, no definite conclusion can be made on the risk for workers for GES 6.

Dermal route: Exposure estimates

The estimated dermal exposure of 0.0004 mg Ni cm^{-2} day-1 as soluble Ni was based on the EU RAR estimate of typical dermal exposure to Ni during chemicals production. No estimate was made of the 75th percentile exposure based on the EU RAR estimates of median and reasonable case exposure because it was believed that the EU RAR is likely to have substantially over-estimated exposure in relation to the modern chemicals industry.

The RCR are as follows for dermal exposure: RCR = 0.9 excluding gloves.

Considering the classification as skin sensitizer for NiSO4, wearing PPE is required during these tasks.

According to registrant (see Annex 3 Table 6), gloves and other appropriate protective clothing suitable for working with aqueous solutions and acids are required. For dermal contact with dried product, gloves and other suitable protective clothing suitable for handling powders are required.

3.5.2.7 GES 7: Use of nickel sulphate in the manufacturing of micronutrient additives for biogas production

The exposure assessment for GES 7 is based on a redrafted version of the CSR (2012 updates) including new information on processes and exposure data provided to the nickel Consortia.

This GES describes the use of hydrated $NiSO_4$ and $NiSO_4$ solution in the production of micronutrient additives. These additives are used in the biogas production industry.

Contributing Exposure Scenarios

Only one company (Company 1) submitted process information on this use to the Nickel Consortia. Company 1 operates a plant for the production of nickel-containing micronutrient additives for use in biogas production plants. The nickel content for the additive is provided by $NiSO_46H_2O$ powder or as $NiSO_4$ solution.

Biogas is a methane-rich gas produced from natural feedstocks such as slurry, manure, green waste and industrial and municipal waste by controlled anaerobic bacterial digestion. This product provides trace elements, such as nickel, which support bacterial function in the anaerobic digestion process, together with other substances which might aid process stability, optimisation of methane production and reduction of by-products (e.g. digestate). These products are used where the feedstock employed is deficient in essential metals needed to support bacterial activity. This means that such products may also contain iron, zinc, copper, cobalt, molybdenum, selenium and tungsten as well as nickel. They are used in small quantities in biogas production operations which use a plant-based feedstock (as opposed for example to manure and slurry). In some cases the solid digestate product may be used as a fertiliser.

Table 30 summarizes the Contributing Exposure Scenarios (CES) developed from the contextual data reported on the process in the Nickel Institute's Questionnaire.

Table 30. CES developed for GES 7: $NiSO_4$ use in the manufacture of micronutrient additives for biogas production

CES title	**PROC Codes**	**Description**
7.1: Nickel sulfate reception	PROC 4 and PROC 8b	Nickel sulfate solution and powder, supplied in intermediate bulk containers (IBC), cans and bags, are placed in the dispensing bin which automatically feeds the blender.
7.2: Preparing the additive (for biogas production) powder or solutions	PROC 3	Dosing (measuring out and dispensing) and mixing the $NiSO_46H_2O$ powder or the $NiSO_4$ solution with other micronutrients and performance-enhancing ingredients in a closed blender fitted with a dedicated aspiration system.
7.3: Packaging the additive product	PROC 9	Packaging the additive mixture product in IBCs or bags
7.4 Palletising the packaged additive	PROC 3	Stacking and wrapping the bags of additive product
7.5: Cleaning & Maintenance	PROC 10	Cleaning and maintenance of plant and premises

The first stage of the production process involves preparation of the additive powder (CES 7.1 and 7.2) and the second stage of the production process involves packaging the finished product (CES 7.3 and CES 7.4). From the second stage of the process onwards, i.e. after blending, it is not clear if nickel is present as $NiSO_4$ or another form. When nickel becomes incorporated into the additive product, it may be present as either $NiSO_4$ or as a reaction product of $NiSO_4$ that is generated during the mixing of the additive ingredients. In the powder product nickel is more likely to be in a form which will be released and become airborne compared to the liquid product.

The plant, operating conditions (OC) and risk management measures (RMM), used in each stage are described below and summarized in Table 31.

Table 31. Reported RMMs by CES for manufacture of micronutrient additives for biogas production

CES	**RMM**	
	Engineering controls	**PPE**
7.1: Nickel sulfate reception	Open system during filling of dispensing bin No LEV	- Air-assisted filtering visor, masks or hood with P3 filter element (**APF = 40** based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) required for charging the dispensing bin where exposure to $NiSO_4$ containing mist or dust is possible. - Chemical gloves with EN 374, protection level 6 required when charging the dispensing bin.
7.2: Preparing the additive powder	Enclosed and aspirated (LEV) blender for mixing ingredients	In case of entry into the production area for inspections/emergency situations where exposure to $NiSO_4$ containing mist or dust is possible: - Air-assisted filtering visor, masks or hood with P3 filter element (**APF = 20** based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection)) - Chemical gloves with EN 374, protection level 6,
7.3: Packaging	Semi-enclosed with aspiration (LEV) and semi-automated valve bag filler	None
7.4 Palletising	None	- Air-assisted filtering visor, masks or hood with P3 filter element (**APF ~20** based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) - Chemical gloves with EN 374, protection level 6,
7.5: Cleaning & Maintenance	None	- Air-assisted filtering visor, masks or hood with P3 filter element (**APF ~20** based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) - Chemical gloves with EN 374, protection level 6

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in the Table 32.

Table 32. CES developed for GES 7: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Confidence in the RCR**
	mg Ni/m^3	**Method calculation**				

CES 7.1 nickel sulphate reception	1.026	**MEASE modeling (tier1 model):** -PROC8b -5-25% Ni concentration -incidental expo -duration 4 hrs - GV	0.01	**102.5**	**2.55****	RCR > 1 (MEASE modelling, RPE 40)
CES 7.2 preparing the additive powder	0.047	**MEASE modeling (tier1 model):** -PROC 3 -5-25% Ni concentration -incidental expo -duration 4 hrs - LEV	0.01	**4.7**	**0.23***	RCR < 1 (MEASE modeling, RPE 20
CES 7.3 packaging the additive product	0.023	Read across 75th percentile for personal exposure measurement (face) reported for an analogous operation for packaging of NiSO46H2O and nickel hydroxycarbonate	0.01	**2.3**	**0.11***	N° measure: 7 GSD: not specified
CES 7.4 palletising the packaged additive	0.023	**MEASE modeling (tier1 model):** -PROC 3 -1-5% Ni concentration -incidental expo -duration less than 1 hr - GV	0.01	**2.3**	**0.11***	RCR < 1 (MEASE modelling, RPE 20)
CES 7.5 cleaning & maintenance	0.324	**MEASE modeling (tier1 model):** -PROC 10 -5-25% Ni concentration -incidental expo -duration less than 1 hr - GV	0.01	**32.4**	**1.6*** **0.8****	RCR < 1 (MEASE modelling, RPE 40)

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

-*RPE=20

-**RPE=40

- CES 7.3

For packaging in the $NiSO_4$ (and hydroxycarbonate) packaging area of a nickel salt production line (CES 7.3), seven personal inhalation samples were collected in 2004. The results of the measurements ranged from 0.011 to 0.101 mg Ni m^{-3}.

The 75th percentile measurement for this packaging line was considered a conservative read across exposure. This is because these inhalation measurements together with a set of dermal exposure measurements {IOM 2011} were recorded for what has been considered to represent a state-of-the art/high performance packaging system equipped with RMM technologies, including a highly automated/robotic packaging system requiring little manual involvement. The valve bag filler is considered to operate in a similar manner and as such to effectively reduce exposure to the lowest levels practicable. However, pure $NiSO_46H_2O$ was packaged on this high performance line while in this GES the $NiSO_4$ is just one component in a micronutrient mixture.

Table 29 shows that the calculated RCR is below 1 (RCR < 1) only when worker used RPE with an APF of 20. No RPE was reported by the Registrant for this task (Table 28).

In addition, the small number of measurements means there is high level of uncertainty associated with the exposure estimates and the associated RCR. Indeed, according to the REACh guidance on occupational exposure estimation a minimum of 12 measurements is required to validate a RCR, with a GSD comprised between 2 and 3.5.

Thus, no definite conclusion can be made for this scenario.

- CES 7.1, CES 7.2, CES 7.4, CES 7.5

For the other CES, no inhalation exposure monitoring data were available. For these cases, inhalation exposure concentrations were estimated using the Tier 1 model MEASE.

For CES 7.1, the calculated RCR is above 1 (RCR> 1) even when worker used RPE with an APF of 40. **The risk for worker is not acceptable for this scenario.**

For CES 7.2 and CES 7.4, Table 29 shows that the calculated RCR is below 1 (RCR < 1) only when worker used RPE with an APF of 20. This level of protection is consistent with the PPE reported by the Registrant for these tasks (Table 28). **Thus, considering the RPE reported by the Registrant, the risk for worker is acceptable for CES 7.2 and CES 7.4**

For CES 7.5, the calculated RCR is below 1 (RCR < 1) only when worker used RPE with an APF of 40. **However, considering that only RPE with an APF of 20 is proposed by registrants for these task (Table 28), RCR for long term inhalation exposure is above 1 for CES 7.5 leading to an unacceptable risk for CES 7.5**

Dermal route: Exposure estimates

Table 33 shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures.

For packaging in the $NiSO_4$ (and hydroxycarbonate) packaging area of a nickel salt production line (CES 7.3), dermal exposures measured across all body parts ranged from 0.00001 to 0.00153 mg Ni cm^{-2} (IOM, 2010). A 75^{th} percentile dermal exposure value of 0.00054 mg Ni cm^{-1} for hands and arms and 0.00067 µg Ni cm^{-1} for full body was derived from eight personal exposure measurement. However the (similarly derived) 75^{th} percentile value of 0.00086 mg Ni cm^{-1} for the face has been used as the exposure estimate.

For other CES of the GES 7, no dermal exposure measurements were available. The long-term estimates were modeled with the MEASE model as the 90th percentile value (mg Ni cm^{-2} day^{-1}) for dermal (soluble) nickel.

Table 33. CES developed for GES 7: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 7.1	4 &8b	- Solid medium dustiness- Content in preparation: 5-25% - Non-direct handling- non dispersive use - Incidental – duration exposure: 2h - Area of skin (cm^2) : 480 - GV / PPE: yes.	0.000018	0.041
		-Solution - Content in preparation: 5-25% - Non-direct handling- non dispersive use - Incidental – duration exposure: 2h - Area of skin (cm^2) : 480 - GV / PPE: yes.		
CES 7.2	3	- Solid, medium dustiness- Content in preparation: 5-25% - Non-direct handling- non dispersive use - Incidental – duration exposure: 8h* & 4h** - Area of skin (cm^2) : 240 - LEV/enclosure- PPE: no.	0.00003	0.068
CES 7.3		Dermal measurements: 75th percentile value for the face derived from eight personal exposure measurements.	0.00086 0.00043$^{\#}$	1.95 0.98$^{\#}$
CES 7.4	3	- Solid, medium dustiness - Content in preparation: 1-5%*** - Non-direct handling-Non disperse use - Incidental – duration exposure: 1h - Area of skin (cm^2) : 240 - GV- PPE: yes.	0.000002	<0.01
CES 7.5	10	- Solid, medium dustiness -Content in preparation: 5-25% - Non-direct handling-Non disperse use - Incidental – duration exposure: 1h - Area of skin (cm^2) : 960 - GV - PPE: yes.	0.000006	0.014

* Reported duration

** Duration required to obtain an RCR < 1 without using RPE

*** Estimated value taken as the next level down in the 'content in preparation' option from that used in modelling exposures in CES 7.1, 7.2 and 7.5

for a 4 h exposure duration and when this duration is exceeded, the worker would have to wash hands and replace (e.g. disposable) gloves with new gloves in order to continue working.

It should be noted that micronutrient manufacture only takes place for two days out of every five working days and is carried out by two workers who must move between all the different tasks. Therefore although the mixer is running for a full 8 hour shift, it would seem unlikely that a worker is stationed permanently by the mixer for the full shift. It is more likely the worker is present only during the loading and emptying of the mixer and is exposed only at those times.

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for NiSO4, wearing PPE is required during all these tasks.

According to registrant (see table 28), gloves is required for all task of GES 5 excepting CES 7.3.

3.5.2.8 GES 8: Production of nickel containing pigments from nickel sulphate

The production of inorganic pigments from $NiSO_4$ has been identified by a pigment manufacturer (Company 5) as using the same production process as is used to make pigments from nickel oxide, NiO. Therefore this HH EAR uses 'read across' exposure measurements for nickel from the production of nickel-containing pigments from the NiO exposure scenario (GES) together with modeled exposures based on contextual data (brief process descriptions, PROC codes and task duration) supplied by Company 5 in order to determine relevant exposure estimates for this ES.

Contributing Exposure Scenarios

The process description is based on that developed for the production of nickel-containing inorganic pigments from NiO. Therefore this ES has been developed from the exposure data as process description by process step and operational conditions (OC), exposure measurements, exposure monitoring details and risk management measures (RMM) supplied by the Inorganic Pigments Consortium (IPC) and one non-EU manufacturing company. The earlier process steps (8.1, 8.2 and 8.3) now include (limited) RMM, OC and process step (PROC Codes) data provided by Company 5 on handling and processing of $NiSO_4$, a soluble raw material in what is assumed to be a largely manual and discontinuous (batch) production systems. The latter process steps (CES 8.4, 8.5 and 8.6) are assumed to be similar to those described by IPC and so are considered to be largely automated. However the reported milling, washing/drying and packaging operations are unlikely to present exposure to $NiSO_4$ because after calcining the Ni contained in the powder pigment is no longer present as $NiSO_4$.

Table 34 summarizes the CES for pigment production from $NiSO_4$. Note that two alternative calcining steps are described based on information supplied by the IPC, the non-EU company and Company 5: firstly a more automated continuous (8.3a) and secondly a more manual batch (8.3b) operation. Automation is usually applied to continuous calcining operations. These have been treated together (8.3) in order to establish the summary exposure estimate for the CES. Assignment of the few nickel exposure measurement data to each of these calcining steps has been attempted based on limited contextual data.

Table 34. CES developed for GES8 production of nickel-containing pigments from NiSO4

CES title	PROC	Description
8.1: Raw materials handling – reception and dissolution of $NiSO_4$	8b	Manually or automatically loading the mixer with NiSO4 powder and water and stirring in a sealed and ventilated reactor to make a NiSO4 solution
8.2: Mixing (preparation of granular pigment precursor)	2, 5 & 8b	Loading the mixer with the raw materials including the NiSO4 solution and mixing all the pigment ingredients into the pigment precursor.
8.3: Continuous drying and calcining		
8.3a: Continuous drying and calcining	22	Continuous and automated drying of the wet mix and calcining in (tunnel or rotary) ovens
8.3b: Batch drying and calcining	9, 4 & 22	'Discontinuous' drying and calcining where the pigment precursor is loaded into crucibles and the filled crucibles are transported through the oven on wagons. The calcined product is conveyed to milling.
8.4: Dry milling	24	Milling of calcined product to a powder
8.5: Wet milling, washing and drying	22,24	Calcined product containing salts are ground wet, washed to remove the excess soluble salts and dried
8.6: Packaging	2&9	Bagging the calcined product (neat or as a blend) into bags or bulk containers
8.7: Cleaning and Maintenance	10	Cleaning & maintenance of plant and premises

Available Contextual Data

Company 5 (Co 5) reports the plant used in the $NiSO_4$-based pigment production operations are closed except for charging the crucibles with the pigment precursor. This is the only operation of an 8 hour duration which suggests it is a largely manual task or alternatively is mechanised with a worker stationed close by for most of the shift in order to operate the controls. No LEV or RPE (mask) are reported as required during charging the crucibles and this is assumed to be because the pigment precursor is wet and granular and so emits little dust to the atmosphere and/or the worker is operating the process largely from a factory floor-based control booth (Table 20).

Company 5 reported that the raw material reception, mixing the raw material charge (for preparing the pigment precursor) and drying and calcining (excluding filling crucibles) operations (CES 8.1, 8.2 and the end part of 8.3b) are enclosed but require ventilation to control emissions to the atmosphere. These RMM reported by Company 5 are presented in Table 32.

The IPC reported identical RMM for the all process steps it covered as follows:-

- RPE - dust masks FFP 1, 2 or 3 and face mask (thermal & mechanical protection (FFP 1 for raw materials handling),
- Gloves (thermal & mechanical protection),
- Other PPE - safety shoes, hearing protection, goggles* and special safety clothing* (*used for specific operations or tasks)
- local & general exhaust ventilation.

These have been assigned appropriately to the remaining operations (CES 8.3a, 8.4, 8.5 and 8.6) and only PPE in CES8.7 (Table 32).

The short duration of CES8.1 and CES 8.2 operations suggests that workers enter these production areas for inspection rounds only and this is carried out twice or three times per shift (Table 35). The rest of the shift is assumed to be largely spent operating the automated process from a control room.

Table 35. RMM by process step for a NiSO4-based pigment manufacturer

CES / Process step	**Duration (from Co 5)**	**RMM**	
		Engineering controls (from Co 5 & IPC)	**PPE (from a non-EU company)**
8.1 Raw materials handling : Raw material is received in bags/drums and emptied into the reactor	< 1h	LEV & enclosed	RPE {half face mask (HEPA filter) or FFP 1} and PVC or equivalent gloves
8.2: Mixing (preparation of granular pigment precursor) Wet blending	< 1h	LEV & enclosed	RPE {half face mask (HEPA filter) or FFP 1, 2 or 3} and PVC or equivalent gloves
8.3a: Continuous drying and calcining: Drying & calcining	<8 h**	LEV & partially or totally enclosed	
8.3b: Batch drying and calcining: i) Loading crucibles ii) Drying & calcining	<8h 4h<duration<8h*	No LEV and open LEV & assumed enclosed	PVC or equivalent gloves
8.4: Dry milling Size reduction	<8 h**	LEV & assumed enclosed	RPE {half face mask (HEPA filter) or FFP 1, 2} and PVC or equivalent gloves
8.5: Wet milling, washing and drying: Size reduction, water wash and dried	<8 h**		
8.6: Packaging: Bagging or filling containers	<8 h**	LEV	RPE {dust masks FFP 1, 2 or 3} and PVC or equivalent gloves
8.7 Cleaning and Maintenance : Cleaning equipment with water	<4 h		RPE {half face mask (HEPA filter) or FFP 1, 2 or 3} and PVC or equivalent gloves

* reported as 'not restricted' and duration has been assigned based on the assumption that some manual intervention or direct supervision of oven operation requires workers to be stationed in the production area for a minimum time equal to half that for loading crucibles

** duration not reported and duration has been assigned based on the assumption that these processes are automated and continuous

Co 5 Company 5

▨ a shaded entry indicates no control measures are used for that operation/CES

<u>Inhalation route: Exposure estimates and calculated RCR</u>

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in the Table 36.

Table 36. CES developed for GES 8: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m^3	**Method calculation**	**mg Ni/m^3**	**Tier 1**	**Tier 2**	
CES 8.1 Raw materials handling	0.006	**Exposure data measurements:** Based on 7 personal exposure measurements for dosing and mixing	0.01	**0.6**	-	N° measure: 7 GSD: not specified *Not clear how the average was calculated and a full data set was not available*
CES 8.2 mixing raw materials	0.003	**Exposure data measurements:** Based on 8 personal exposure measurements for dosing and mixing (range)	0.01	**0.3**	-	N° measure: 8 GSD: not specified
CES 8.3 Drying and calcining of product	0.02	**Exposure data measurements:** Based on 8 personal exposure measurements assigned to charging the crucibles.	0.01	**2**	**0.1***	N° measure: 8 GSD: not specified *Not clear how the average was calculated and a full data set was not available*
CES 8.4 Dry milling	0.04	**Exposure data measurements:** Based on a single personal exposure measurement, reported for milling. Assumed to be inhalable fraction.	0.01	**4**	**0.2***	N° measure: 1 GSD: not specified **<u>Insufficient</u>**
CES 8.5 Wet milling, Washing and Drying	0.004	**Exposure data measurements:** Based on a single personal exposure measurement for drying final product	0.01	**0.4**	-	N° measure: 1 GSD: not specified **<u>Insufficient</u>**
CES 8.6 Blending and packaging	0.03	**Exposure data measurements:** The highest of 5 personal exposure measurements for	0.01	**3**	**0.15***	N° measure: 5 GSD: not specified

		mixing and/or Packaging				
CES 8.7 Cleaning and maintenance	0.34	**Exposure data measurements:** Based on a read across from a solution/suspension preparation operation in the catalyst industry. 3 personal measurements for solution make up. Range: 0,027-0,46	0.01	**34**	**0.85****	N° measure: 3 GSD: not specified **Insufficient**

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

-*RPE=20

-**RPE=40

No long term inhalation exposures have been measured specifically for any of the CES reported in this GES. IPC Questionnaire reports the use of nickel carbonate, nickel hydroxycarbonate, nickel (assumed to be as metal) and NiO in the manufacture of inorganic nickel-containing pigments. The nickel measurement data from the questionnaire were used as read across exposures for this GES. Further, it is not clear what form of nickel was used during the pigment production process which was monitored.

Forty eight nickel personal exposure measurements reported by the IPC have been assigned to the operations represented within the individual CES for the production of Ni-based pigments made from NiSO4.

- CES 8.1

For CES 8.1, measurements were 'averaged' over a number (8) of individual measurements. It is not clear how the average was calculated and a full data set was not available to elucidate this further. It also has to be remembered that this could be mixed exposure from the four nickel compounds reported to be in general use.

For CES 8.1, the read across inhalation value of 0.006 mg Ni m^{-3} was adopted as the inhalation summary exposure estimate. This read across value was obtained as an undefined average measurement from the IPC.

Table 33 shows that the calculated RCR is below the unit (RCR < 1) with no RPE. The Registrant reported RPE (FFP 1 approved with regard to EN 149,) at process steps that are not fully enclosed and are likely to give rise to Ni dust or fumes (Table 32).

However, there is a high level of uncertainty associated with the exposure estimates and the associated RCR: measurements were 'averaged' over a small number of individual measurements (8) and it is not clear how the average was calculated.

Thus, although RCR is below the unit leading to an acceptable risk with no RPE, no definite conclusion can be made for CES 8.1

- CES 8.2

For CES 8.2, the inhalation summary exposure estimate for assessing long-term exposure to Ni was taken as the 75th percentile read across value of 0.003 mg Ni m^{-3} derived from 8 measurements reported by the IPC data.

The registrant suggests that from the contextual information, dust emissions from this initial processing of the raw materials (CES 8.1) would be low because the NiSO4 powder is discharged and transferred in a closed system. The $NiSO_4$ is in solution form when it is combined with the other raw materials and so exposure is also expected to be low for making the pigment precursor (CES 8.2).

For CES 8.2, the calculated RCR is below 1 (RCR < 1) with no RPE. The Registrant reported RPE (FFP1, 2 or 3 approved with regard to EN 149, APF 4, 10 or 20) at process steps that are not fully enclosed and are likely to give rise to Ni dust or fumes (Table 32).

Due to the small number of measurement (only 8 instead of 12 required by REACH guidance), **no definite conclusion can be made for this scenario.**

- CES 8.3

For CES 8.3 the inhalation summary exposure estimate was read across as 0.02 mg Ni m^{-3} which is the highest average exposure measurement reported for drying and calcinating the pigment product. This value is assumed to cover exposure for the manual and automated together with batch and continuous processing of $NiSO_4$-based pigments.

Table 33 shows that the calculated RCR is below 1 (RCR < 1) only when worker wears RPE with an APF of 20. No RPE has been reported by the registrant for this task (Table 32).

Moreover, there is a high level of uncertainty associated with the exposure estimates and the associated RCR: measurements were 'averaged' over a small number of individual measurements (8) and it is not clear how the average was calculated.

Thus, no definite conclusion can be made for this scenario.

- CES 8.4

For CES 8.4 the summary inhalation exposure estimate was read across as 0.04 mg Ni m^{-3}. This is based on a single personal exposure measurement reported for milling.

The calculated RCR is below 1 (RCR < 1) only when worker wears RPE with an APF of 20. The Registrant reported RPE approved with regard to EN 149 (FFP 1, APF 4) at process steps that are not fully enclosed and are likely to give rise to Ni containing dust, *e.g.* handling of the final product. When handling powders of particle diameter below 10 µm, RPE approved with regard to EN 149 (FFP2, APF 10) is required.

However, only one inhalation exposure measurement is available which is not sufficient according to REACH guidance. **Thus, no definite conclusion can be made for this scenario.**

- CES 8.5

For CES 8.5 the inhalation summary exposure estimate was read across as 0.004 mg Ni m^{-3} from the only exposure measurement available for what is assumed to be the drying stage of wet milling. This is based on a single personal exposure measurement for drying final product.

The calculated RCR is below 1 (RCR < 1) with no RPE. The Registrant reported RPE (FFP 1 or 2 approved with regard to EN 149, APF 4 or 10) for this task (Table 32).

However, only one inhalation exposure measurement was available which is not sufficient according to REACH guidance. **Thus, no definite conclusion can be made for this scenario.**

- CES 8.6

For CES 8.6, the inhalation summary exposure estimate for mixing and/or packaging was read across as 0.03 mg Ni m^{-3}, the highest result from a range of 5 measurements.

The calculated RCR is below 1 only when workers wear RPE with an APF of 20. The Registrant reported RPE approved with regard to EN 149 (FFP 1, 2 or 3; APF 4, 10 or 20) for this task.

However, only five inhalation exposure measurements were available which is not sufficient according to REACH guidance.

Thus, no definite conclusion can be made for this scenario.

- CES 8.7

As there is no exposure monitoring data available for CES 8.7 (cleaning and maintenance), a read across value of 0.342 mg Ni m^{-3} form the nickel catalyst sector is used as the summary inhalation exposure estimate.

The calculated RCR is below 1 (RCR < 1) only when workers wears RPE with an APF of 20. This level of protection is consistent with the RPE (FFP 1, 2 or 3 approved with regard to EN 149) reported by the Registrant (Table 32).

However, only three inhalation exposure measurements were available which is not sufficient according to REACH guidance.

Thus, no definite conclusion can be made for this scenario.

Dermal route: Exposure estimates

Table 37 shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures.

Table 37. CES developed for GES 8: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 8.1	8b	- Solid medium dustiness- Content in preparation: 5-25% - NDH-NDU - Incidental – duration exposure: < 60 min - Area of skin (cm2): 480 - LEV-Enc / PPE: yes.	0.000006	0.014
CES 8.2	5	Solution- Content in preparation: 5-25% - NDH-NDU - Incidental – duration exposure: < 60 min - Area of skin (cm^2): 480 - LEV-Enc / PPE: yes.	0.000006	0.014

CES 8.3a	22	- Solid low dustiness- Content in preparation: 5-25% - NDH-NDU - Incidental – duration exposure: >240 min - Area of skin (cm^2): 480 - LEV / PPE: yes.	0.00005	0.07
CES 8.3bi	9	- Solid low dustiness- Content in preparation: 5-25%- NDH-NDU- Intermittent – duration exposure: <240 min- Area of skin (cm^2): 480 - no RMMs / PPE: yes.	0.00005	0.114
CES 8.3bii	22	- Solid low dustiness- Content in preparation: 5-25%- NDH -NDU- Incidental – duration exposure: >240 min- Area of skin (cm^2): 1980- LEV-Enc / PPE: yes.	0.00003	0.07
CES 8.4	24	Solid low dustiness- Content in preparation: 5-25%- NDH- NDU - Incidental – duration exposure: >240 min - Area of skin (cm^2): 1980 - Enc. / PPE: yes.	0.00003	0.07
CES 8.5	22 & 24	Solid low dustiness- Content in preparation: 5-25%- NDH -NDU- Incidental – duration exposure: >240 min- Area of skin (cm^2): 1980- Enclosure / PPE: yes.	0.00003	0.07
CES 8.6		Dermal measurements: 75th percentile value for the face derived from eight personal exposure measurements.	0.00086 0.00043#	1.95 0.98#
CES 8.7	10	Solid low dustiness- Content in preparation: 5-25%- NDH-NDU- Incidental – duration exposure: >240 min- Area of skin (cm^2) : 960- PPE: yes.	0.00003	0.07

NDH Non- direct handling	GV General ventilation	Enc Enclosure
NDU Non- dispersive use	LEV Local exhaust ventilation	ExtLEV Exterior LEV
WDU Wide dispersive use		

#for a 4 h exposure duration and when this duration is exceeded, the worker would have to wash hands and replace (e.g. disposable) gloves with new gloves in order to continue working.

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during all these tasks.

According to registrant (see table 32), gloves is required for all task of GES 8 excepting CES 8.3a.

3.5.2.9 GES 9: Selective plating

The exposure assessment for GES 9 is based on a redrafted version of the CSR (2013 updates) including new information on processes and exposure data provided to the nickel Consortia.

This exposure assessment report describes the use of hydrated $NiSO_4$ and $NiSO_4$ solution, in the surface finishing of items using a portable brush plating system.

Contributing Exposure Scenarios

Selective plating or electrochemical metallising is used in the manufacturing industry e.g. computer parts; in the maintenance of industrial plant e.g. machine drive shafts; in the servicing of equipment for non-industrial use e.g. commercial vehicles and in the arts and crafts industry e.g. sculptures.

Selective plating operations appear to be carried out using a manual process together with the application of different levels of risk management measures (RMM). OC and RMM found in this scenario are likely to be different from those applied on a conventional plating line where items are immersed in successive treatment solutions as they are conveyed down the plating line. This is a manual operation where the plating is carried out by hand and uses RMM which are compatible with the brush plating technology. It is likely that one worker carries out all the plating operations in the process therefore one CES was developed as CES 9.1 to consolidate all process steps which are summarized below:

- $NiSO_4$ solution handling at the workpiece or work station,
- storage and carrying of the working $NiSO_4$ solution,
- pouring of into the wand dip tank or loading the $NiSO_4$ solution into the wand mouth feeding system,
- plating the localised areas or the surface of items with the brush plating system,
- emptying spent $NiSO_4$ solution from the dip tank or the wand feeding system,
- wiping, spraying or otherwise cleaning and rinsing the repaired or coated items.

Packaging is not covered in CES 9.1 because the Ni species present at this stage would be the Ni metal which has been deposited over the item's surfaces during the repairing procedure.

CES 9.2 represents the cleaning and maintenance of plant but not of premises and solution preparation and maintenance. It is assumed that for general efficiency purposes and because the company manufactures and sells nickel plating solutions to other companies as well as using it in-house, that the stock solutions of the nickel compounds are made at a central facility in the workshop and stored in silos for workers' use. This means that workers do not make up their own solutions individually but draw what they need, when they need it, from stores. Therefore it is assumed the solutions are made up, accessed (diluted and transferred to portable packaging) and returned (for storage or as spent solution) to a central point in the workshop.

Information on OC and RMM was reported by the Registrant. It appears that LEV is not used and RPE is not worn during the brush plating operation. General ventilation will depend on the premises where the work is carried out. It appears that mobile LEV, which can be positioned close to the work, is used to control emissions. There is no evidence that on-tool LEV systems are available for this process.

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in Table 38.

Table 38. CES developed for GES 9: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m³	**Method calculation**	**mg Ni/m³**	**Tier 1**	**Tier 2**	
CES 9.1 Use of nickel sulphate in selective plating	0.047	**Exposure data measurements:** Highest of three personal exposure Measurements. Represent exposure to Ni from a $NiSO_4$ selective plating system -*RPE=20	0.01	**4.7**	**0.23***	N° measure: 3 GSD = 4.3 **Insufficient**
CES 9.2 Cleaning and Maintenance Industrial use	0.342	**MEASE modeling (tier1 model):** -PROC 10 -Industrial use -Ni content 5-25% -non dispersive use -incidental -duration 1h -GV -*RPE=20 -**RPE=40	0.01	**34.2**	**1.71*** **0.85****	RCR < 1 (MEASE modelling, RPE 40)
CES 9.2 Cleaning and Maintenance Professional use	0.428	**MEASE modeling (tier1 model):** -PROC 10 -Professional use -Ni content 5-25% -non dispersive use -incidental -duration 1h -GV -*RPE=20 -**RPE=40	0.01	**43**	**1.07****	RCR > 1 (MEASE modelling, RPE 40)

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

-*RPE=20

-**RPE=40

- CES 9.1

According to the Registrant, four exposure measurements were available and assumed to be task-specific measurements, taken during the brush plating operation only. Three of these personal exposure measurements (0.003266, 0.047 and 0.0046 mg Ni m^{-3}) are considered to represent exposure to Ni from a $NiSO_4$ selective plating system. Two of these (0.047 and 0.0046 mg Ni m^{-3}) were was taken on a technician operating a $NiSO_4$ selective plating while the third measurement (0.003266 mg Ni m^{-3}) was read across from a $NiCl_2$ plating system. For brush plating, the Ni concentration (100 g L^{-1}) in NiH_2NSO_3 solutions is over double that of the Ni levels in the $NiSO_4$ solution (44 g L^{-1}). Conventional plating solutions also use higher Ni concentrations when plating from NiH_2NSO_3 solutions than when plating from $NiSO_4$ and $NiCl_2$, where the Ni concentrations in a $NiSO_4$-based Watts solution are about the same as that in an all-chloride solution. Further, since the NiH_2NSO_3 exposure was measured the local exhaust ventilation system has been improved and so this exposure measurement is not considered representative of current personal exposure levels. Therefore the highest of the 3 non-NiH_2NSO_3 (task-based) personal exposure measurements, 0.047 mg Ni m^{-3}, was used by the Registrant to represent the long term, full shift personal exposure for brush plating using $NiSO_4$ and the summary exposure estimate for brush plating from $NiSO_4$.

The calculated RCR is below 1 (RCR < 1) only when worker wears RPE with an APF of 20. This level of protection is consistent with the RPE reported by the Registrant for these tasks (see Table 7 Annex 3).

The distribution of the data sets for CES 9.1 has a GSD of 4.3 (determined from 3 measurements) and the RCR lies in the range <1 to 0.5. ECHA therefore classifies this CES as having a high uncertainty (GSD>3.5) which would require between 30 and 50 measurements to be confident that the actual value of the RCR is less than one. This means that there is insufficient number of measurements for CES 9.1 to be confident that the RCR value is below 1.

Thus, no definite conclusion can be made for GES 9.1.

- CES 9.2

Given the limited number of exposure measurements, exposure estimates have been modeled using MEASE Tier 1 model for the industrial and professional use sectors for comparison with the measured values and to inform the derivation of a summary exposure estimate.

Table 35 provides a summary of modelling parameters that were used in MEASE to derive the exposure concentrations for both CES during industrial and professional use of selective plating respectively.

For both industrial and professional use, the calculated RCRs are below 1 (RCR < 1) only when worker wears RPE with an APF of 40. Only RPE of 20 was reported by the Registrant for these scenarios (see Table 7 Annex 3).

Thus, considering the RPE of 20 reported by the Registrant, the RCR is above the unit leading to an unacceptable risk for CES 9.2

Dermal route: Exposure estimates

Table 39 shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures.

Table 39. CES developed for GES 9: dermal exposure estimates and RCR

CES	PROC code	MEASE modeling parameters		Exposure estimation (mg(Ni) cm^{-2} d^{-1})	RCR
CES 9.1	2, 8a, 8b & 13	Solution- Content in preparation: 1-5% - DH - Inclusion into matrix- Extensive – duration exposure: 1h – Area of skin (cm^2): 480 - GV / PPE: yes.	Industrial use	0.0002	0.5
			Professional use	0.0002	
	2, 8a, 8b & 13	Solution- Content in preparation: 1-5% - DH - Inclusion into matrix- Extensive – duration exposure: 4h- Area of skin (cm^2): 480 - GV / PPE: yes.	Industrial use	0.0006	1.38
			Professional use	0.0006	
	2, 8a, 8b & 13	Solution- Content in preparation: 1-5% - DH - inclusion into matrix - Extensive – duration exposure: 8h - Area of skin (cm^2): 480 - GV / PPE: yes.	Industrial use	0.001	2.3
			Professional use	0.001	
CES 9.2	4, 5, 8b, 9&10	Solid medium dustiness- Content in preparation: 5-25% -Industrial- NDH –NDU- Incidental – duration exposure: 1h- Area of skin (cm^2): 480- GV / PPE: yes.	Industrial use	6 x 10^{-6}	0.014
			Professional use	6 x 10^{-6}	0.014

NDU Non-dispersive use

NDH Non-direct handling

DH Direct handling

GV General ventilation

LEV Local exhaust ventilation

Table 39 shows that RCR are below 1 (RCR < 1) for dermal exposure concerning CES 9.2. In CES 9.1, the RCR may be achieved by having a limit to the duration of exposure. This means that the operator would have to wash hands and replace disposable gloves after the specified ‘duration of exposure’ time period has expired in order to continue working. Hand washing and changing of appropriate disposable gloves would be repeated at the end of the each hour of plating when the technician would wash their hands and replace the gloves with new (disposable) gloves.

Considering the classification as skin sensitizer for NiSO$_4$, wearing PPE is required during all these tasks.

According to registrant (see table 7 Annex 3), gloves is required for all task of GES 9.

3.5.2.10 GES 10: Formulation of products for surface treatment of anodised aluminium sheets

The exposure assessment for GES 10 is based on a redrafted version of the CSR (2013 updates) including new information on processes and exposure data provided to the nickel Consortia.

This exposure assessment report describes the use of hydrated $NiSO_4$ and $NiSO_4$ solution in the formulation of products for surface finishing of anodised aluminum sheets.

Contributing Exposure Scenarios

This Exposure Scenario covers the formulation of surface treatment products with $NiSO_4$ but does not cover the anodising process itself or the Ni-based surface treatment of aluminum sheets.

Anodising generates a protective surface finish on aluminum parts using electricity in a process similar to electroplating but where the work piece acts as the anode in the electrolytic cell. The anodising process generates a porous aluminum oxide top layer on the surface of the aluminum work pieces. Subsequently, the work pieces may be coloured by a Ni-based electrolytic process where nickel metal is deposited into the active pores in the aluminium oxide film from an acidic $NiSO_4$ solution using an AC current. This is followed by a two-stage sealing process. Firstly, during a cold sealing process the pores are closed by impregnation with a Ni based sealant in a ~40°C bath. During the second stage, the top layer is closed further by hydration at around 100°C using demineralised or Ni-containing water. During colouring and sealing processes, exposure to nickel metal and nickel hydroxide can also occur as it is assumed there is at least one rinse step after sealing to remove any residual $NiSO_4$ from the work piece.

Two CES have been developed to cover $NiSO_4$-related operations (Table 40). These are

- Preparation of colourant and sealant formulations (CES 10.1),
- Cleaning and maintenance (CES 10.2) representing the cleaning and maintenance of plant, premises and solutions including removal and treatment spent solutions and dirty rinse water from tanks (dumping of spent solutions and rinse water) and solution testing, but is not considered to include solution maintenance tasks such as topping-up.

Table 40. CES developed for GES 10: Formulation of products for surface treatment of anodized aluminum sheets

CES title	**PROC Codes**	**Description**
10.1: Preparation of colorant and sealant formulations	PROC 5, 8a & 8b	This involves the blending of 1) $NiSO_4$ and other ingredients to make the colourant and 2) $NiSO_4$, $Ni(C_2H_3O_3)2$, NiF_2 & $Ni(OH)_2$ and other ingredients to make the sealant. The bags of powdered Ni raw materials are cut open with knives, the contents manually tipped into mixers and blended with other ingredients and the resulting liquid colourant and powder or liquid sealant formulation is packaged into containers (bags, buckets, cans or casks) for transportation and storage prior to use.

10.2: Cleaning &Maintenance	PROC 10	Cleaning and maintenance of plant and premises

Information on operational conditions (OC) and risk management measures (RMM) has been supplied by one company and is summarized in Table 41.

Activities maybe run largely from a control room in a highly automated plant or from a gantry or work station beside the process line when they are required to operate the process more directly.

No information on RMM was reported for CES 10.2 (Table 41) and so assumptions have been made on what would be used.

Table 41. Reported risk management measures (RMM) used by contributing exposure scenario

CES	**Engineering controls**	**Containment level**	**PPE**		
	LEV & named others		**RPE type**	**Glove type**	**Other PPE**
10.1	Reported as 'Exterior LEV for fill in and fill out (Ventilation without separator)'	Assumed open for loading & emptying mixer and enclosed during mixing	FFP3 RPE used (APF 20)	Nitrile or Neoprene	Glasses & overalls
10.2	NR, assumed general ventilation	NR, assumed open	NR, assumed as10.1	NR, assumed as10.1	NR, assumed as10.1

NR Not reported

<u>Inhalation route: Exposure estimates and calculated RCR</u>

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in Table 42.

Table 42. CES developed for GES 10: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m^3	**Method calculation**	**mg Ni/m^3**	**Tier 1**	**Tier 2**	
CES 10.1 Preparation of colorant and sealant formulations	0.114	**MEASE modeling (tier1 model):** -PROC 8 -Ni content 5-25% -non dispersive use -incidental -duration 1h	0.01	11.4	0.57*	**RCR < 1** **((MEASE modeling RPE 20)**

		-LEV - ° RPE = 10- *RPE=20-**RPE=40				
CES 10.2 Cleaning & Maintenance	0.342	**MEASE modeling (tier1 model):** -PROC 10 -Ni content 5-25% -non dispersive use -incidental -duration 1h -GV -*RPE=20-**RPE=40	0.01	**34.2**	**1.7*** **0.8****	**RCR < 1** **(MEASE modelling, RPE 40)**

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

-*RPE=20

-**RPE=40

No inhalation exposure monitoring data were available for this or similar processes and so all exposure estimates are based on the MEASE model.

- CES 10.1

For CES 10.1, calculated RCRs are below 1 (RCR < 1) only when worker wears RPE with an APF of 20. This level of protection is consistent with the RPE proposed by the Registrant for this task (Table 38)

Thus, considering the RPE of 20 reported by the Registrant, the RCR is below the unit leading to an acceptable risk for CES 10.1

- CES 10.2

For CES 10.2, calculated RCRs are below 1 (RCR < 1) only when worker wears RPE with an APF of 40. Only RPE of 20 was reported by the Registrant for these scenarios (Table 38).

Thus, considering the RPE of 20 reported by the Registrant, the RCR is above the unit leading to an unacceptable risk for CES 10.2.

Dermal route: Exposure estimates

Table 43 shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures.

Table 43. CES developed for GES 10: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 10.1	5, 8a&	Solid, medium dustiness- Content in preparation: 5-25% - Industrial- NDH - NDU- Incidental – duration exposure: 8h – Area of skin (cm^2): 480 - LEV / PPE: yes.	0.00006	0.14
	8b	Solid, medium dustiness- Content in preparation: 5-25% - Industrial- NDH - NDU- Incidental – duration exposure: 8h – Area of skin (cm^2): 960 - LEV / PPE: yes.		
CES 10.2	10	Solid, medium dustiness- Content in preparation: 5-25% - Industrial- NDH - NDU- Incidental – duration exposure: 1h – Area of skin (cm^2): 960 - GV / PPE: yes.	6×10^{-6}	0.014

NDH Non- direct handling	GV General ventilation	Enc Enclosure
NDU Non- dispersive use	LEV Local exhaust ventilation	ExtLEV Exterior LEV
WDU Wide dispersive use		

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for NiSO4, wearing PPE is required during all these tasks.

According to registrant (see table 38), gloves is required for all task of GES 10.

3.5.2.11 GES 11: Surface treatment of anodised aluminium sheets

The exposure assessment for GES 11 is based on a redrafted version of the CSR (2013 updates) including new information on processes and exposure data provided to the nickel Consortia.

This exposure assessment report describes the use of hydrated $NiSO_4$ and $NiSO_4$ solution in the surface finishing of anodised aluminium sheets.

1) **Contribution Exposure Scenarios**

This Exposure Scenario does not cover the anodising process itself. It covers the Ni-based surface treatment of aluminum sheets, following the anodising process and the fabrication of the surface treated anodised sheets.

Anodising generates a protective surface finish on aluminum parts using electricity in a process similar to electroplating but where the work piece acts as the anode in the electrolytic cell. The anodising process generates a porous aluminum oxide top layer on the surface of the aluminum work pieces. Subsequently, the work pieces may be colored by a Ni-based electrolytic process where nickel metal is deposited into the active pores in the aluminum oxide film from an acidic $NiSO_4$ solution using an AC current. This is followed by a two-stage sealing process. Firstly, during a cold sealing process the pores are closed by impregnation with a Ni based sealant in a ~40°C bath. During the second stage, the top layer is closed further by hydration at around 100°C using demineralised or Ni-containing water. During colouring and sealing processes, exposure to nickel metal and nickel hydroxide can also occur as it is assumed there is at least one rinse step after sealing to remove any residual $NiSO_4$ from the work piece.

Three CES have been developed to cover $NiSO_4$-related operations (Table 44). These are:

- the (post-anodising work piece) processing and solution maintenance operations carried out on the dipping line (CES 11.1):
  - preparation of electrolytic $NiSO_4$ solution,
  - preparation of $NiSO_4$, $Ni(C_2H_3O_3)_2$, NiF_2 and $Ni(OH)_2$ -containing sealant solutions or dry powder,
  - addition of $NiSO_4$-based solution formulations to electrolytic and $NiSO_4$-based powder formulations to sealant solutions during replenishment (dosing or topping-up) to maintain coloring solution concentration of ~10 g Ni L^{-1} and a sealant solution concentration of ~2 g Ni L^{-1},
  - dipping items with surfaces to be coloured (around 30 minutes residence in the solution tank) and sealed (around 15 minutes residence in the solution tank) into the respective solutions,
  - rinsing treated items,
  - removal of treated items from jigs,
  - testing working solution composition,
  - fabrication – drilling, cutting and assembly of the treated sheets into a finished product.
- cleaning and maintenance (CES 11.3) representing the cleaning and maintenance of plant, premises and solutions including removal and treatment spent solutions and dirty rinse water from tanks (dumping of spent solutions and rinse water) and solution testing, but is not considered to include solution maintenance tasks such as topping-up.

Table 44. CES developed for GES 11: Metal surface treatment of anodised aluminum sheets

CES title	**PROC Codes**	**Description**
11.1: Plating - Coloring, Cold Sealing & Hot sealing	PROC 13 for dipping & PROC 8a for topping up	Operating the post-anodising dipping line which includes replenishing the Ni levels of solutions with the prepared formulations by adding, dissolving and mixing the colouring and sealant powder formulations in the respective tank solutions.
11.2 Fabrication	PROC 21 &24	Automated and manual cutting of sheets to size and drilling for final assembly into finished products
11.3: Cleaning	PROC 10	Cleaning and maintenance of plant and

&Maintenance		premises

🟪 A purple shaded entry indicates that there is likely no NiSO4 exposure for that operation/CES

Information on operating conditions (OC) and risk management measures (RMM) has been supplied by one company and is summarized in Table 45.

Activities maybe run largely from a control room in a highly automated plant or from a gantry or work station beside the process line when they are required to operate the process more directly.

No information on RMM was reported for CES 11.3 (Table 45) and so assumptions have been made on what would be used.

Table 45. Reported risk management measures (RMM) used by contributing exposure scenario

CES	**Engineering controls**	**Containment level**	**PPE**		
	LEV & named others		**RPE type**	**Glove type**	**Other PPE**
11.1	Reported as 'Generic LEV or exterior LEV' – assumed for Dipping General ventilation is assumed for topping-up	Open	P2 or P3 RPE used when handling solids (APF 20)	Gloves worn & assumed Nitrile or Neoprene	Glasses & overalls
11.2	Reported as 'Eventually exterior LEV'	NR, assumed open	None	None	Glasses
11.3	NR, assumed general ventilation	NR, assumed open	NR, assumed as 10.1	NR, assumed as 10.1	NR, assumed as 10.1

NR Not reported

Inhalation route: Exposure estimates and calculated RCR

Exposure estimates and calculated Risk Characterization Ratios (RCR) are presented in the Table 46.

Table 46. CES developed for GES 11: inhalation exposure estimates and RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure estimation**		**DNEL**	**RCR**	**RCR**	**Confidence in the RCR**
	mg Ni/m^3	**Method calculation**	**mg Ni/m^3**	**Tier 1**	**Tier 2**	
CES 11.1a Surface treatment (cold & hot sealing) as dipping	0.001	**MEASE modeling (tier1 model):** 90th percentile exposure modeled exposure estimate using MEASE for PROC 13 (Ni content 1-5%, incidental exposure, inclusion into matrix, duration 8 hours, LEV,	0.01	**0.1**	-	RCR < 1 (MEASE modeling, no RPE)

		gloves)				🟩
CES 11.1b Surface treatment (cold & hot sealing) as topping-up	0.324	**MEASE modeling (tier1 model):** 90th percentile exposure estimate using MEASE for PROC 10 { Ni content 5- 25%, incidental exposure, nondispersive use, duration 1 hour, general ventilation, RPE, gloves} **RPE 40	0.01	**34.2**	**0.8****	RCR < 1 (MEASE modelling, RPE 40)
CES 11.2 Fabrication	0.057	**MEASE modeling (tier1 model):** 90th percentile exposure modeled exposure estimate using MEASE for PROC 24 (Ni content <1%, incidental exposure, non-dispersive use, duration 8 hours, LEV, RPE, gloves) * RPE 20	0.01	**5.7**	**0.28***	RCR < 1 (MEASE modelling, RPE 20)
CES 11.3 Cleaning & Maintenance	0.324	**MEASE modeling (tier1 model):** 90th percentile exposure estimate using MEASE for PROC 10 { Ni content 5-25%, incidental exposure, nondispersive use, duration 1 hour, general ventilation, RPE, gloves} **RPE 40	0.01	**34.2**	**0.8****	RCR < 1 (MEASE modelling, RPE 40)

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

-*RPE=20

-**RPE=40

No inhalation exposure monitoring data were available for this or similar processes and so all exposure estimates are based on the MEASE model

For CES 11.1a, the calculated RCR is below 1 (RCR < 1) with no RPE. **Thus, the risk for worker is acceptable for this scenario.**

For CES 11.2, calculated RCR is below 1 (RCR < 1) only when workers wears RPE of 20. No RPE have been reported by the Registrant for this task (see Table 42). **Thus, considering no RPE, RCR are above the unit leading to an unacceptable risk for this scenario.**

For CES 11.1b and CES 11.3, calculated RCRs are below 1 (RCR < 1) only with the wear of RPE with an APF of 40). Only an RPE of 20 was proposed by the Registrant for CES 11.3. **Thus, the risk for worker is unacceptable for both scenarios considering the RPE level proposed by the Registrant.**

Dermal route: Exposure estimates

Table 47 shows the summary exposure estimates used to derive the risk characterization ratios (RCR) for dermal exposures.

Table 47. CES developed for GES 10: dermal exposure estimates and RCR

CES	**PROC code**	**MEASE modeling parameters**	**Exposure estimation (mg(Ni) cm^{-2} d^{-1})**	**RCR**
CES 11.1a	13	Solution- Content in preparation: 1-5% - Industrial- NDH –Inclusion into matrix- Incidental – duration exposure: 8h – Area of skin (cm^2): 480 - LEV / PPE: yes.	1×10^{-5}	0.023
CES 11.1b	8a	Solid, medium dustiness- Content in preparation: 5-25% - Industrial- NDH - WDU- Incidental – duration exposure: 1h – Area of skin (cm^2): 480 - GV / PPE: yes.	6×10^{-6}	0.014
CES 11.2	24	Solid, medium dustiness- Content in preparation: <1%- Industrial- NDH - NDU- Incidental – duration exposure: 8h – Area of skin (cm^2): 1980 – Ext LEV / PPE: yes.	1×10^{-5}	0.023
CES 11.3	10	Solid, medium dustiness- Content in preparation: 5-25% - Industrial- NDH - NDU- Incidental – duration exposure: 1h – Area of skin (cm^2): 960 - GV / PPE: yes.	6×10^{-6}	0.014

NDH Non- direct handling GV General ventilation Enc Enclosure

NDU Non- dispersive use LEV Local exhaust ventilation ExtLEV Exterior LEV

WDU Wide dispersive use

RCR are below 1 (RCR < 1) in all cases dermal exposure.

Considering the classification as skin sensitizer for $NiSO_4$, wearing PPE is required during all these tasks.

According to registrant (see table 42), gloves is required for all task of GES 11 excepting CES 11.2.

3.5.3 Overall conclusion on exposure assessment and risk characterization

Inhalation and dermal routes are the main exposure paths to $NiSO_4$ for workers.

Measured exposure data or modelled exposure data (Tier I model MEASE) used in this risk characterization are from the CSR of the registration dossiers. The Risk

Characterization Ratios (RCRs) have been re-calculated with the DNEL for long term inhalation exposure considered relevant by Anses and set at 0.01 mg Ni/m^3. Indeed the DNEL used so far by the registrant in its chemical safety assessment (i.e. [confidential] mg Ni/m^3) is considered not sufficiently protective, thus inappropriate.

Risk characterization from exposure measurements data

According to the exposure measurement data presented in the Registrant's dossier, no definitive conclusion can be drawn regarding the risk assessment for workers using $NiSO_4$.

Indeed, there is high level of uncertainty associated with the exposure estimates and their associated RCR making difficult the interpretation of the results of the risk assessment. The following uncertainties were identified for Ni exposure measurements:

- Some of exposure measurements for the majority of scenarios are below the minimum set of 12 measurements required to validate a RCR according to REACH guidance on information requirements and chemical safety assessment[25].
- The required full data set is not available in most scenarios, which makes the determination of the data distribution impossible; indeed the Geometric Standard Deviation value (GSD) is required to validate the RCR according to REACH guidance 7.
- Some data are aggregated from several steps of the process leading to a possible underestimation of worker exposure (for instance in CES 2.4).
- The description of processes and RMMs in place provided by downstream users are not sufficiently detailed.

Considering all these uncertainties, it is impossible to conclude on the risk for all CES including inhalation exposure measurements.

Risk characterization from modeled exposure data (MEASE):

When no inhalation exposure monitoring data were available, the inhalation exposure concentrations have been estimated using the Tier I model MEASE. For all these scenarios including modeled exposure data, the risk for workers is considered:

- Acceptable if RCR < 1 and when RPE reported by the Registrant are consistent with the risk assessment,
- Unacceptable if RCR > 1 or if RCR <1 but the RPE reported by the Registrant is not consistent with the risk assessment.

Even if some CES individually show an acceptable risk for workers, at least one CES per GES is considered at risk and cannot be further refined in a Tier 2 approach without additional information. Therefore no acceptable risk can be identified for any entire GES.

This level of uncertainty raised in the registration dossiers can also be illustrated from exposure measurements that have been gathered in the surface treatment sector for the purpose of SEA exercises. Indeed gathering relevant information on exposure from the supply chain appears to be complicated and sometimes impossible for the registrants. SEA date show large ranges of values and are not always consistent with data used so far

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[25] Chapter R.14: Occupationnal exposure estimation, version2.1, November 2012

in a CSR (especially before the last update in 2013[26]); whatever the confidence in those data is, the quality and robustness of exposure data available on site within Industry and the relevancy of the data selection used for the chemical safety assessment under REACH can reasonably be questioned. Also, a concern in the current control of the occupational risk by companies is thus raised.

3.6 Need and objectives for further risk assessment and risk management

3.6.1 Need for further risk assessment

As previously stated, it is not possible to verify that the risk is adequately controlled nor clearly identify a risk all scenarios (all uses) because of the uncertainty on the calculated RCR. The quality of exposure data from the registration dossiers is the main issue. Therefore the risk assessment should be updated once new and reliable data on exposure (preferably in situ measurements rather than modelling) would be provided by the registrants.

The chemical safety assessment carried out so far by the registrants has used the DNEL value of 0.05 mg Ni/m^3, exposure data either measured either modelled and risk management measures that have been fitted to reach this DNEL. Considering that Anses has considered a 5 times lower DNEL value (0,01 mg Ni/m^3) as relevant for its evaluation, an iteration of the chemical safety assessment would be needed from the registrants in order to know if the risk can be adequately managed, if needed by implementing other risk management measures, changes in the processes, enclosed systems or automation, etc.

A formal frame to achieve otherwise an equivalent exercise is the substance evaluation procedure under REACH (SEV), as it would allow the evaluating Member State to formally require the expected information in a draft decision and to reassess the dossier update consequently. A 3 years' time from the inclusion of the substance in the CoRAP is expected in order to proceed with the decision, collect the data, update the dossier, reassess and conclude on the raised concern. Once the risk assessment finalized, the RMOA would need to be updated. More time would be needed however in the case where a group approach of several nickel salts would be relevant under substance evaluation; indeed same concerns on the registration dossiers quality may be raised for other nickel salts.

3.6.2 Need for further risk management

The non-conclusive situation stated above has to be overstepped for the purpose of the RMOA which aims at identifying and assessing potential risk management options as soon as a possible risk concern is raised, as it is the case. To that respect, although the non-conclusive situation, a concern on the risk management of $NiSO_4$ is still raised because, as already explained, an inappropriate DNEL ([confidential] mg Ni/m^3) has been used so far by the registrants in their CSA and because of potential significant exposure of the workers population above the DNEL considered as appropriate (0.01 mg Ni/m^3).

As a result, the expected target of a potential risk management option/tool for $NiSO_4$ would be at least both the formal setting of an appropriate DNEL at 0.01 mg Ni/m^3 and the control of the on-site occupational exposure to $NiSO_4$ by inhalation below this exposure limit.

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[26] Meaning that the last update has taken into account the best available knowledge shared by companies

Therefore several risk management options are assessed in the following section (i.e. formal binding OEL under European regulations, restriction and authorisation under REACH) aiming at identifying their potential effectiveness and appropriateness in implementing such setting and control. For the restriction assessment particularly, an estimation of the current level of risk has been derived from the available risk assessment, for each GES, in order to target and scope appropriate restrictions (see section 4.2.1.).

4 IDENTIFICATION AND ASSESSMENT OF CURRENT AND FURTHER RISK MANAGEMENT OPTIONS

This section explores the potential of REACH and non-REACH risk management instruments to manage the hazards of $NiSO_4$ and potential occupational health risks arising from its manufacture and uses. The target of the risk reduction strategy is the control of the exposure below the set DNEL. Therefore each following risk management option is assessed in this way. They include existing pieces of European legislation which aim at avoiding, controlling and/or reducing emissions on nickel compounds and exposure of workers. To a limited extent, pieces of European legislation that are dedicated to environment protection are also considered when they may indirectly reduce workers' exposure. No voluntarily concerted commitment from Industry (for instance on the phase out of nickel compounds or on a risk reduction strategy) has been identified so far.

Table 48 summarizes the RMOs identified and assessed as regards their consistency in addressing the risks related to $NiSO_4$.

Table 48. Risk management options assessed

EU general legislations on hazardous chemicals	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP regulation)
	Directive 94/27/EC of 30 June 1994 on the restrictions on the marketing and use of certain dangerous substances and preparations.
EU workplace legislation and recommendations regarding occupational health	Recommendations of OELs (SCOEL)
	Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work ("Chemical Agents Directive – CAD) AND Directive 2004/37/EC on carcinogens at work
Other workplace EU legislations	Directive 2001/58/EC on "Safety Data Sheets" Directive 89/656/EEC on the use of personal protective equipment. Directive 92/85/EC (pregnant workers directive) Directive 94/33/EC (young workers directive) on the protection of young people at work.
EU legislation on environment protection and/or covering human health safety through environmental exposure	Directive 96/61/EC concerning integrated pollution prevention and control (IPPC)

REACH risk management measures	REACH restriction (Annex XVII)
	REACH SVHC identification and authorisation (Annex XIV)

4.1 Existing non-REACH legislations or recommendations

4.1.1 EU general legislations on hazardous chemicals

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) requires from companies that they appropriately classify, label and package their substances and mixtures according to the set classification and before placing them on the market. It aims to protect workers, consumers and the environment by means of labelling which reflects possible hazardous effects of a particular chemical. It also takes over provisions of the REACH Regulation regarding the notification of classifications, the establishment of a list of harmonised classifications and the creation of a classification and labelling inventory.

This Regulation doesn't indicate any exposure limit value nor require specific exposure control. However the classification and labelling of nickel compounds as formal CMR substances have made these substances eligible to the provisions of other legislation aiming at controlling exposure such as Directive 2004/37/EC (Carcinogens at work Directive) and Directive 98/24/EC (Chemicals agents Directive, see infra) on the protection of workers from the risks related to exposure to carcinogens and chemicals at work.

As a result, the CLP regulation is not suited to directly reduce occupational exposure and is therefore considered not relevant for the $NiSO_4$ risk reduction strategy.

Directive 94/27/EC of 30 June 1994 (amending for the 12th time Directive 76/769/EEC) on the restrictions on the marketing and use of certain dangerous substances and preparations is also called the "Nickel Directive". It regulates the use of nickel in jewellery and other products coming into direct and prolonged contact with the skin, which may cause sensitisation of humans to nickel and may lead to allergic reactions. Since 1 June 2009, it has been merged with the REACH Regulation (see entrance 27 of Annex XVII on restrictions).

Focusing only on the dermal sensitisation of $NiSO_4$, this Directive is not suited to reduce occupational inhalation exposure and considered not relevant for the $NiSO_4$ risk reduction strategy.

4.1.2 EU workplace legislation and recommendations regarding occupational health

The current regulatory regime aims at protecting workers from exposure to nickel and its compounds through a number of legislative instruments including Carcinogens at work (Directive 2004/37/EC), Chemicals at work (Directive 98/24/EC), specific legislation protecting young workers and pregnant or breast-feeding women and also recommendations from SCOEL.

4.1.2.1 Background on occupational exposure limits (OELs)

The Commission can at any time make a proposal for setting an informal or binding Occupational Exposure Limit either under Directive 2004/37/EC or under Directive

98/27/EC especially when a limit value has already been recommended by the Scientific Committee on Occupational Exposure Limits - SCOEL.

OEL limits are somehow different than DNEL values as they are set based on non effect levels[27] (as DNELs are) but adjusted to the technical feasibility of European companies and Member States to reach this limit in order to ensure an harmonized implementation in Europe. Thus socio-economical aspects are usually taken into consideration whatever the status of the value is (binding or indicative). Setting an OEL in the existing legal framework is always a tripartite agreement with representatives of Industry and workers trade unions that allow its social acceptance and thus facilitate its implementation.

In June 2011 SCOEL adopted a recommendation setting an indicative inhalable size OEL of 0.01 mg Ni/m^3 for nickel compounds (excluding nickel metal) and an indicative respirable size OEL of 0.005 mg Ni/m^3 for nickel compounds and metallic nickel as well. Therefore the $NiSO_4$ (and other nickel salts) can at any time be proposed by the Commission for setting a formal OEL under Directive 2004/37/EC or Directive 98/27/EC.

4.1.2.2 Directive 98/24/EC (Chemical Agents Directive) and Directive 2004/37/EC (Carcinogens at work Directive)

Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work and Directive 2004/37/EC on carcinogens at work aim at protecting workers from the risk related to exposure to chemicals at the workplace. They set minimum requirements to protect and prevent workers from health and safety risks which might arise from exposure to chemicals (for Directive 98/24/EC) and to carcinogens or mutagens specifically (for Directive 2004/37/EC). Both lay down limit values of exposure and recommend the implementation of very similar risk management measures in order to control the risk at the workplace. Main differences concern the binding versus indicative status of the limit values and the type of chemicals (carcinogens or mutagens versus other hazardous chemicals). "Indicative" means that Member States are free to follow or not the proposed numerical value when transposing it into national laws and free to enforce an indicative or a binding value.

Setting a binding occupational exposure limit for $NiSO_4$ is the expected objective of the risk reduction strategy in order to allow a harmonized measure within the EU and to oblige Industry to comply with the requirements. Otherwise in the case of an indicative limit value, imbalances would be expected between countries both for Industries and workers protection.

Content and scope of Directive 98/24/EC (Chemical agent directive)

Directive 98/24/EC proposes to set indicative or binding occupational exposure limit values (IOELVs or BOELVs) as well as binding biological limit values (BLVs) at Community level (BLVs are always binding contrary to OELs).. Several limit values are set in Directive 98/24/EC and in the daughter Directives 2000/39/EC and 2006/15/EC.

Employers' obligations

Employers must determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health arising from their presence taking into account any necessary information (hazard properties, exposure measurements, existing OELs or biological limit values, effectiveness of any preventive measure, etc.) and all uses including those expected with higher exposure such as maintenance. Risk

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[27] This is carried out by the SCOEL when recommending OELs

assessment shall be documented in a suitable form according to national law and practice and kept up to date. In the case of activities involving exposure to several hazardous chemical agents, the overall risk must be assessed on the basis of risks presented by all chemical agents in combination.

Employers are required to ensure that the risk from hazardous chemical agents is eliminated or reduced to a minimum. To this purpose, substitution shall by preference be undertaken. When substitution is not possible, employers shall ensure that the risk is reduced to a minimum by the application of protection and prevention measures, including in order of priority:

- design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents,
- application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organizational measures,
- where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

Such measures shall be accompanied by health surveillance if it is appropriate to the nature of the risk. When an indicative or binding OEL value established on the territory of a Member State has been exceeded, the employer shall immediately take remediation by carrying out preventive and protective measures. Training of workers is also requested from employers.

Member States obligations

For any chemical agent for which an indicative OEL value is established at Community level, Member States must establish a national OEL value (informal or binding depending on the willingness of the Member State) taking into account the Community limit value at the minimum requirement. Any chemical agent for which a binding OEL or biological limit value is established at Community level, Member States must establish a corresponding national binding OEL or biological limit value that does not exceed the Community limit value. Member States shall introduce arrangements for carrying out appropriate health surveillance of workers. Where a binding biological limit value has been set, health surveillance shall be a compulsory requirement for work with the hazardous chemical agent in question.

Content and scope of Directive 2004/37/EC (Carcinogens at work Directive)

Directive 2004/37/EC is the codified version of former Directive 90/394/EEC on the Protection of Workers from Risks to Exposure to Carcinogens at Work. The directive sets BOELVs for several substances that are already classified carcinogens or mutagens according to Annex VI of the CLP. Contrary to Directive 98/24/EC, OELs are always binding and no BLVs are set.

Employers and Member States obligations are similar to those required for BOELVs in Directive 98/24/EC.

The Directive also provides substitution as a priority otherwise encourages to avoid exposure or to keep it as low as possible and below the binding limit that is set. Employers are required to "reduce the use of a carcinogen or mutagen […] in particular by replacing it, in so far as it is technically possible by a substance, preparation or process which, […] is not dangerous or is less dangerous to workers […]". "Workers exposure must be prevented when the results of the assessment reveal a risk to worker's health or safety". "Where it is not technically possible to replace the carcinogen or mutagen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system". "Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible".

Limit values set by this Directive are binding and shall be transposed in national laws by each Member States either with same value either with a more restrictive value. This ensures efficiency and harmonised implementation within Member States without imbalance both for Industry's competition and workers protection.

Discussion on Directive 98/24/EC and Directive 2004/37/EC

Discussion on Directive 98/24/EC (Chemicals agent Directive)

Except one available BLV for lead and lead compounds, only IOELs are currently set by this Directive.

There is currently no EU indicative nor BOELV nor BLV for nickel and nickel compounds. Nickel metal and some nickel salts (dinickel trioxide and nickel acetate, carbonate, chloride, dioxide, hydroxide, monoxide, nitrate, subsulphide, sulphide and nickel sulphate) are in the "pipeline"[28] for the upcoming Directive update that is scheduled in 2015. However as nickel salts are all identified as carcinogen substances under the CLP regulation, they would probably be redirected and covered by Directive 2004/37/EC (i.e. with a binding value) as soon as a limit value would be set by the relevant committee.

If nickel compounds would only be covered by Directive 98/24/EC, only an indicative limit value would reasonably be expected by experience. Member States would then be free to set either an indicative or a binding national limit value (with a possibly more stringent numerical value than the one set at the EU level). No harmonized limit values would therefore be expected at the EU level and an agreement between Member States for commonly implementing the same binding value is not deemed realistic.

Therefore a binding value for $NiSO_4$is not yet expected easily achievable in the frame of this Directive.

Discussion on Directive 2004/37/EC (Carcinogens at work Directive)

Neither $NiSO_4$nor other nickel compounds is yet covered by this Directive or included in the list of the substances under discussion for the upcoming update of this Directive. However as already said, nickel metal and some nickel salts (dinickel trioxide and nickel acetate, carbonate, chloride, dioxide, hydroxide, monoxide, nitrate, subsulphide, sulphide and nickel sulphate) are in the pipeline for the update of Directive 98/24/EC and would be rather addressed under Directive 2004/37/EC due to their classification as carcinogens. One or both values recommended by SCOEL (0,01 and 0,005 mg Ni/m3) could be agreed soon[29] by the relevant Committee. Given that an update of Directive 2004/37/EC is expected soon (no date is yet available but reasonably envisaged around 2015), nickel salts could be included. Considering a maximum 2 years period for transposition in national laws by Member States and enforcement by companies, 2017 may be seen as an effective date for those limit value to be enforced by Member States.

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[28] proposal for a work plan for the 4th list of indicative occupational exposure limit values to be discussed in 2014-June

[29] probably in June 2014

However if nickel salts miss the next update of this Directive, no indication for another update is yet available and it is not known if the Directive will be updated on a frequent basis or not. The recent experience shows that many years are needed to update the Directive, partly explained by extended discussions between stakeholders on the addition of new limit values, especially in a context where the new REACH regulation adds legal requirements on Industry on same issues (occupational health and safety, substances of very high concern, etc.).

Common discussion on both Directives

As stated in the Directive's provisions, priority should be given to avoid exposure (by substitution or closed systems e.g.) but this option is not mandatory. Drivers for substitution are weak and generally speaking, these directives may be seen as providing low incentives to substitution; therefore it is not anticipated that substitution will be implemented by companies and the question of the hazard/risk of the potential substitutes compared to $NiSO_4$ is thus not further considered for this risk management option. The choice of the best option is left to each company. It can be anticipated that companies won't abandon a use and would rather prefer to implement more stringent on site risk management measures. Moreover from the SEA conclusions (analysis of alternatives) (see section 2), Industry doesn't consider the substitution as a relevant nor feasible option. Note that the cost of such risk management measures is not known which doesn't allow considering the criterion "balance of the costs compared to the benefits" in the current analysis.

Based on the current knowledge on uses, processes and exposure estimations, both from the risk assessment and from Industry point of views, the improvement of protective equipments (whatever the costs are) may be sufficient to keep exposure below the set limit value of the 0,01 mg Ni/m^3 in most cases. Unfortunately no modelling/calculation is possible in the risk assessment to anticipate this possibility, given the low reliability of exposure values provided in the registration dossiers. The feasibility to keep exposure below the lowest limit value of 0,005 mg Ni/m^3 is not known however, even if anticipated successful by some registrants in specific applications. This would however impose costly adjustments for companies which may be considered as an economic burden especially for small and medium companies and could represent a risk of technical non-compliance with the legal provisions.

In the case where risk remains uncontrolled for a scenario because the implemented solutions are insufficient to keep exposure below the limit value, additional risk management measures would be required in a later step (i.e. via restrictions or authorization under REACH). This could happen for the "cleaning and maintenance" steps (manual tasks) for which the highest exposure is observed in almost all provided global exposure scenarios. The technical possibility to implement closed systems for such manual tasks is not known, but anticipated difficult.

The legal enforceability will be ensured at national level by Member States in the case where a binding value would be set. This process is not EU harmonized but usually Member States use to require at least one control per year in each concerned company (based for instance on 3 campaigns of a minimum of 9 measurements) with retaliation measures. No systematic control would be carried out in the case of an informal limit value and the risk management objective would be missed.

Conclusion on Directive 98/24/EC and Directive 2004/37/EC

Nickel sulphate can be covered by Directive 98/24/EC based on its toxicological properties (Repr. 1B, skin and respiratory sensitizers, Stot RE 1) but will rationally be covered by Directive 2004/37/EC based on its classification as carcinogen and mutagen compound (Carc. 1A and Muta 2).

Since specifically designed for risk management of chemicals at the workplace, both Directives appear relevant for implementing a European OEL for $NiSO_4$. Setting a binding limit value (BOELV) rather than an indicative value is seen as an efficient tool in order to allow a harmonized measure within the EU and to oblige Industry to comply with the requirements. In that, Directive 98/24/EC may fail based on the current experience (no BOELV value agreed so far); starting from an EU IEOLV, is not considered foreseeable to rely on an agreement between all Member States for transposing in each country an agreed value with a binding status. For these reasons, Directive 2004/37/EC is considered better suited than Directive 98/24/EC regarding the substance classification and part of the expected objective stated in section 3.6.2.

By legally enforcing BOELVs for $NiSO_4$ around 2015 (if nickel compounds are effectively included in the coming update), Directive 2004/37/EC could be seen as a relevant preliminary measure, where the risk can be technically managed by lowering or if possible preventing exposure. Obligations imposed to operators are clear and could in theory be technically achievable.

It is also considered proportional as

- uses/processes for which the risk is considered already managed by a relevant exposure control will be maintained,
- Industry will have to implement without delay significant technical adaptations of processes for at least part of exposure scenarios that are currently seen at risk because of high and uncontrolled exposure,
- a more drastic measure will be decided later on if needed, based on results from on site surveys and national controls.

The efficiency of the measure will rely on the efficacy of the labour inspection bodies of each Member States and the harmonization of the national retaliation measures.

However the pressure for substitution is nonexistent in practice and Directive 2004/37/EC is not seen as an efficient measure for this specific purpose.

By implementing a BOEL, this measure will also require registrants to revise and update their registration dossiers under REACH with a relevant chemical safety assessment showing that risks are adequately controlled; responsibility under REACH is therefore still kept on the operators.

In conclusion, Directive 2004/37/EC on Carcinogens at work is considered consistent with the objective of the risk reduction strategy stated in section 3.6.2 (i.e. as a minimum setting a formal DNEL and keeping exposure below it). Moreover it appears to be a clear, proportional and an efficient measure, achievable in a short timeframe.

Would however the $NiSO_4$finally not included in the next Directive 2004/37/EC update, other risk management options should be investigated without delay. Besides, if the chosen OEL in this Directive is over the considered appropriate DNEL of 0,01 mg Ni/m^3, the control of the occupational risk would be questioned and additional risk management options should also be investigated without delay.

4.1.2.3 Other workplace EU legislations

In addition to the OEL legislation, risk at workplace arising from exposure to hazardous substances may also be managed at European level by the following Directives related to the protection of occupational safety and health. They impose minimum standards for health and safety of workers and provide a framework of directions and safeguards to ensure that the occupational risk to health from hazardous substances is controlled. These Directives do not specifically address nickel compounds, but cover indirectly nickel and its compounds regarding to their classification as hazardous substances. They are:

- Directive 2001/58/EC on "Safety Data Sheets" defines and lays down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive67/548/EEC (safety data sheets). This directive is now covered by annex II of the REACH regulation;
- Directive 89/656/EEC on the use of personal protective equipment;
- Directive 92/85/EC (pregnant workers directive) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC);
- Directive 94/33/EC (young workers directive) on the protection of young people at work.

Directive 92/85/EC and Directive 94/33/EC are not considered fitted to the risk reduction strategy since the risk concerns all workers populations and not only the most sensible ones (pregnant or young workers). Safety data sheets are not fitted to the control of exposure, but remain nevertheless important additional tools in order to achieve the global goal of exposure prevention through information and awareness of workers. Directive 89/656/EEC alone is considered insufficient as it only lays down minimum requirements for personal protective equipment used by workers at work.

Note that EU legislation on consumer protection covering directly or indirectly nickel compounds and listed in section 1.5.3 is not discussed further as it doesn't target the occupational population.

4.1.2.4 EU legislation on environment protection

EU legislation targeted on environment protection may also indirectly reduce occupational exposure to a limited extent.

Directive 96/61/EC concerning integrated pollution prevention and control (IPPC) is primarily focused on the reduction of impact from human activities to the environment. As such, its primary use is as a tool to ensure environmental protection and to reduce risks for humans indirectly exposed via the environment, rather than directly to ensure worker protection. Emission limit values to the environment are based on Best Available Techniques that are published by the Commission as IPPC BAT Reference Documents (BREFs). BREFs and their BAT conclusions continue to serve as the reference at the EU level concerning the techniques to control/reduce environmental emissions and indirectly exposure at work. Only some of the available BREFs are obviously relevant in the production and use of nickel compounds.

However the technologies defined as BAT also have an impact on the reduction of risks for workers, consumers and population in general by lowering exposure. Regarding worker protection, the "reduction of exposure to workers of dusts and gases" are often reported in various BREFs, for example on plating, catalysts, pigments, dyes (etc.) activities for which nickel compounds are used. Those recommendations are not binding but voluntarily implemented by industries.

The IPPC Directive (along with several other sectoral Directives) has been replaced on 7 January 2014 by Directive 2010/75/EU on Industrial Emissions (IED), which maintains the same principles, while strengthening the requirements concerning the application of BAT.

Current BREFs' recommendations are normally implemented by Industry. Registration dossiers under REACH should reflect the on sites situation. Considering the risk assessment result, it is considered that the current BREFs are not sufficient to keep the occupational exposure below the limit value of 0,01 mg Ni/m^3 and thus to fit with the risk reduction strategy for $NiSO_4$.

4.2 Risk management measures under REACH

Under REACH, the restriction or the authorisation requirement or a combination of both (e.g. restriction on certain uses and possible subsequent control of others under authorisation) can be considered to introduce further regulatory requirements on $NiSO_4$.

Taking a decision on measures under REACH for $NiSO_4$ may also require consideration of other nickel compounds having same or similar uses and hazard classification that therefore could be addressed in a grouping approach. However thiswould need to analyze the substitution ability between the nickel salts process on a strict technical point of view, which is considered not possible in the frame of this RMOA.

4.2.1 REACH Annex XVII - Restriction

According to Reach regulation, "when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended (...) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles (…)" (article 68-1). In other words, a restriction can be proposed as soon as an unacceptable risk has been demonstrated by a Member State (or ECHA) on one or several uses related to one substance.

4.2.1.1 Restriction prerequisites

A restriction proposal under REACH aims at tackling a risk by reducing the exposure to the hazardous substance down to a safe level, otherwise at removing it. A restriction has to meet the REACH Annex XV requirements. For this purpose, a restriction proposal may have several forms such as e.g. limiting the concentration or the migration of a substance in one specific article to protect consumers and users; or, more specifically in the case of workers protection, it may also consist in limiting the exposure from the devices handled and/or occurring during the processing operations. The limits proposed may be so low that the restriction might be in some cases equivalent to a total ban of the use of the substance. In those cases, the existence of available and suitable alternatives is of great importance.

The Annex XV restriction proposals are the remit of the Member State Competent Authorities and ECHA.

A REACH restriction shows several advantages (over the REACH authorisation procedure in particular):

- It can be targeted and tailored for one specific risky use of a substance instead of restricting the substance as a whole.;
- It may be coupled with derogations to take into account some particular situations of market actors or uses;
- This is a rather fast process to reduce the risks;
- It may cover EU imports of articles containing hazardous substances (SVHC or others) which are not addressed by the authorisation route.

Submitting a REACH restriction proposal to address a particular risk requires the following preliminary conditions:

- First of all, the submitting dossier submitter (DS) has to be sure that the substance of concern and the risks targeted can be legally addressed under the REACH restriction procedure. In those circumstances, REACH restrictions may cover a wide range of situations; the only exception being the use of a substance as an on-site isolated intermediate (article 68-1 of REACH). To that respect, the uses of $NiSO_4$ determined as to be "at risk" (see table 46), could then in principle be covered by a restriction.

- Then, the scope of the restriction has to be defined very precisely, including the substance or group of substances of concern as well as the definitions of the articles or the working conditions/workstation targeted. This requirement is important to ensure the effectiveness, the enforceability and the monitorability of the restriction but also its consistency with other existing pieces of legislations which may cover the same or close field. To what extent restricting under REACH the uses of $NiSO_4$ considered as "at risk" above while meeting this requirement is dependent on the specificities of each GES. Nevertheless, as shown in the tables below, commonly for all GES, some difficulties are expected regarding the possibility to provide a precise and generic definition of the workstations/tasks of concern. These difficulties might lead to an unclear scope.

- Last, an "unacceptable" risk has to be demonstrated. This "unacceptability" is not strictly defined in the REACH technical guidances but it implies that the argumentation has to be scientifically-based and the risk robustly demonstrated, such as described in the Guidance on Annex XV Restrictions. The proposal submitted by the Member State or ECHA thus has to include a hazards assessment, an exposure assessment as well as a risk characterization. Although a certain level of uncertainty might remain (if highlighted and treated) in the demonstration, the analysis has to be the most precise as possible and supported by evidences. To that respect, given all the uncertainties already listed in section 3 that lead to the impossibility to conclude on the risk based on the current registration dossiers, this requirement is expected to be difficulty met for the uses of $NiSO_4$. This issue will be more specifically developed below for every single GES.

In terms of timing, a REACH restriction proposal is procedurally scheduled to be elaborated within 12 months by the dossier submitter, from the official date of intention (announced on the ECHA Register of Intention). Then, the proposal is scrutinized in RAC and SEAC within at least 12 extra months, depending on different factors and steps (success or not during the conformity check step and consistency between RAC and SEAC opinions). Finally, the European Commission has to take their decision within 3 months. As a whole, the REACH restriction procedure thus takes at least 27 months to be finally adopted. Taking also into account the transitional period (usually at least 12 months) proposed by the dossier submitter to allow the industry to comply with the new restriction (tailored to the uses and markets concerned), this timescale may be actually even longer.

The following analyzes the previous considerations for every single GES, in order to assess whether a restriction under REACH would be appropriate and feasible to address the risks.

4.2.1.2 Estimation of the level of risk for each use of nickel sulphate

For the purpose of the RMOA and especially for the restriction option analysis, the non-conclusive situation stated in section 3 has been overstepped and a "level of risk" has been estimated based on the risk assessment results. The realism of this assessment cannot be anticipated without an in depth review of the exposure data.

Beyond the raised uncertainties on the data quality, the minimum level of protection (i.e. APF 10, 20 or 40 of the respiratory protective equipment - RPE) needed to calculate a RCR below 1 has been compared with the RPE information provided by the registrant in the CSR for each GES and CES (RPE type and APF reported to be available or implemented). The reliability of the information has not been checked. The risk is considered controlled when the RPE said available or implemented by the registrant is consistent with or higher than the APF needed to calculate a RCR below 1. The risk is considered uncontrolled when the highest RPE said available or implemented by the registrant is below the APF needed to calculate a RCR below 1. The risk is also considered uncontrolled when no RPE is specified (if a RPE is necessary) or if the provided information is unclear or if inconsistencies between information have been identified from the provided documents (CSR, annexes of the CSR, etc.).. If at least one CES is considered at risk in a GES, the risk is considered uncontrolled for the whole GES.

From this estimation (see Table 49), it is concluded for the inhalation exposure that the risk is estimated uncontrolled for all the GES. Regarding the dermal exposure, it is concluded that the risk is controlled for all the GES when gloves are used, which is a priori consistent with the on-site implemented measures for all uses.

Table 49. Results of the level of risk estimated for each GES of $NiSO_4$

GES / Uses	Is the risk from inhalation estimated controlled?	Explanation based on the available data on RPE: APF needed / APF available (declared in the CSR)	Is the risk from dermal exposure estimated controlled?
1: Ni SO4 production from copper refining	NO	Higher than 40 / 40	YES
2: Ni SO4 production: solvent extraction of NiSO4 leachate	NO	Higher than 40 / 40	YES
3: Crystallisation from a purified nickel sulphate leachate	NO	40 / 20	YES
4: Metal surface treatment: nickel electroplating, electroforming, electroless plating	NO	40 / 20	YES
5: Production of batteries	NO	20-40 / no proposed RPE	YES
6: Production of Ni salts from Ni sulphate	NO	20 / APF not specified	YES
7: Use of nickel sulphate in the manufacturing of micronutrient additives for biogas production	NO	Higher than 40 / 40	YES
8: Production of nickel-containing pigments from nickel sulfate	NO	20 / 10	YES
9: Selective plating with nickel sulphate	NO	40 / 20	YES
10: Formulation of Products for Surface Treatment of Anodised	NO	40 / 20	YES

Aluminium Sheets			
11: Surface Treatment of Anodised Aluminium Sheets	NO	40 / 20	YES

4.2.1.3 Analysis of the restriction option for each GES of nickel sulphate

Table 50. Analysis of restriction pros and cons per GES

GES 1. Nickel sulphate production from copper refining

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 1.1. Reception of spent (Cu-Ni) electrolyte obtained from electrolysis (of Ni containing Cu anode to give Cu cathode) from the copper refinery	RPE APF 40 (insufficient)	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for one single task/workstation: Difficulty to define the specific targeted workstation and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	<u>Risk issue:</u> Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. Shortcomings indentified in data provided for CES 1.1. MEASE modelling suitability is questioned. <u>Scope issue</u>: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	• No expected overlapping with the PPEs Directive that is very superficial and generic • Not possible considering that the maximum APF of 40 is not sufficient	
		Automation of the process (at least part of process where exposure is of concern)	• Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means) • Might not be suitable for that specific task as manual handling would still be necessary (as much as efficient? technically feasible?)	
		Switch to an alternative (safer?) to produce NiSO4	• would imply to propose a ban of the whole GES: possible under REACH restriction procedure? • alternative processes of $NiSO_4$ manufacturing exist	
		Technical improvement of the process of reception and handling in order to lower exposure (dust release etc.)	• can be developed based on the current BAT (BREFs) • possible under a restriction procedure?	

GES 2. Solvent extraction of $NiSO_4$ leachate

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 2.1. Impure NiSO4 and nickel carbonate, NiCO3, are charged into a reactor and dissolved in sulfuric acid together with the solution of crude NiSO4.6H2O to give an impure NiSO4 solution CES 2.5 Cleaning and Maintenance reported as examples	RPE APF 40 (insufficient)	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for one single task/workstation: Difficulty to define the specific targeted workstation and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. MEASE modelling suitability is questioned. Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	• Overlapping with PPEs Directive (which however remains superficial) • not possible for CES 2.5 as the maximum APF of 40 is not sufficient	
		Automation of the process (at least part of process where exposure is of concern)	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means • not suitable for CES 2.5 which may require manual handlings (as much as efficient? technically feasible?)	
		Switch to a alternative to produce NiSO4	•would imply to propose a ban of the whole GES: possible under REACH restriction procedure? • alternative processes do exist for NISO4 manufacturing	

GES 3. Crystallisation from a purified $NiSO_4$ leachate ($NiSO_4$ production from nickel matte)

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 3.5. Cleaning and maintenace	PPE APF 20 (PPE APF 40 needed)	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for one single task/workstation: Difficulty to define the specific targeted workstation and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. MEASE modelling suitability is questioned. Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlapping with PPEs Directive • Possible as APF 40 would be sufficient (4 hours task per day)	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not be suitable for that specific task (as much as efficient? technically feasible?)	
		Switch to an alternative to produce NiSO4	•would imply to propose a ban of the whole GES: possible under REACH restriction procedure? • alternative processes do exist for NISO4 manufacturing	

GES 4. Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating (Use of $NiSO_4$ in surface finishing and electroforming)

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 4.2 Cleaning and maintenance of plant, solutions and premises	PPE with APF 20 (APF 40 needed)	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for one single task/workstation: Difficulty to define the specific targeted workstation and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	<u>Risk issue:</u> Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk <u>Scope issue</u>: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlapping with PPEs Directive • Possible as APF 40 would be sufficient (1 hour task per day)	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not be suitable for that specific task which requires manual handlings (as much as efficient? technically feasible to clean without any handlings?)	
		Limitation of $NiSO_4$ concentration in the solutions of the whole process (it is expected that each step of the process should be cleaned and maintained)	•would imply to restrict the NiSO4 concentration for the whole process •might not be technically feasible to determine a safe level of NiSO4: -Since its is not obvious that an reliable correlation can be established between the NiSO4 concentration in solutions - aerosols - dusts and the real amount inhaled by workers -Given all the possible interactions with other parameters and factors likely to influence the exposure other than the NiSO4 content (LEV, etc.) •if no safe level determined, particular attention	

			would have to be paid on the existence of alternatives	
		Switch to an alternative substance or technology	•would imply to propose a ban of the whole GES: possible under REACH restriction procedure?	

GES 5. Production of batteries: production of batteries using electrodes with nickel containing active materials

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
•CES 5.2 Preparation of NiSO4 solution by dissolving nickel briquettes in sulphuric acid and filtering and pumping the solution into a vessel (process not fully enclosed - handlings) •CES 5.3 NiSO4 solution is mixed with caustic soda or sodium carbonate (process not fully enclosed - handlings)	No PPE proposed (PPE with APF 20 needed)	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for some specific tasks/workstations: Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
•CES 5.6 Nickel electroplating {maintenance of NiSO4 electroplating solution & manufacture of electrode strip by nickel plating a steel strip} Nickel electroplating of strips and of other 'jigged' items using a NiSO4 richsolution (process not fully enclosed-handlings)	No PPE proposed (PPE with APF 40 needed)	Additional PPE/more appropriate PPE	•overlapping with PPEs Directive • Possible as APF 40 would be sufficient	
		Full automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not suitable for high volume productions (if not already implemented) but not suitable for many SMEs and specific applications that require manual handlings (as much as efficient? technically feasible to clean without any handlings? – for CES 5.7)	
CES 5.7 Cleaning and maintenance of plant and premises (process not enclosed - handlings)		Limitation of NiSO4 concentration in the solutions of the whole process (prepared and handled and the NiSO4 contained in the dust cleaned in plant and premises)	•would imply to restrict the NiSO4 concentration for the whole process •might not be technically feasible to determine a safe level of NiSO4: - Since its is not obvious that an reliable correlation can be established between the NiSO4 concentration in solutions - aerosols - dusts and the real amount inhaled by workers.	

			- Given all the possible interactions with other parameters and factors likely to influence the exposure other than the NiSO4 content (LEV, etc.) •if no safe level determined, particular attention would have to be paid on the existence of alternatives	

GES 6. Production of Ni salts from $NiSO_4$ Production of Ni salts to be used in production of catalysts

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
Production of Ni salts from Ni sulphate - Production of Ni salts to be used in production of catalysts (only one single CES for this GES)	PPE proposed without APF information + enclosure and automation (APF 20 needed)	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL's remit	Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlapping with PPEs Directive • Possible as APF 20 would be sufficient	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •not relevant as automation is already a prerequisite from the registrant	
		Switch to an alternative to produce NiSO4	•would imply to propose a total ban of the GES: possible under REACH restriction procedure?	

GES 7. Use of $NiSO_4$ in the manufacturing of micronutrient additives for biogas production

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 7.1 Nickel sulfate reception (no automation –handlings) CES 7.5 Cleaning and maintenance (no automation - handlings)	PPE APF 40 (insufficient) PPE APF 40 required	Stricter/Binding OEL	•Overlapping with OELs Directive and SCOEL’s remit •Hindrances related to the proposal of a specific OEL for some specific tasks/workstations: Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	<u>Risk issue:</u> Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. MEASE modelling reliability is questioned. <u>Scope issue</u>: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlapping with PPEs Directive • Not possible for CES 7.1 (APF 40 is not sufficient)	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might be suitable for CES 7.1 but not for CES 7.5 as manual handlings is needed (as much as efficient? technically feasible to clean without any handlings? - for CES 7.5)	
		Limitation of NiSO4 content in this manufacturing process? (process not known)	•would imply to restrict the NiSO4 for the whole process •might not be technically feasible to determine a safe level of NiSO4: - Since its is not obvious that an reliable correlation can be established between the NiSO4 concentration in solutions - aerosols - dusts and the real amount inhaled by workers	

			- Given all the possible interactions with other parameters and factors likely to influence the exposure other than the NiSO4 content (LEV, etc.) •if no safe level determined, particular attention would have to be paid on the existence of alternatives	
		Switch to an alternative substance or technology	• A priori not possible as Ni is used as a micronutrient (cannot be replaced)	

GES 8. Production of nickel-containing inorganic pigments from NiSO4

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 8.3 Drying and calcining of wet product mix or calcining of dry product mix CES 8.4 Dry milling; Milling of calcined product to a powder CES 8.6 Blending and packaging. The calcined powder product is blended with additives and packed (bags or big bags)	PPE proposed without APF information (APF 20 needed) PPE APF 10 proposed (APF 20 needed) PPE APF 10 proposed (APF 20 needed)	Stricter/Binding OEL	•Overlap with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for some specific tasks/workstations: Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	<u>Risk issue:</u> Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. Many shortcomings identified in the data provided in the CSR (as regards PPE and RMMs) <u>Scope issue</u>: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlap with PPEs Directive • Possible as APF 20 is sufficient	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not be suitable for those specific tasks (as much as efficient? technically feasible?)	
		Limitation of NiSO4 content in this manufacturing process	•would imply to restrict the NiSO4 for the whole process •might not be technically feasible to determine a safe level of NiSO4: - Since its is not obvious that an reliable correlation can be established between the NiSO4 concentration in solutions - aerosols - dusts and the real amount inhaled by workers - Given all the possible interactions with other parameters and factors likely to influence the exposure other than the NiSO4	

			content (LEV, etc.) •if no safe level determined, particular attention would have to be paid on the existence of alternatives	

GES 9. Selective Area Plating with $NiSO_4$ (Ni selective plating using a brush plating system)

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 9.2 Cleaning and maintenance (industrial use) (no automation - handlings) CES 9.5 Cleaning and maintenance (professional use)	PPE with APF 20 (APF 40 needed)	Stricter/Binding OEL	•Overlap with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for one single task/workstation: Difficulty to define the specific targeted workstation and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. MEASE modelling reliability is questioned Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	• Overlap with PPEs Directive • Possible for CES 9.2 but not possible for CES 9.5 = not possible for the whole GES	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not be suitable for that specific task (as much as efficient? technically feasible to clean without any handlings?)	
		Limitation of the $NiSO_4$ used in the plating process	•would imply to restrict the $NiSO_4$ for the whole process •might not be technically feasible to determine a safe level of $NiSO_4$: - Since its is not obvious that an reliable correlation can be established between the $NiSO_4$ concentration in solutions - aerosols - dusts and the real amount inhaled by workers - Given all the possible interactions	

			with other parameters and factors likely to influence the exposure other than the NiSO4 content (LEV, etc.) •if no safe level determined, particular attention would have to be paid on the existence of alternatives	

GES 10. Formulation of products (preparation = sealant formulation) for surface treatment of anodised aluminium sheets with $NiSO_4$. To be linked with GES 11

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 10.1 Preparation of colourant and sealant formulations (open systems or not fully enclosed) CES 10.2 Cleaning and maintenance of plant and premises (no automation)	PPE with APF 20 (APF 40 needed)	Stricter/Binding OEL	•Overlap with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for targeted tasks/workstations: Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	<u>Risk issue:</u> Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. Shortcomings identified in the data provided; <u>Scope issue</u>: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlap with PPEs Directive • Not possible (APF 40 insufficient)	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not be suitable for those specific tasks (as much as efficient? technically feasible to clean without any handlings? – for CES 10.2)	
		Limitation of the NiSO4 concentration in the formulations prepared	•would imply to restrict the NiSO4 for the whole process •might not be technically feasible to determine a safe level of NiSO4: - Since its is not obvious that an reliable correlation can be established between the NiSO4 concentration in solutions - aerosols - dusts and the real amount inhaled by workers	

			- Given all the possible interactions with other parameters and factors likely to influence the exposure other than the NiSO4 content (LEV, etc.) •if no safe level determined, particular attention would have to be paid on the existence of alternatives	

GES 11. Use of $NiSO_4$ in surface treatment of anodised aluminium sheets (use of $NiSO_4$ in surface finishing and electroforming). To be linked with GES 10

CES for which RCR >1	RMM proposed in the CSR	Possible forms of the restriction to limit the exposure	Conclusion / Caveat	
CES 11.1b Surface treatment (cold & hot sealing) as topping-up (not fully enclosed) CES 11.3 Cleaning & Maintenance (no automation –handlings)	PPE with APF 10 or 20 or not reported (APF 20 or 40 needed)	Stricter/Binding OEL	•Overlap with OELs Directive and SCOEL's remit • Hindrances related to the proposal of a specific OEL for targeted tasks/workstations: Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms Might not be implementable by the company => the proposed OEL should be applied for the whole GES	Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern
		Additional/more appropriate PPE	•Overlap with PPEs Directive • Possible with a highest APF (task duration 1 hour per day for APF 40)	
		Automation of the process	•Might be difficult to be imposed via a REACH restriction: the reduction of exposure can be imposed (obligation of result) –but not the means to achieve this reduction (vs. obligation of means •might not be suitable for those specific tasks (as much as efficient? technically feasible to clean without any handlings? –for CES 11.3)	
		Limitation of the NiSO4 used for the plating	•would imply to restrict the NiSO4 for the whole process •might not be technically feasible to determine a safe level of NiSO4: - Since its is not obvious that an reliable correlation can be established between the NiSO4 concentration in solutions - aerosols - dusts and the real	

			amount inhaled by workers - Given all the possible interactions with other parameters and factors likely to influence the exposure other than the NiSO4 content (LEV, etc.) •if no safe level determined, particular attention would have to be paid on the existence of alternatives	

4.2.1.4 Conclusion of the restriction option analysis

As regards the suitability of the REACH restriction in achieving the objectives of the risk reduction strategy stated in section 3.6.2:

- As an alternative to the workplace legislation previously discussed, a restriction could also propose a European binding limit value of 0.01 mg Ni/m^3 for the occupational inhalation exposure to $NiSO_4$. However, some difficulties might be encountered due to possible overlap with existing occupational legislation (OEL related Directives) and to some extent also to the SCOEL's remit. This limit value would apply to all the uses and manufacturing processes of $NiSO_4$, without distinction, and would logically cover all other nickel compounds considering that this value has been recommended by the SCOEL for all nickel compounds excluding nickel metal.
- For the purpose of keeping occupational exposure below this limit value, a restriction could require the use of a specific respiratory protective equipment with a minimum assigned protection factor (APF) when necessary (i.e. for GES where RCR above 1 have been estimated based on the available data in the registration dossiers, see table 46) and where other priority equipments have been implemented and appear still insufficient. Considering that Directive 86/656/EEC on personal protective equipments only provides a global recommendation on PPE implementation at work, no overlap is expected since this restriction would be fitted to the case of $NiSO_4$ in specific processes and may and could be partly based on this Directive too. But a certain degree of technical infeasibility could appear in trying to determine which specific RPE and associated APF in combination for one specific (or some targeted) workstation or task. Failing that, requiring a RPE with a minimum APF for a whole use/process (an entire GES) may be seen not proportional if only one step of the process/use is considered at risk. Finally the question of the acceptance to manage an occupational risk due to inhalation exposure by requiring for one or several workstations a RPE is still open, especially when the task duration exceeds a certain time, even when other practical means (like fully enclosed or automated systems) are not technically implementable and without cost consideration
- Otherwise, a restriction could require the use of fully enclosed or automated systems to limit/avoid workers' exposure, but there are still some doubts about the possibility of a restriction under REACH to practically impose it (see previous tables), as it is also the case for the RPE requirement above. Additionally, automation might not be technically feasible for every CES identified as at risk.
- When reducing the exposure to $NiSO_4$ could in principle be achieved by limiting the $NiSO_4$ content/concentration (or migration) in the exposing material, real technical and scientific difficulties might be encountered in defining a safe level of content/migration for all or each type of exposing material. Indeed the real inhalation exposure of a worker is not directly correlated to the content/concentration of the item but conditioned to several other and unstable parameters (local exhaust ventilation, distance with the item, use of chelating agents, etc.).
- Finally, the possibility of restricting one entire use of $NiSO_4$ when only one CES is estimated at risk might not be proportionate.

As regards the practical elaboration of a REACH restriction proposal in order to address the risks targeted herein:

- Some uses identified as at risk and for which possibilities of substitution seem to exist (e.g. the decorative applications) could in principle be targeted and subject to a restriction proposal. However, some doubts remain as to the actual possibility for the dossier submitter to demonstrate an unacceptable risk given the significant uncertainties surrounding the data provided in the registration dossiers on the exposure assessments and thus in the reliability of the risk characterisation. This is actually the case for all the uses described herein. Identifying the uses eligible to a restriction proposal could be alternatively to target the uses for which protection measures are feasible and expected to be implemented. Nonetheless, reliable information on this issue is again difficult to get.

- In the current state of incomplete information on exposures and substitution, selecting and targeting a restriction would require to discriminate to some extent arbitrarily between the uses considered as the most "at risk" and the others, which is not easy for the time being.
- Commonly to all GES, a scope issue can be expected linked to the complexity of defining the workstations and tasks of concern in clear and generic terms applicable and understandable by all market actors and authorities. However, experience has demonstrated that an unclear restriction scope might hinder its implementability and enforceability and increases its chance of not being supported by RAC and SEAC and not adopted by COM
- Given the timescale scheduled by ECHA for a restriction proposal, from the elaboration for the Annex XV dossier to the COM decision, the risks targeted herein could be only addressed within at least 27 months, such as explained above.

Overall, a restriction under REACH could be a possible management option to address the risks generated by the manufacturing and uses of $NiSO_4$. However, given the difficulties and uncertainties related to its practical feasibility and relevancy, some reservation is expressed that it might not be the best option.

Prior to the submission of a restriction proposal, a good way to proceed could be to get or generate additional information related to the exposures in order to mitigate as much as possible the uncertainties surrounding the data provided in the $NiSO_4$ registration dossiers and have a better picture of the risk characterisation. Three options could be then envisaged to solve these uncertainties and further consider the restriction as a possible tool:

- Performing first a substance evaluation under REACH in order to clarify the raised concerns. As expressed here below, this formal procedure is expected to last at least 3 years
- Refining the risk assessment by modeling the exposure with a Tier II approach based on the current information, would it be sufficient.
- Gathering additional and relevant exposure data from external sources (Member States, occupational health organizations surveys, national inspections, etc.) in order to refine the risk characterization; such information gathering could be targeted on the $NiSO_4$ applications or manufacturing processes considered of priority (highest volumes used, high number of exposed workers, uses known at risk and thus already covered by specific surveys, etc.). However this proposal already raise the following possible drawbacks: the work is anticipated time/resource-consuming for the dossier submitter, without certainty on the possibility to efficiently conclude on an unacceptable risk; the availability of the expected data is not known and such data might not suit the current detail level of the registration dossiers (i.e. exposure assessment per sub-scenario), thus not allowing a precise risk characterization, complementary to the available data from the registration dossier; considering the current available on-site monitoring programs and their outcomes, data collected are not substance-specific but cover all used nickel compounds at the site without distinction. Hence, the scope should

be revised to cover several nickel compounds. The same problem goes for the lack of robust data and in-depth analysis of substitution. REACH does not allow getting such detailed information because it does not require information on substitutes to industry from the very first step of the CSRs provided in registration dossiers.

4.2.2 REACH Annex XIV - Authorisation

The Authorisation component of REACH is intended to assure that the risks from SVHC are properly controlled and that these substances are progressively replaced by by less hazardous or safe substances. Contrary to a restriction, the authorisation doesn’t distinguishing between uses. All uses of a substance are indeed covered by the authorisation obligation, except the substance’s manufacturing, the uses considered as intermediates and in case there are grounds for specific exemptions (e.g. substance only used in scientific research and development “product and process orientated research and development” - PPORD).

For any substances listed on the Annex XIV of REACH, its continued use, beyond an agreed sunset date, will only be allowed if an authorisation for a specific use has been applied for, has been scrutinized by the ECHA committees and finally granted by the European Commission, or if the use is exempted from authorisation requirements.

4.2.2.1 Authorisation prerequisites

A prerequisite for a substance to be included on the Annex XIV of REACH is to be identified as a SVHC (substance of very high concern). Due to its harmonized classification under Annex VI of the CLP as a carcinogenic, mutagenic and reprotoxic substance, $NiSO_4$ could be de facto identified as SVHC under article 57(a,b,c) of REACH and thus included in the candidate list. An additional SVHC identification under article 57(f) as an equivalent of concern, due to its skin sensitizing property, is not considered relevant given that skin sensitizers are not yet of priority for 57(f) identification. SVHC identification under article 57(d,e) is also not foreseen since metals are not relevant substances from PBT identification. For the time being, no nickel compound is already included in the candidate list.

Contrary to a restriction that is eligible when a risk is demonstrated, the prioritisation for inclusion in the Annex XIV from the candidate list is not risk-based. Priority is driven by several criteria that are set by Article 58 of REACH and implemented by ECHA following a methodology that has been agreed by the Member State Committee. Once on the candidate list and due to its high aggregated tonnages used within the EU (over [confidential] reported by the Nickel Institute and from which [confidential] are considered non-intermediate uses; between 33,775 and 55,149 t/y from other sources), $NiSO_4$ would most probably be prioritised in ECHA recommendation list for inclusion in Annex XIV; however for consistency reason, inclusion in the Annex XIV may have to be delayed once other nickel compounds that may be substituted for a same use will be included in the candidate list first, in order to allow a potential grouping approach for the recommendation step. This grouping is however not mandatory and a sole nickel compound can be included in the Annex XIV.

Based on the SVHC Roadmap Relevance Assessment Support Tool provided to Member States by ECHA in 2013, $NiSO_4$ meets all the SVHC Roadmap 2020 criteria (see Table 51). $NiSO_4$ is a substance that could be regarded as relevant under the SVHC roadmap.

Table 51. Fulfilment of SVHC Roadmap 2020 criteria for $NiSO_4$

	Yes	No
a) Art 57 criteria fulfilled?	×	
b) Registrations in accordance with Article 10?	×	
c) Registrations include uses within scope of authorisation?	×	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	×	

In terms of timing, a REACH Annex XIV listing depends on the timing of two successive processes, the first being the substance SVHC identification and the candidate listing and the second being the substance recommendation process for inclusion in REACH Annex XIV. Once the Annex XV-SVHC dossier is submitted, the inclusion of a substance into the candidate list is rather quick (one year at the maximum, especially for a CMR substance). The Annex XIV listing is dependent of several criteria (the 'recommendation criteria'); the time needed may greatly vary according to the substance and cannot be anticipated.

4.2.2.2 Efficiency, advantages and drawbacks of the authorisation route

The threshold nature of the $NiSO_4$ adverse effects (for all carcinogenic, mutagenic and reprotoxic properties – indirect genotoxicity) means that authorisation could be granted either via the adequate control route either via the socio-economic analysis route. In the first case, authorisation may be granted if the risk is considered as adequately controlled and if no suitable alternatives are available. These considerations are subjected to the expertise of RAC for the Commission decision. In the second case, although the risk might not be adequately controlled, authorisation may be granted if the applicant demonstrates that the socio-economic benefits from the continued use of the substance he applies for outweigh the risks to human health and if there are no suitable alternative substances or technologies. These considerations are subjected to the expertise of SEAC for the Commission decision. It is not yet possible to anticipate which route would be preferably chosen by the applicants as regards the uses of $NiSO_4$ considering the complexity and the number of uses reported.

Generally speaking, the authorisation process shows some advantages over the restriction process:

- Except when the socioeconomic route is chosen by the applicant, an authorisation is granted only when the risk is clearly controlled; the appropriateness of the proposed risk management measures is evaluated and it may be imposed some additional or alternative conditions to the granting; the applicant should address use and supply chain specific risk management measures which would be assessed too.
- In principle, the application for authorisation would require a better documented and clearer risk assessment of the use applied for, since the applicant has an incentive to demonstrate that its risk is adequately controlled.
- Given the complexity of the processes at stake, the applicants may have the highest capacity to obtain and share the information needed to build a robust analysis of exposures as well as alternatives.

- The total substitution of the hazardous substance of concern remains the final goal of the process, which is beneficial from a sanitary and environmental standpoint; indeed since getting an authorisation is expensive and always temporary, authorisation is a relevant tool for substitution and therefore a helpful mechanism to ensure workers protection.
- The authorisation process keeps the burden of proof to the applicants, which reduces the workload of the authorities and ECHA, but increases the applicants' costs.

However, the authorisation process may also have some limits:

- Authorisation (all uses covered) might not be considered as proportionate if only one or some uses are actually sources of risk.
- The data provided by the applicants in an application for authorisation might be difficult to check and challenge by the ECHA Committees, the other stakeholders (during the public consultation) and the European Commission; there is an information asymmetry in favour of the applicants which could stand for a hindrance to assess the reliability of the information disclosed. Whatever the route ("socio-economic" or "controlled risk") chosen by the applicant is, it would be difficult to verify the robustness of certain data owned by the industry. Furthermore, it would be difficult or even impossible to produce alternative, more robust, datasets, for confidential aspects of the production processes. The time available for ECHA to check the dossiers submitted by the industry is short and the applications for authorisation scheduled for the next years numerous, which stand for other limitations to a careful evaluation of data quality.
- The timescale might be long between the decision from a dossier submitter to propose an annex SVHC identification, the Commission decision to include the substance in annex XIV and the sunset date from which the non-use is efficient. Meanwhile, risk remains.
- The substance's manufacturing is not part of the scope of the authorisation[30]; therefore any occupational risk arising from manufacturing cannot be covered by the authorisation route; from table 46, the manufacture of $NiSO_4$ is estimated at risk.
- The intermediate uses are exempted from authorisation requirements; therefore any occupational risk arising from intermediate uses cannot be covered by the authorisation route.

4.2.2.3 Analysis of the authorisation option for each use of nickel sulphate

The potential assets and drawbacks of subjecting the uses of $NiSO_4$ to REACH authorisation are discussed below in relation to each identified use.

The Nickel Institute has drafted socioeconomic analysis (SEA) reports for several uses in the economic sectors considered of high interest for the nickel industry in order to assess the possibility that an application for authorisation could be granted in the case $NiSO_4$ would be included in Annex XIV. These reports are based on the SEA route; the SEA consists in an analytical approach describing and assessing all relevant impacts (i.e. both

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[30] However beyond the synthesis step, a manufacturing process contains various additional steps/activities that are not the specific chemical reaction/synthesis and could in theory fall under the scope of the authorization (storage, transfer, cleaning, packaging, etc.). but this is not yet clarified under REACH and cannot be used in this RMOA.

positive and negative) of granting compared to refusing an authorisation. The purpose is indeed to document whether the socio-economic benefits of the continued use of a substance (such as $NiSO_4$) outweigh the risks for human health and the environment of this continued use. The impacts can be qualitatively evaluated or (when possible) quantitatively valued.

Information collected from those SEA reports provides a technical basis and starting point for subsequent discussion on decision-making within the REACH framework. Within the framework of this RMOA, this type of information gives some insight of the economic orders of magnitude at stake. Indeed any application for an authorisation is expected to be submitted to ECHA in a similar form and content. Again such information has not been peer-reviewed and challenged and has to be considered as Industry's view only. SEA reports have been provided not for all uses identified herein but only for some of them. When provided, the socio-economic data available are summarized below.

Nickel sulphate production

Uses covering the manufacture of the substance are exempted from the authorisation. Therefore authorisation is not relevant to manage the risk identified in each provided exposure scenarios for $NiSO_4$ manufacturing.

Industry didn't carry out any SEA for the same reason.

Use in metal surface treatments

Eligibility under authorisation (volumes covered)

Industry considers the use in surface treatment as an intermediate use given that the used substance is transformed in another substance (nickel metal) by the plating processes. On the opposite, surface treatment is specifically identified in ECHA's Guidance on Intermediates as not fulfilling the criteria as an intermediate chemical use and therefore would not be exempted from the authorisation process. In this way the authorisation under REACH may address the risks related to surface treatments and put pressure for substitution. The eligible tonnage of $NiSO_4$ is ~12,000 t/y. A high number of workers exposed to $NiSO_4$ is expected but not known as many SMEs are involved in this process with many various RMMs implemented and using also other nickel compounds.

Analysis of alternatives: substitutability

From the provided analysis of alternatives in section 2, the Nickel Institute considers that few alternatives/substitutes already exist for limited uses or are still in development and could be released at short or medium term.

The increasing use of nickel plating solutions as the best available substitute to cadmium and chromate plating that are being restricted under REACH and other regulations (RoHS, ELV, etc.) is not an argument in favour of the authorisation proportionality and its final objective (substitution). R&D is still ongoing on these applications and three or four years are still considered necessary according to Industry to achieve a substitution in some applications only.

Substitution would be expected possible in activity sectors such as decorative purposes, bathroom fittings, some corrosion treatments in the automobile sector, etc. Some alternatives already exist and may be implemented once the remaining technical barriers will be removed. However some alternatives will not provide the same efficiency and result final shape, aspect, etc.) as for nickel plating solutions, which may encourage the market to switch through imported articles outside from Europe with nickel treated surfaces. Indeed R&D is still ongoing and the chances of success are not yet known, especially where specifications are constraining and especially about corrosion protection. In this context, the authorisation measure could be envisaged with an appropriate sunset date that should be set based on the real time needed (expected to be) to success the substitution. However authorisation may inevitably bring socio-economical constraints and market loss. It is not known if Industry would apply for authorisation for such uses based on the socioeconomic route.

Substitution may be not available and not expected to be available at short nor medium term in activity sectors where security is a prerequisite (especially in the aerospace and automotive sectors) and may need extended R&D and then testing against specifications which may thus require several years. It is not known yet if the current R&D will be able to solve several tricky issues (especially corrosion protection for both electronic and structural elements) and if solutions will meet the expected standards.

Therefore if the authorisation is way to speed up R&D on $NiSO_4$ substitution in some surface treatment applications, this measure could be premature for other economic sectors (aerospace as an example), particularly where $NiSO_4$ is already used as an alternative to cadmium and chromate plating.

Socio-economic analysis

As far as the socio-economic consequences of a refused authorisation are concerned, two SEA reports have been provided by Industry for the use of $NiSO_4$ in two applications of surface treatment: bathroom fittings and printing rotary screens. These reports provide a assessment of the costs and benefits of a hypothetical refused authorisation (the so-called "non-use scenario").

Plating of bathroom fittings

As regards the SEA report for the plating of bathroom fittings, costs and benefits of a hypothetical refused authorisation have both been assessed.

On one side, the economic impacts for the EU industry in this particular sector are evaluated showing the relocation of manufacturing as the most likely reaction of the market (around 90%-95%). The extra costs associated with relocation are a loss of production value estimated at €29 billion per year and a loss of residual value of production equipment due to premature shutdown (not quantified), likely to be borne by around 2,500 manufacturing enterprises. As regards economic benefits, additional production value within the EU due to alternative products (stainless steel taps and taps with coloured finishes) is expected and estimated between €1billion and €4 billion per year depending on the alternative adopted.

Some wider economic impacts are also assessed in the report provided by Industry, concluding that up to 0.22-0.24% of EU GDP (Gross Domestic Product) may be lost from a net reduction in production value such as valued above. The Italian and German economies would be most affected given their dominance in bathroom fittings production.

As far as the social impacts of a refused authorization are concerned in the plating sector of bathroom fittings, significant impact is expected due to massive relocation with a loss of skills jobs. There might be up to 150,000 jobs at risk, according to Industry in the whole sector. Loss of training within the EU associated with job duties may be expected as well. Nevertheless, some jobs may be also created from production, distribution and marketing of alternatives but not enough to compensate the job losses.

Overall, the analysis of socio-economic impacts in this report is based on the (main) following input data and assumptions: it is reported that around 164 million taps (164,578 thousand units) and around 54 million showerheads (54,859 thousand units) are produced in the EU in 2008; the majority of taps sales (80%) are for bathroom taps; there are 2g of nickel chrome per product; 105 million of units are sold per year; and based on production data, around 373 tonnes of nickel chrome is used per year for showerheads and taps, or 366 tonnes of Ni based 98:2 ratio of nickel and chrome. As already said above, the sector accounts for 2,500 enterprises and 154,740 jobs in the EU (among which workers may be exposed between 30% and 60%). Regarding the alternatives in general no precise data on prices are provided.

It can be noted that the socio-economic impacts assessment for this application has been carried out in a macroeconomic perspective and the detailed expected reaction of each actor of the supply chain as well as distributional impact are not described.

On the other side, the SEA report provides a human health and environmental impacts assessment of a refused authorisation for this specific application. The health benefits are calculated from avoided exposure of workers (lung cancers and dermatitis) and indirect exposure to the general population. According to Industry, between 46,000 and 93,000 workers would no longer be exposed to $NiSO_4$ in the EU and the total corresponding benefit is estimated between €1.2 million per year (best estimate) to €7.2 million per year (worst estimate), mainly attributable to avoided cancers. It has to be noted that reproductive effects in workers and their children are considered unlikely to occur in the report as workplace exposure levels are lower than the worker-specific inhalation DNEL for this endpoint. Avoided releases of nickel to air could also bring a (negligible) benefit for general population of €500 per year (worst-case estimate). Some health costs may also be associated with a refused authorization due to potential increase in workers exposure to a range of substances from production of alternative products in the EU (as above: stainless steel taps and taps with coloured finishes) but they have not been quantified.

Regarding environment, benefits are likely due to avoided releases to wastewater, leading to a potential improvement in surface water status for 100-150 water bodies (subcatchments) across the EU27 and some avoided emissions of greenhouse gases (GHGs) and regional air pollutants in Europe as well as reduction of sludge production due to the shutdown of EU manufacturing sites. These environmental benefits have not been valued however. No effects are forecast via secondary poisoning or for the terrestrial compartment. Furthermore, some environmental costs are also expected due on the one hand, to an increase in CO_2, NO_x and SO_x releases from transportation of bathroom fittings newly imported (estimated at least at €0.9 million per year, including regional pollutant impacts in Europe only) and on the other hand, to (slight) increased release of heavy metals due to the production of alternative products and potential increase in life cycle emissions of products where production transfers outside the EU (not quantified).

The assessment of health impacts is (mainly) based on the incidence rates over working lifetime, value of fatal cancer and the value of working days lost. It is thus somehow rather restrictive and could have also included other indirect costs such as the loss of life quality. The human health impact assessment might thus be underestimated to some extent. The analysis of environmental impacts is based on the damage cost values of the kg Ni emission and external costs for NO_x and SO_2 releases. However, the benefits for water bodies are not quantified and valued.

Table 52 summarizes the results of a refused authorisation for the EU according to industry.

Table 52. Summary of the impacts of a refused authorization according to Industry – Surface treatment – bathroom fittings

	Costs	Benefits
Economic impacts	Manufacturers - Costs>€29 billion per year	• additional production value from alternative products= €1-4 billion per year
Social impacts	Up to 150,000 jobs at risk	Jobs creation < 150,000
Health impacts	Increase exposure from alternative products: cost>0	• 46,000-93,000 workers no longer exposed: Benefit= €1.2-7.2 million/y • Avoided releases of Ni to air : Benefit= €500/y
Environmental impacts	•increase in GHGs due to new imports: cost> €0.9 million/y •slight increase release of heavy metals from alternative products: cost>0 •potential increase in life cycle emissions (production transfers): cost>0	•100-150 water bodies status improved: Benefit>0 •avoided releases of GHGs: Benefit>0 •avoided sludge production: Benefit>0
Wider economic impacts	up to 0.22-0.24% of EU GDP (Gross Domestic Product) may be lost from a net reduction in production value	/

The report concludes that the costs would largely outweigh the benefits. It has to be highlighted that these figures have not been challenged and are surrounded with many uncertainties. They thus have to be read with high precaution. The costs might be overestimated since they are calculated taking into consideration relocation as the main (though not the sole) reaction of the market. The benefits may be underestimated. This situation may be considered to some extent as a worst case scenario.

Plating of printing rotary screens

As regards the SEA report for the plating of printing rotary screens, costs and benefits of a hypothetical refused authorisation have been assessed in a similar way. However, the results are only presented herein in a qualitative way since they are considered as confidential due to the monopolistic production of these products in the EU.

On one side, the economic impacts for the EU industry of the plating of printing rotary screens (one single manufacturer) are evaluated showing the relocation of manufacturing as the most likely reaction of the producer. He is expected to lose his sales revenue as well as a residual value of his production equipment due to premature shutdown. No cost related to alternatives is evaluated since substitution is not claimed to be likely. For the consumers, a consequent increase in price is expected due to newly imported screens into the EU (due to transportation and administrative costs associated to imports). No significant economic benefits of a refused authorisation have been identified by Industry.

As far as the social impacts of a refused authorization are concerned in the plating sector for printing rotary screens, significant impact is expected due to relocation of the entire market. A certain amount of jobs are considered as at risk depending on whether other activities such as distribution, R&D sales, marketing and services are also lost to outside the EU. According to Industry, there would also be a loss of skills and training within the EU associated to job duties. No significant social benefits have been identified by Industry.

On the other side, the SEA report provides a human health and environmental impacts assessment of a refused authorisation for this specific application. The health benefits are due to avoided exposure of workers (lung cancers and dermatitis) as well as (negligible) avoided exposure to general population. The assessment of health impacts is (mainly) based on the incidence rates over working lifetime, value of fatal cancer and the value of working days lost. It has to be noted that reproductive effects in workers and their children are considered unlikely to occur in the report as workplace exposure levels are lower than the worker-specific inhalation DNEL for this endpoint. Like for bathroom fittings, the analysis can thus be somehow considered as restrictive and could have also included other indirect costs such as the loss of life quality. The human health impact assessment might thus be underestimated.

The positive impacts for environment are expected to benefit to wastewater, air from cyclones and sludge production but are estimated -qualitatively- to be negligible. The environmental cost of relocation, due to higher transport releases of GHGs (due to new imports) from outside the EU, is also analysed. The environmental impacts have not been valued but expressed in physical quantities only.

It is reported that the sector counts for about 750 jobs among which 160 workers may be exposed. [confidential] rotary screens are sold per year to between [confidential] customers worldwide.

Table 53 summarizes the results of a refused authorisation for the EU according to industry.

Table 53. Summary of the impacts of a refused authorization according to Industry – Surface treatment – rotary screens (only qualitatively presented)

	Costs	Benefits
Economic impacts	<u>Manufacturer</u> • Loss of sales revenue • Loss of residual value of production equipment <u>Consumers</u> • Increased price	/
Social impacts	Loss of jobs Loss of skills and training	/
Health impacts	/	• workers no longer exposed • public health benefit
Environmental impacts	•increase in GHGs	•avoided releases to wastewater •avoided releases to air from cyclones •avoided sludge production

The report concludes that the costs would largely outweigh the benefits. However, this assessment has not been challenged and is surrounded with some uncertainty such as raised above. It thus has to be considered with high precaution.

<u>Use in batteries manufacturing</u>

Eligibility under authorisation (volumes covered)

The use of $NiSO_4$ in manufacturing the positive electrode of batteries has to be considered as an intermediate use and will therefore be exempted from the authorisation. The respective known volume used is [confidential] tones per year. This argument in itself is sufficient to conclude that authorisation is not the relevant option to control the risk estimated for this use.

Over the [confidential] tones used for batteries manufacturing, approximately 1% (~[confidential] t/y) is added to the cadmium electrode (anode) of the NiCd batteries; this use is not considered as an intermediate use and would thus be covered by the authorisation. However no risk has been currently estimated so far for this contributing exposure scenario and therefore no risk management measure is needed.

The $NiSO_4$ volume used for the preparation of the electroplating baths is around [confidential]. Industry stipulates that exposure and risk of metal surface treatments within battery manufacturing are similar to other metal surface processes and should be covered by the GES 4 (see table 4). A risk could thus be estimated for this contributing exposure scenario and would be covered by the authorisation.

Analysis of alternatives: substitutability

From the provided analysis of alternatives (see section 2), the registrant indicates that there are a number of possible alternatives on a case by case basis that are however considered not currently suitable for all applications when considering technical and economic feasibility in the various markets in which the registrants operate. In the replacement battery market, preference would indeed be given to Ni-based cells for the simple reason that it is not yet practicable to fit other batteries either on grounds of space, or compatibility with supporting circuitry. Lifespan of current engines equipped with batteries may reach up to 30 years (trains, planes, etc...) and will probably still need Ni-based batteries for maintenance over such a period of time. Without cost consideration however, a switch to available alternatives the Li-ion alternative is considered technically possible when designing new equipments. Ni based batteries may remain the preferred choice of industrial markets because of its experienced reliability.

Socio-economic analysis

A SEA report has been provided by Industry for this use. Costs and benefits of a hypothetical refused authorisation have been assessed, similarly to the other SEA reports mentioned above for the use of $NiSO_4$ in surface treatment. However, the results are only presented herein in a qualitative way since they are claimed to be confidential by Industry.

On one side, the economic costs for the EU industry in the pocket plate battery sector are evaluated showing the relocation of EU manufacturing sites as the most likely reaction of the market. These impacts are assessed for the major manufacturer and its (comparatively very minor) competitors as well as for end-users. The EU producers of pocket plate batteries are expected to lose their EU sales revenue and residual value of building due to the premature shutdown of their EU manufacturing sites as well as to face to some extent also a (small) administrative burden for the new imports of PP technology into the EU as ‘articles’. According to Industry however, the loss of residual value of building may be somehow mitigated since some pocket plate production equipment may be re-used in plants being relocated outside the EU. As regards the end-users, their expected reaction in stationary applications as well as railways markets is extensively elaborated in the SEA report, in order to take into account the different possible transfers of demand from pocket plate batteries to alternative batteries in short and long-term. Those who would switch to lead-acid batteries are likely to bear some additional costs associated with increased lifecycle cost of these alternatives (due to their reduced durability compared to pocket plate) whereas those who would purchase newly imported PP batteries would have to pay probable increased price.

Economic benefits are also assessed in the SEA report as a result of a refused authorisation, attributable to some increase in sales revenue in the EU for the producers of alternatives who would capture a share of the demand (assuming that alternative battery producers are located in the EU).

As a whole, a net cost to the EU is estimated between €1.6bn and €2bn (NPV[31]) over a 20 years period. This excludes the cost of maintenance and retrofitting and any price premium EU customers may have to pay for imported batteries into the EU. This number also excludes the cost to the producer of expanding existing non EU based manufacturing infrastructure.

As far as the social impacts of a refused authorization are concerned, loss of jobs is expected in the EU from the closure of battery production sites using pocket plate technology, as well as the loss of job training and skills for EU workers. These losses (up to 1,150 jobs) may however be offset if productions of any alternative batteries being newly purchased are located in the EU.

Overall, the analysis of socio-economic impacts of pocket plate battery sector is based on the (main) following input data and assumptions: the value of pocket plate batteries sales is estimated between € [confidential] per year; the number of suppliers is over 435 (standing for € [confidential] of sales value). As already said above, the pocket plate battery sector in the EU accounts for about 1000 workers, among which 20 may be exposed to $NiSO_4$. Regarding the alternatives in general no precise data on prices are provided.

On the other side, the SEA report on batteries provides a human health and environmental impacts assessment of a refused authorisation. The health benefits of a refused authorisation are due to avoided exposure of workers (lung cancers and dermatitis) and (marginal) indirect exposure to the general population. The health benefits associated to these avoided exposures are valued but are small, compared to the economic negative impacts mentioned above. The analysis of health impacts is based on (among others) the value of fatal cancer, the value of working days lost and the damage cost values of the kg Ni emission. Although a quantitative assessment is carried out to value health benefits of a refused authorisation (in the range from €312 to €84,000 per year), the report states that this would be a worst case and finally concludes that there is no evidence to suggest a significant change in risks of respiratory cancer or lung damage to workers directly involved in the $NiSO_4$ areas during battery production (this statement is however challenged, see below). It is yet stated that there could be a reduction or elimination of the low level incidence of dermatitis predicted for use of $NiSO_4$ in battery production. This conclusion is however not further justified. It has to be noted also that the health benefits associated to the toxicity of $NiSO_4$ for reproduction and development are considered to be unlikely to occur in the report as workplace exposure levels are lower than the worker-specific inhalation DNEL for this endpoint and are thus estimated to be zero. As a whole, like the SEA performed for the applications of surface treatment such as presented above, this assessment is somehow restrictive and might be underestimated since there is a systematic use of the value of statistical life and other indirect costs such as the loss of life quality could have been also included.

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[31] Net present value

As far as the health impact assessment related with the use of alternative batteries, the SEA reports that there are similar levels of risk associated with worker exposure for lead-acid battery production although these risks are well controlled, as for Ni and Cd in current production techniques. Likewise, there may be identical risks associated with worker exposure for nickel nitrate using sintered technology for nickel batteries although these risks are well controlled according to Industry. This statement assumes that nickel nitrate would not be subjected to authorisation, which is considered unlikely in the event that $NiSO_4$ could prioritized for inclusion on Annex XIV of REACH together with other nickel compounds in a grouping approach. Furthermore, some extra health adverse effects might occur due to the use of lead-acid batteries associated with their climate impacts and higher GHGs emissions. As a whole, the report concludes that although the use of alternative battery technologies may result in the substitution of $NiSO_4$ with chemicals with less hazardous classification, given levels of $NiSO_4$ exposure are below the considered safe level (namely the DNEL), it is unlikely in practice that there would be an overall reduction in risk. It has to be noted that this benefits assessment is made based on an inappropriate DNEL and should be updated considering the appropriate DNEL of 0,01 mg Ni/m^3 for which occupational risks are estimated and therefore much higher benefits would be expected.

Regarding the environmental impacts, some benefits and costs are analyzed in the report provided by industry. On the one hand, no significant environmental benefits (close to zero) are expected. This conclusion is grounded on the fact that environmental concentrations of Ni are below the WFD EQS and that solid wastes generated from manufacturing are subject to internal recycling. As a consequence, it is considered that there is no evidence that the use of alternative technologies would result in a significant reduction in environmental impact and thus in significant benefits. On the other hand, some costs are possible due to reduced supply of recycled Ni from a reduction in the volume of Ni batteries in circulation and some others due to expected increase in resources and energy consumption from the use of lead-acid batteries (which are less durable) as well as higher emissions and waste. Moreover, the damages associated to potential increase in NOx and SO2 emissions from transportation of batteries newly imported are uncertain and considered as small. However, these costs are not considered as significant. As a result of his assessment, the report concludes that the overall environmental benefits of a refused authorisation would be close to zero. It may be noted that the argumentation grounding this conclusion is rather brief.

Table 54 summarizes the results of a refused authorisation for the EU according to industry.

Table 54. Summary of the impacts of a refused authorization according to Industry – Surface treatment – pocket plate batteries (only qualitatively presented)

	Costs	Benefits
Economic impacts	Manufacturer • Loss of sales revenue • Loss of residual value of building • Administrative burden from imports End-users • Increased price from imports • Increased lifecycle cost from alternatives Total: €1.6bn and €2bn (NPV) over a 20 years period	• increase in sales revenue for EU alternative manufacturers /
Social impacts	• Loss of jobs • Loss of skills and training Up to 1,150 jobs	New jobs and skills in alternatives markets
Health impacts	• Similar levels of risk from lead acid battery • Identical risks from Ni nitrate sintered battery • Additional NOx and SO2 emissions (uncertain)	• no significant benefit (€312 to €84,000 per year)
Environmental impacts	•(small) increase in GHGs due to new imports •(possible) reduced supply of recycled Ni •increase energy and resources consumption due to alternatives+higher emissions and waste	• no significant benefit (close to zero)

The report concludes that the costs would largely outweigh the benefits. However, this assessment has not been challenged, is surrounded with high uncertainty and has been carried out on an inappropriate DNEL which largely underestimates the expected health benefits. It thus has to be read with high precaution.

Use in other nickel salts production

Several nickel salts (hydroxide, hydroxycarbonate, chloride, nitrate, ammonium and oxide) are produced from $NiSO_4$. Given that $NiSO_4$ would be used as an intermediate in the involved chemical reactions (but again no information on the detailed processes have been provided by Industry), this use would be exempted from authorisation. The respective known volume used is ~4,800 t/y.

Therefore the authorisation option is not considered relevant in order to adequately manage the risk estimated from nickel salt production from $NiSO_4$.

No socio-economic data have been provided for this use.

Conclusion

Feasibility

Authorisation is based on a hazard (substance identified with a very high concern) and a probable exposure and would therefore be better suited than the restriction given the current difficulty to demonstrate an unacceptable risk based on the available information; authorisation is technically feasible as $NiSO_4$ can be easily identified as an SVHC (given its current CLP classifications) and would be prioritized for annex XIV listing regarding the volumes used and the diversity of uses.

However authorisation doesn't cover the substance's manufacturing and its uses as intermediate that are exempted and would thus not allow controlling the associated risks. Authorisation may only cover the metal treatment uses and a very minor part of the battery manufacturing. In term of volumes (which is not the best criteria to illustrate this issue compared to the number of workers of concern, that is not known), authorisation will cover less than half of the used tonnage.

Ability to achieve the objective set by the risk reduction strategy

By phasing out uses and promoting substitution of $NiSO_4$, and by then only authorising uses for which risk is demonstrated controlled or for which socio-economic benefits outweigh the human health risks, authorisation indirectly fulfils but also exceeds the objective of the risk reduction strategy. Indeed authorisation plays on a different scale than the control of occupational exposure.

Proportionality

Authorisation applies to all uses without distinction. From table 46, all uses (GES) of $NiSO_4$ are currently estimated at risk which may support the authorisation in term of proportionality. However most GES are seen to be at risk based on one or two deficient CES, almost always the cleaning and maintenance step that requires handlings and sometimes the reception step of the raw material (for 3 GES over 11); in that the proportionality of the authorisation may be questioned since other targeted risk management options (restriction, binding OEL, etc. or at least process' improvements) could potentially be sufficient to lower exposure below the DNEL.

By largely exceeding the objectives stated in risk reduction strategy, authorisation may also be seen as disproportionate in term of level of risk management implemented.

Authorisation aims at speeding up the substitution when this is expected possible. A reasonable approach could then be to recommend authorisation for the uses where substitutes exist or where R&D might identify safer and suitable alternatives on the short or medium term. However, as already explained, authorisation cannot be targeted on specific uses but concerns all the uses of one substance, which in the case of NiSO4 might make it disproportionate. Moreover, the analysis of alternatives conducted by Industry so far concluded that even if alternative/substitution is already possible or expected soon for several uses or several applications per type of uses, no alternative is expected in metal surface treatment for activity sector where security is required (aerospace, automotive sectors) and where nickel compounds are already implemented as an alternative to cadmium and chromate uses. For these uses, authorisation may possibly fail its objective of promoting substitution.

Cost benefits analysis

From the provided SEAs, no reliable conclusion can be stated on the balance of the costs compared to the benefits given the raised uncertainties but one can anticipate that authorisation would be costly for Industry (cost of the applications, cost of potential not granted authorisations, etc.) and the real benefit (for health and environment in particular) is still not well identified. It could also be noted that the high number of companies involved in nickel surface treatments, especially small and medium companies, with strong economic and technical competition will not facilitate a common approach towards a joint, easier and cheaper application for an authorisation; therefore, many small companies could be left out of possible applications.

Regarding the administrative burden, authorisation is a simpler risk management tool than restriction has it has not to be targeted nor scoped and the risk has not to be demonstrated by the dossier submitter; as already stated, the burden of proof and the "costs" are kept on applicants. Nonetheless once the sunset date will be reached, authorisation may lead to a significant administrative burden to manage the applications for authorisation; indeed as regards the provided SEA, applications for authorisation are already intended and should be awaited for several uses of $NiSO_4$.

5 CONCLUSIONS ON THE MOST APPROPRIATE (COMBINATION OF) RISK MANAGEMENT OPTION(S)

Nickel sulphate is manufactured by three different routes (from copper refining, from solvent extraction of $NiSO_4$ leachate and from crystallisation of a purified $NiSO_4$ leachate) and used in 5 main uses: metal surface treatments (covering 4 specific applications), batteries manufacturing, production of other nickel salts / nickel metal powder and manufacturing of micronutrient additives for biogas production.

From an in depth Industry consultation by Anses in which the Nickel Institute was the main contact point, several technical documents and three socioeconomic analysis (SEA) focused on the two main $NiSO_4$ activity sectors (metal surface treatment and batteries manufacturing) have been provided by Industry and used in this RMOA to clarify the uses, the volumes manufactured and used, the intermediate status of the uses, the alternatives, the socio-economic impacts of a non-use scenario in the case of a ban of the substance's uses. A clear picture of the volumes used is not available despite the consultation of Industry; the available data identified from different sources are not fully consistent together. The aggregated volumes provided by the Nickel Institute have been used for the purpose of this RMOA and, even if possibly not fully relevant, are considered to be enough to properly carry out the RMO exercise. The elements used so far from the provided SEAs have not been challenged and it shall be noted that a socio-economic analysis carried out by a MSCA (for instance in the framework of a restriction) could lead to a different analysis and conclusion.

A European risk assessment on $NiSO_4$ has been carried out by Denmark and published in 2008. For the purpose of the RMOA, a new risk assessment has been carried out by FR MSCA based on the data provided in the registration dossiers and targeted on the occupational risk only (dermal and inhalation exposure), as EU RAR concluded on no risk for consumers. No definitive conclusion can be drawn on the occupational risk because of the high level of uncertainty associated with the exposure estimates and data provided (either modelled either measured) making difficult the interpretation of the risk assessment results. The substance evaluation process under REACH should allow to answer the raised concerns on the exposure data quality and to allow the registrants to update their chemical safety assessment with the appropriate DNEL. This process may have the ability to gather information on exposure. However the timeline of such evaluation (around 2-3 years) that would also consider other nickel compounds in a grouping approach may not be acceptable regarding the potential risk raised.

For the purpose of the RMOA, this non-conclusive situation has been overstepped and a level of risk (acceptable/unacceptable) has been estimated beyond those uncertainties. Based on the considered appropriate DNEL by FR MSCA (0,01 mg $NiSO_4/m^3$) which differs from the registrants' DNEL ([confidential] mg $NiSO_4/m^3$) and the data provided in the registration dossiers, risk might be not controlled for all the 11 GES. The minimum objective of a risk reduction strategy (RRS) would be to formally set a binding inhalable occupational exposure limit of 0,01 mg $NiSO_4/m^3$ and to keep exposure below this limit at the workplace. A more ambitious RRS is not excluded (i.e. ban of uses considered to be at risk, substitution where possible and feasible, etc.) but a full substitution of $NiSO_4$ for each reported use is not seen as a relevant objective for the time being since substitutes are not available or technically/economically feasible today for all the uses and applications of $NiSO_4$.

Some evidence exists that feasible alternatives are already available or expected in a short timeframe for some applications which may generate a significant change of the market and possible loss of benefit for Industry at short term (see the summary table below for the sectors for which data have been provided). However two activity sectors of importance (aerospace and automotive) may not find any suitable alternative even in a long term in specific applications of metal surface treatment where the safety of persons and assets is at stake.

Table 55. The substitution possibilities per activity sector according to Industry

Activity sector	**Substitution possibility**
Aerospace	Very low possibility
Automotive	Low possibility (*very low* for security property and *possibility* for not security-related properties)
Decorative coatings	Possibility
Rotary screens	Impossibility
NiCd batteries (pocket plate)	Low possibility for the maintenance of engines; possibility when designing new engines

From the currently identified legislation covering directly or indirectly the risk from the manufacturing and uses of $NiSO_4$, three risk management options have been considered relevant for further processing: a binding OEL under Directive 2004/37/EC that is out of REACH scope and the restriction and the authorisation routes under REACH. Those options have been scrutinized against the objectives of the RMOA: feasibility, ability to achieve the expected risk reduction objectives, clarity of the obligations, proportionality, balance between the costs and the benefits, timing, consistency and acceptability.

An attempt to synthesize the main RMOA outcome is presented in Tables 56 and 57 which however don't intend to replace the more detailed analysis provided in section 4 of this document. Each option has indeed a different impact, mode of action, scope and target and a comparison based on simple drivers / criteria is not self-standing to conclude. Moreover different conclusions on the best option could be derived use by use considering that the situation (existing alternatives, importance of the use, cost/benefit analysis, etc.) varies from one use to another and may also be unknown. Overall, no single option is yet clearly identified as the best relevant option and a combination of several options could also be envisaged.

Table 56. Comparative assessment of the selected risk management options

	Directive 2004/37/EC (workplace EU legislation)	**Authorisation under REACH**	**Restriction under REACH**
Time period to achieve the objective	Short term (Directive update scheduled in 2015)	Medium-long term (5 to 10 years)	Short-medium term
Consistency towards the Risk Reduction Strategy (1) **RRS=worker exposure < 0.01 mg/m^3**	Well fitted	Oversized	Possibly fitted
Ability to achieve the RRS(1)	Yes	Yes	Possibly if OEL would be accepted as a possible restriction proposal (overlapping with the workplace legislation)
Proportionality towards the RRS(1)	Proportionate	Possibly disproportionate	Possibly proportionate
Clarity of the obligations imposed on the operators	Clear regarding the OEL objective (RMM left to the operators ; obligation of results)	Clear (i.e. substitution/socio-economic route/adequate control route)	Depending on the conditions and scope (not yet identified)
Balance of the costs compared to the benefits of the reduced risks, cost- (for Industry)	Balanced	Potentially unbalanced	Possibly balanced (depending on the conditions and scope)
Technical feasibility for the operators	Expected feasible	Substitution: possible for a limited number of applications Application for an authorisation: feasible	Depending on the conditions and scope (not yet identified)
Acceptability for the operators	Expected well accepted	Expected not accepted	Expected accepted
Technical feasibility for the MSCA	Feasible	Feasible	Expected difficult (definition of scope and demonstration of unacceptable risk)
Overall relevancy at short term	(Significant)	(Limited)	(Limited)

(1): the RRS (Risk Reduction Strategy) is here defined as the minimum proposal, i.e. binding OEL and exposure below the OEL at the workplace (RRS= worker exposure < 0.01 mg/m^3)

Table 57. Comparative assessment of the selected risk management options use by use of $NiSO_4$

Uses (corresponding GES)	Tonnage (t/y)	Interme-diate status	Substitution	Socio-economic benefits of the continued use	OEL relevancy (Directive 2004/37/EC)	Authorisation relevancy	Restriction relevancy[(1)]
Manufacture of $NiSO_4$							
$NiSO_4$ production from copper refining (GES 1)	unclear	n/a	possible	unknown	yes	no	possible
$NiSO_4$ production: solvent extraction of NiSO4 leachate (GES 2)							
Crystallization from a purified $NiSO_4$ leachate (GES 3)							
Downstream uses of $NiSO_4$							
1-1. Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating: rotary screen (GES 4)	12,000	no	possible (short / medium term)	high	yes	yes	possible
1-2. Idem: bathroom fittings (GES 4)			possible	moderate to high		yes	possible
1-3. Idem: automotive/aerospace uses with security requirements (GES 4)			not possible	Expected high		no	possible
1-4. Idem: other uses (decorative), automotive/aerospace uses without security requirements (GES 4)			possible (short term)	Expected moderate		yes	possible
2. Selective plating with $NiSO_4$ (GES 9)			unknown	unknown		unknown	possible
3. Formulation of products for anodized aluminium sheets (GES 10)			unknown	unknown		unknown	possible
4. Metal surface treatment of anodized aluminium sheets (GES 11)			unknown	unknown		unknown	possible
5. Production of batteries (GES 5)	[confidential]	no (except [confidential] t)	low possibility (maintenance); possible (new engines)	high	yes	yes	possible
6. Production of Ni metal powder and Ni salts from $NiSO_4$, including Ni Salts used for catalysts (GES 6)	7,800	yes	possible with other Ni salts	unknown	yes	no	possible
7. Use of $NiSO_4$ in the manufacturing of micronutrient additives for biogas production (GES 7)	unknown	unknown	unknown	unknown	expected yes	unknown	possible
8. Production of Nickel-containing pigments from $NiSO_4$ (one producer) (GES 8)	unknown	unknown	possible with other Ni salts	unknown	expected yes	unknown	possible

(1) The relevancy of the restriction is assessed without considering the raised major issues on the definition of the scope and the difficulty to prove an unacceptable risk based on the available exposure data.

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Appendix 1: List of nickel compounds registered under REACH (last update January 2014)

EC n°	CAS n°	**Name** (synonym)	Registration type(s)
206-761-7	373-02-4	nickel di(acetate)	[confidential]
208-933-7	547-67-1	nickel oxalate	[confidential]
215-215-7	1313-99-1	nickel monoxide	[confidential]
222-102-6	3349-08-4	nickel(2+) propionate	[confidential]
224-699-9	4454-16-4	nickel bis(2-ethylhexanoate)	[confidential]
227-873-2	6018-92-4	trinickel dicitrate	[confidential]
231-111-4	7440-02-0	Nickel *(metal)*	[confidential]
231-743-0	7718-54-9	nickel dichloride	[confidential]
232-104-9	7786-81-4	nickel sulphate	[confidential]
233-071-3	10028-18-9	nickel difluoride	[confidential]
234-454-8	12004-35-2	dialuminium nickel tetraoxide	[confidential]
234-829-6	12035-72-2	trinickel disulphide *(nickel subsulfide)*	[confidential]
235-008-5	12054-48-7	nickel dihydroxide	[confidential]
235-715-9	12607-70-4	[carbonato(2-)]tetrahydroxytrinickel *(nickel hydroxycarbonate)*	[confidential]
236-068-5	13138-45-9	nickel dinitrate	[confidential]
237-396-1	13770-89-3	nickel bis(sulphamidate) *(nickel sulphamate)*	[confidential]
238-032-4	14177-51-6	nickel tungsten tetraoxide	[confidential]
238-034-5	14177-55-0	molybdenum nickel tetraoxide	[confidential]
238-154-8	14264-16-5	bis(triphenylphosphine)nickel(II) chloride	[confidential]
240-841-2	16812-54-7	nickel sulphide	[confidential]
242-522-3	18718-11-1	nickel bis(dihydrogen phosphate)	[confidential]
242-533-3	18721-51-2	nickel(2+) hydrogen citrate	[confidential]
245-119-0	22605-92-1	citric acid, nickel salt	[confidential]
252-777-2	35884-66-3	tetrakis(tritolyl phosphite)nickel	[confidential]
273-749-6	69012-50-6	Matte, nickel	[confidential]
275-738-1	71631-15-7	nickel iron chromite black spinel	[confidential]

Appendix 2: Overview of the 2007 RAR conclusions on human health for Nickel sulphate

Main conclusions from the risk assessment

Regarding occupational assessment

Conclusion (i) on hold (there is need for further information and/or testing) is reached because there is a need for further studies to evaluate the possible effects of nickel sulphate on germ cells, but further testing is not considered practicable.

Conclusion (iii) (there is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account) is reached because the risk assessment has shown that for certain endpoints (acute toxicity, respiratory sensitisation, repeated dose toxicity, carcinogenicity, effects on fertility and development) effects on human health cannot be excluded following inhalational exposure for the following scenarios:

Scenario	Acute toxicity		Repeated dose toxicity		Carcinogenicity[1]	Fertility		Developmental toxicity	
			Inhalation – full-shift			Inhalation Full shift		Inhalation Full shift	
	Inhalational Short-term	Respiratory sensitisation	Typical	Worst-case	Inhalation Full shift Typical	Typical	Worst-case	Typical	Worst-case
A1: Production from nickel matte	iii	iii	iii	iii	iii	iii	iii	iii	iii
A2: Production from secondary nickel matte or roasted residues	iii	iii	iii	iii	iii	iii	iii	iii	iii
A3: Other leaching processes	iii	iii	iii	iii	iii	iii	iii	iii	iii
A4: Production from copper refining	iii	iii	iii	iii	iii		iii	iii	iii
A5: Purification of impure nickel sulphate	iii	iii	iii	iii	iii	iii	iii	iii	iii
A6: Production from metallic nickel	iii	iii	iii	iii	iii		iii	iii	iii
B1: Production of metallic nickel	iii	iii	iii	iii	iii		iii	iii	iii
B2: Nickel plating	iii	iii	iii	iii	iii		iii	iii	iii
B3: Production of catalysts	iii	iii	iii	iii	iii		iii		iii
B4: Production of chemicals	iii	iii	iii	iii	iii	ii-iii[2]	iii	ii-iii[2]	iii

1: Includes somatic cell mutagenicity linked to inhalational cancer.

2: The scenario covers an enormous range of processes (see section 4.1.1.2.3.4). Conclusion (ii) applies to some processes.

Conclusion (ii) (there is at present no need for further information and/or testing or for risk reduction) measures beyond those which are being applied n is reached because for all other scenarios for inhalational exposure for effects on fertility and development and for all scenarios for dermal exposures for acute and repeated dose toxicity, irritation, skin sensitisation, carcinogenicity and reproductive toxicity there is no need for limiting the risks taking into account the risk reduction measures that are already being applied.

Regarding consumer assessment and combined exposure, the risk assessment report concluded in 2007 that

Conclusion	Endpoints of concern	Reasoning
(i), on hold. There is need for further information and/or testing	Effects on fertility and development	There is need for further studies to evaluate the possible effects of nickel sulphate on germ cells, but further testing is not considered practicable
(iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account	Sensitisation	Patients with severe nickel sensitisation constitute a particularly sensitive population to oral challenge with nickel and are potentially at risk from excessive exposure to nickel in food and water. Additional risk reduction measures may be needed to limit exposure to nickel in food supplements.
(ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied	Sensitisation	There is no concern for the general population that are not already sensitised to nickel from exposure to nickel in food supplements. There is no concern for patients with severe nickel sensitisation for other endpoints than there possible reaction to oral challenge with nickel.

Summary from the risk assessment of the fifth nickel compounds

The risk assessment has shown that there is concern for many of the scenarios that were evaluated.

Overall, for most worst-case and many typical exposure levels concern is expressed for the majority of the end points/ exposure scenarios. Only three scenarios (contact with tools and other nickel releasing surfaces, use of batteries and the use of catalysts) were not regarded as being of any concern.

The human health risk assessment has been reviewed by SCHER, who have supported the conclusions indicating that further risk reduction measures are required (SCHER, 2006).

2.1. Concerns for human health effects

The risk assessment concluded that there is a need for limiting the risks to human health for some but not all of the health effects assessed. The health effects that are relevant for risk reduction are:

- acute inhalational toxicity (short-term peak exposures to nickel salts for workers);
- skin sensitisation (elicitation of dermatitis by oral exposure for consumers);
- respiratory sensitisation (occupational asthma following inhalation exposure to nickel salts);
- chronic inhalational toxicity (full-shift exposure for workers);
- inhalational carcinogenicity (for workers for all scenarios except those where the exposure is purely to metallic nickel);
- reproductive toxicity (fertility and developmental toxicity following inhalation for workers).

In drawing these conclusions, the risk assessment report has as far as possible taken into account possible differences between different species of nickel compound. The risk assessment report recognises that in some cases the risks are likely to be overestimated.

There is no concern for either workers or consumers for systemic effects by dermal exposure. Absorption of nickel following dermal contact with various nickel compounds can take place to a limited extent, with a large part of the applied dose remaining on the skin surface or in the stratum corneum. A value of 2% is taken as the absorbed fraction of nickel following dermal contact to the four nickel salts and a value of 0.2% for metallic nickel.

There is no concern for workers for effects after oral exposure, as it is assumed that this is prevented by personal hygiene measures.

Acute toxicity

For assessing acute inhalational toxicity, a LOAEC for local effects in the respiratory tract of 0.7 mg Ni/m3 from a 16-day repeated dose toxicity study with nickel sulphate was used for all the four nickel salts (nickel sulphate, nickel chloride, nickel dinitrate and nickel hydroxycarbonate.) The use of this LOAEC is considered to be a conservative approach, since greater toxicity is expected from repeated exposure (12 exposures during 16 days) compared to a single 4h exposure.

Acute toxicity is a concern for short-term inhalational exposure to the nickel salts. There is no concern for acute inhalational toxicity for nickel metal.

Irritation

Nickel sulphate, nickel dichloride, nickel dinitrate and nickel hydroxycarbonate are skin irritants. In addition, nickel dinitrate is a severe eye irritant.

As classification for this effect will lead to appropriate risk reduction measures, conclusion (ii) applies to all workplace situations. There is a concern for respiratory irritation for the four nickel salts, but this concern is however considered to be more appropriately covered by the risk assessment for repeated dose effects.

There is no concern for irritation for metallic nickel, although there is the possibility of mechanical eye irritation with finely divided metal powders. Whilst uncontrolled contact with the nickel salts is of concern, personal protective equipment, properly selected and worn, will significantly reduce exposure.

Skin sensitisation

With respect to sensitisation, both the induction of nickel allergy in non-sensitive people and the elicitation of allergic reactions in people already sensitive to nickel are relevant for a risk assessment. Nickel sulphate, nickel dichloride, nickel dinitrate, nickel hydroxycarbonate and metallic nickel are all skin sensitisers.

For the four nickel salts, an empirical threshold for elicitation and sensitisation of skin sensitisation of 0.3 µg/cm2 is used in the quantitative risk characterisation. Whilst the worst-case occupational dermal exposure levels to the four nickel salts are somewhat higher than the empirical cut-off of 0.3 µg/cm2, this is still considered to be acceptable (conclusion (ii)) as the cut-off value is based on prolonged (48 h) contact under occlusion exaggerating the assumed workplace exposure.

With respect to metallic nickel, whilst release of nickel from the metal or nickel-containing alloys during occupational exposure is possible, skin contact to these materials is unlikely to be prolonged, and therefore the possibility of induction of allergy is much reduced compared to the effects of soluble nickel. Thus a conclusion (ii) is considered justified for all workplace scenarios for induction of nickel allergy. The exposure levels are also considered sufficiently low to justify a conclusion (ii) for the elicitation of symptoms of nickel allergy in previously sensitised individuals for workplace exposure.

The situation with respect to consumer exposure is very different, and for certain materials direct and prolonged exposure to metallic nickel or nickel-containing alloys can potentially occur, resulting in both the induction of skin sensitisation in non-sensitive people and the elicitation of allergic reactions in people already sensitive to nickel. Whilst there is already EU legislation in force designed to prevent this, (see section 3.1.4.1 below) the risk assessment report concludes that the effects of this legislation and the associated CEN standard should be monitored in the wider EU population to ensure that the threshold for nickel release is adequate to prevent new cases of nickel allergy (conclusion (i)).

In addition, consumers that are already sensitised to nickel may respond to nickel orally by changes in their skin allergy. It is, however, not possible to establish a NOAEL for oral challenge in patients with nickel dermatitis. The LOAEL established after provocation of patients given nickel on an empty stomach where the uptake is expected to be highest is 12µg/kg body weight. A LOAEL after repeated exposure may be lower and a LOAEL in non-fasting patients is probably higher because of reduced absorption of nickel ions when mixed in food.

Occupational asthma

Nickel sulphate, nickel dichloride, nickel dinitrate and nickel hydroxycarbonate are all classified as respiratory sensitisers. This conclusion is based on a limited number of cases, all involving exposure to nickel sulphate. Classification of nickel metal was also discussed by the TC C&L, but there was agreement not to classify the metal for this effect.

In their comments to the first draft of this report, Industry provided additional information that asthma occurs in platters and in welders, but the specific role of nickel is established in only anecdotal cases (Fernandez Nieto 2006, Cruz 2006).

From the data available it is not possible to determine a no-effect level or exposure-response relationship for respiratory sensitisation for the four nickel salts, and thus it is not possible make a quantitative evaluation of the risk. However, given the severe nature of this effect, and that once the hypersensitive state is induced in an individual, then even low levels of exposure might induce an asthmatic response, occupational asthma is a concern (conclusion iii) in all workplace situations resulting in inhalational exposure to the nickel salts.

However, experience suggests that this effect does not present a problem in practice as exposure to metallic nickel does not result in excess mortality from non-malignant respiratory disease including asthma. Further, according to Industry, nickel workers are closely monitored for respiratory health, and so for metallic nickel there is at present no need for risk reduction measures beyond those which are being applied already (conclusion (ii)).

Chronic toxicity

When nickel sulphate is inhaled, the main target in animals is the respiratory system, where serious effects are induced in the form of chronic inflammation and fibrosis. A LOAEC of 0.056 mg Ni/m3 derived from a study with nickel sulphate is used in the risk characterisation for the four nickel salts. For metallic nickel a LOAEC of 1 mg Ni/m3 was derived for local effects.

Regarding occupational exposures by inhalation of nickel and its salts, the risk assessment report derives conclusion (iii) for many of the developed exposure scenarios regarding repeated dose toxicity, even when using reasonable exposure assessment approaches. Conclusion (iii) in these cases is supported by SCHER (2006).

CSTEE (2001) has noted in their review of the Commission Ambient Air paper that soluble nickel species rather than other nickel species are "key contributors to the non-cancer respiratory effects of nickel compounds" (CSTEE, 2001). Some exposure scenarios include cases where all the nickel is assumed to be to soluble nickel salts (rather than other nickel species), and in these cases the possible effect is likely to be overestimated.

Carcinogenicity

The four nickel salts are classified as Carc. Cat. 1; R49 and metallic nickel as Carc. Cat. 3; R40. As there is concern for the genotoxic effects of the nickel compounds in somatic cells following inhalation, the carcinogenicity risk characterisation is carried out using a non-threshold approach.

A unit risk for cancer following inhalation of nickel compounds has been calculated by a number of bodies. The lifetime dose that theoretically will cause cancer in 25% of the exposed population (HT 25) can also be calculated from the unit risk estimates derived by Sanner and co-workers (Sanner, 2002, Sanner et al., 2001).

The risk characterisation is based on the WHO unit risk estimate, which is the estimate accepted by the CSTEE in their opinion on the Commission Ambient Air Position Paper (CSTEE, 2001). The lifetime increased cancer risk at a workplace exposure level of 1 mg/m3 is equal to 95 x 10-3 (Sanner, 2002). This figure is based on the HT25 dose descriptor for humans from the figure in WHO (1999) of 188 □g/kg/day, corrected for the difference between continuous and workplace exposures.

The exposures that resulted in the increased lung cancer frequencies seen in the epidemiological studies represent complex mixtures of different nickel species that may have varied from study to study as well as within a study. From these studies it is not possible to identify the risk of the individual nickel species. The risk estimation is therefore based on the estimated total exposure to nickel species. It is apparent that the HT25 data presented above differ by a factor of about 9 and that the WHO risk estimate used is close to the average of the numbers presented. Thus, if the complex mixtures representing the exposure scenarios are similar to those in the epidemiological studies and the dose response is linear also at low doses, the actual lifetime cancer risk does probably not differ from the calculated risk by a factor of more than 3 (Sanner, 2002).

The exposures in most scenarios involve varying degrees of mixed exposure to a number of different species of nickel. Several of the scenarios relate to refineries, and hence the exposure scenario is similar to the exposures on which the lifetime increased cancer risk levels are based.

As the four nickel salts are classified for genotoxicity, the risk characterisation for these compounds is carried out using a non-threshold approach. The risk characterisation for nickel metal has also been carried out using a non-threshold approach, for cases where there is exposure to a number of different nickel species.

SCHER (2006) concluded that conclusion (iii) for the developed occupational scenarios with inhalation exposure to nickel is justified since high cancer risks are predicted using unit risks derived from the occupational studies. Moreover, SCHER also agreed that no threshold for the carcinogenicity of nickel can be identified based on epidemiology and the available experimental studies on nickel carcinogenicity after inhalation in rodents (SCHER, 2006).

In their comments to the first draft of this risk reduction strategy report, the Industry have questioned the SCHER conclusion that the available experimental studies on nickel carcinogenicity after inhalation in rodents support a non-threshold evaluation. Industry argued in their comments that as the inhalation study with nickel sulphate in rats showed no tumours at exposure levels up to 0.1 mg Ni/m3, a threshold at or above this concentration has been identified. Furthermore, the study of high temperature nickel oxide in rats shows a non linearity consistent with a threshold (Seilkop and Oller, 2003). These arguments were considered in the discussion of the risk assessment report in the TC NES, and are included in the risk assessment report.

However, in some cases, the inhalational exposure is almost entirely due to exposure to metallic nickel (handling of metal products under the final stages of metal production, certain types of alloy production, the use of metallic nickel as a feedstock for batteries and catalysts and contact with coins). Since there is inadequate data on which to base a HT25 estimate for nickel metal alone, a conclusion (i) has been drawn for these scenarios. This conclusion has been formally implemented (EC 2006b).

It should be noted that the conclusion of the risk assessment report that the carcinogenicity should be regarded as a non-threshold effect, a conclusion supported by SCHER, has important consequences for the risk reduction strategy, both for the choice of legal instrument for setting occupational exposure limits (the Carcinogens Directive or the Chemical Agents Directive) and for the measures to be applied under REACH if these compounds are prioritised to Annex XIV.

Reproductive toxicity

No effects on fertility have been seen in animal studies following oral administration and no data are available for inhalation and dermal contact. The NOAEL used for the risk characterisation is 2.2 mg Ni/kg bw/day, the highest dose of nickel sulphate investigated given by gavage. This value is used in the risk characterization although it is recognised that the NOAEL is probably higher. The NOAEC has been calculated from this oral NOAEL as 0.55 mg Ni /m3. The use of this figure leads to concern for a number of different exposure scenarios. It can be debated whether conclusion (i) on hold would be more appropriate for this end-point given the uncertainties regarding a proper NOAEC value and proper studies for examining this end-point. However, as all the scenarios for the fertility end-point that have been identified as of concern are also of concern for developmental toxicity for (which a lower NOAEC value is used) this is academic, as risk reduction measures for these scenarios are already recommended.

The four nickel salts are classified in Category 2 for reproductive toxicity for development (Repr. Cat. 2; R61). The NOAEL used for risk characterisation is 1.1 mg Ni/kg bw/day and the calculated NOAEC is 0.277 mg Ni /m3.

2.2. Outcome of risk characterisation

2.2.1. Groups of particular concern

The risk characterisation evaluated the risks for both workers and consumers.

In doing so, it was recognised that the main group of people where there is particular concern are those who are already nickel-sensitive. Much of the nickel allergy on the general population is due to prolonged and close contact with nickel-releasing metal objects. EU legislation (see 3.1.4.1 below) has come into force that is intended to prevent future exposure to this type of objects leading to nickel allergy. Experience in Denmark suggests that this legislation may well be largely effective in preventing further cases of nickel allergy, and that as a result, the numbers of people who are sensitised to nickel will fall. There is however a substantial proportion of the general population who are already nickel-sensitive, and this is a group especially at risk from both dermal and oral exposure to nickel.

No genetic variations that influence adverse reactions to nickel have been identified (UK EGVM, 2003), and there is no data on which to judge whether children are a group that is particularly sensitive to the adverse effects of nickel.

2.2.2. Workers

The risk assessment report concluded that there is a need for limiting the risks to worker health for all the manufacture and the use scenarios considered in the risk assessment report and shown below. These are:

1. Production of nickel metal: refining

2 Production of nickel salts

3 Production of alloys

- melting and foundry techniques
- powder metallurgy
- nickel plating
- chemical pre-treatment of metals

4 Battery production

5 Catalyst production

6 Production of nickel-containing chemicals

7 Contact with coins

Most workplace exposure is characterised by exposure to a number of different nickel species. In many of the processes described in the risk assessment reports, more than one nickel species is involved in the process, and in some cases data may be available to assess exposure levels to the different nickel species individually. Where such data is available, this has been shown in the individual risk assessment reports.

Appendix 3: Information provided by the Registrant on the Control workers exposure Operational conditions (OCs), risk Management Measures (RMM) and Personal Protection Equipment (PPE)

Table 1: GES 1: Ni SO4 production from copper refining

CES 1.1		
OCs affecting worker exposure		The Cu-Ni spent electrolyte is pumped in pipes from the copper refinery into the purification plant.
RMM	**LEV**	None
	Enclosure conditions	The transfer of the spent electrolyte solution shall be totally enclosed with no emission to the workplace.
PPE	**Inhalation**	Use of **RPE (APF 40)** is required for operations where exposure to Ni dust or powder is possible.
	Dermal	Use of properly designed gloves is required for operations where direct contact is possible.
CES 1.2		
OCs affecting worker exposure		The copper impurity is removed from this electrolyte by evaporation/crystallisation (Cu as copper sulphate, CuSO4) and electrowinning by cascade electrolysis (of Cu as cathode) to give a NiSO4 solution
RMM	**LEV**	None
	Enclosure conditions	The transfer of the spent electrolyte solution shall be totally enclosed with no emission to the workplace. Electrowinning is usually carried out in open cascade electrolysis cells.
PPE	PPE required for all production processes after reception of spent electrolyte and for maintenance, cleaning, and nonroutine production (clearing up spills and clearing obstructions inside pant) activities.	
	Inhalation	Inhalation exposure to mists controlled by: - full or half- face respirator e.g. 3M 6800, **APF = 20** (based on use of P3) or

		- full face mask EN136 with EN 143 filter.**APF = 40**
	Dermal	Acid resistant gloves are required to control skin exposure to liquid splashes which may occur during both de-copperisation processes.
CES 1.3		
Operational conditions affecting worker exposure		The resulting NiSO4 solution is heated (submerged arc burners) and concentrated by evaporation under reduced pressure. The NiSO46H2O or NiSO42H2O, is crystallised out of solution in a crystallising unit {surface (coat and coil) cooled crystallisers} and separated from the solution by centrifugation or filtration (belt filter). Washed NiSO46H2O, recovered on the belt filter, is redissolved to produce a commercial NiSO4 solution. The solid product(s) NiSO46H2O or NiSO42H2O is (are) moist after recovery. The waste solution and washings, containing sulfuric acid, is directed to a storage container from which it is neutralised and disposed.
RMM	**LEV**	LEV shall be installed on the belt filters. Fixed capturing hoods located in close proximity of and directed at the source of emission for belt filters and packaging units are required. The design shall enable that the work is performed in the capture zone of the ventilation system and the capture zone shall be indicated at the workplace.
	Enclosure conditions	The concentrated solution shall be piped from the evaporator into an enclosed crystallising unit. The steam and sulfuric acid mist from the enclosed evaporator shall be extracted and the airflow cleaned by demisters and condensers. The moist NiSO46H2O or NiSO42H2O solid shall be recovered from solution using either i) a partially enclosed belt filter, with extraction fitted close to the openings at both ends of the belt filter casing, or ii) a centrifuge which is closed by design.
PPE	PPE is required for all production processes after reception of spent electrolyte and for maintenance, cleaning, and nonroutine production (clearing up spills and clearing obstructions inside pant) activities. There is little particulate emission from the moist product. Inhalation exposure to mists generated during separation and skin exposure to liquid splashes, mists or the NiSO46H2O or NiSO42H2O solid during operating the centrifuge and routing the sulfuric acid solution to a treatment plant are controlled by RPE and acid proof gloves respectively.These activities shall be automated and closed.	
	Inhalation	- Full or half- face respirator e.g. 3M 6800, **APF = 20** (based on use of P3), - Full face mask EN136 with EN 143 filter, **APF = 40** should be available for instances of unforeseen release of mists from evaporators.
	Dermal	**A**cid proof gloves are required to control skin exposure to any liquid splashes and during cleaning of spills.
CES 1.4		
OCs affecting		The hydrated nickel sulphate is weighed and packed into bulk containers (1000 kg) or other forms of packaging. Bagging

worker exposure		is usually carried out by a worker using a manually operated bagging unit and then warehoused
RMM	**LEV**	LEV shall be installed on bagging units in the packaging area at the end of the production process. Fixed capturing hoods located in close proximity of and directed at the source of emission for belt filters and packaging units are required. The design shall enable that the work is performed in the capture zone of the ventilation system and the capture zone shall be indicated at the workplace.
	Enclosure conditions	Enclosement is required for screw conveyors that transfer the moist NiSO46H2O or NiSO42H2O to the packaging units where it is bagged into bulk containers (big bags)
PPE	PPE is required for all production processes after reception of spent electrolyte and for maintenance, cleaning, and nonroutine production (clearing up spills and clearing obstructions inside pant) activities.	
	Inhalation	- Full or half- face respirator e.g. 3M 6800, **APF = 20** (based on use of P3) or - Full face mask EN136 with EN 143 filter, **APF = 40**
	Dermal	Acid proof gloves are required to control dermal exposure to particulate NiSO46H2O or NiSO42H2O
CES 1.5		
OCs affecting worker exposure		The inspection includes: cleaning of the installation (by flushing with hot water), checking burners and the integrity of the evaporator lining and repairing any leaks in this system.
RMM	**LEV**	None
	Enclosure conditions	None
PPE	**Inhalation**	During cleaning and inhalation exposure to mists and particulates shall be controlled by: - Full or half- face respirator e.g. 3M 6800, **APF = 20** (based on use of P3) or - Full face mask EN136 with EN 143 filter, **APF = 40**
	Dermal	During cleaning and maintenance dermal exposure shall be controlled by wearing acid proof gloves

Table 2: GES 2: Ni SO4 production: solvent extraction of NiSO4 leachate

CES 2.1		
OCs affecting worker exposure		The reactor is charged by enclosed tipping of crude NiSO4 and NiCO3 from bulk containers bags and piping of sulfuric acid and crude NiSO4 solution into the reactor
RMM	**LEV**	LEV is required to control inhalation exposure to particulate generated during loading reactor
	Enclosure conditions	The reactor shall be closed during the leaching of the NiSO4 and NiCO3 into the H2SO4 solution.
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) and rigger gloves are required for all activities. RPE is required to control inhalation exposure to particulate generated during loading reactor.
	Dermal	Gloves are also required to control against any skin contact with the raw materials.
CES 2.2		
OCs affecting worker exposure		Cu and Fe are precipitated chemically or by evaporation/crystallisation in a closed reactor and separated from the solution by a covered belt filter/open filter press. These solids are sent off site for waste disposal by landfill
RMM	**LEV**	LEV is required to control inhalation exposure to particulate generated during filter press operation.
	Enclosure conditions	Precipitation and filtration of Cu and Fe impurities are largely closed operations.
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) and rigger gloves are required for all activities. Masks are required to control inhalation exposure during certain tasks.
	Dermal	Gloves are also required to control against any dermal exposure to Cu and Fe solids being stored in preparation for being sent to landfill.
CES 2.3		
Operational		The filtrate, containing NiSO4, is pumped to the enclosed solvent extraction unit where it is purified to give NiSO4 in the

conditions affecting worker exposure		raffinate. The NiSO46H2O is crystallised from the raffinate in the crystalliser and then these crystals are transferred to the drier in enclosed conveyors. containing sulfuric acid, is directed to a storage container from which it is neutralised and disposed.
RMM	**LEV / Enclosure conditions**	Solvent extraction, crystallising and drying shall be enclosed and fitted with LEV to control inhalation exposure to mists. LEV is required to control inhalation exposure to particulate generated during drying and to vapours during volume reduction and (unspecified) masks are required for certain (unspecified) tasks
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) and rigger gloves are required for all activities. RPE is required to control inhalation exposure in certain (unidentified) tasks.
	Dermal	Gloves are required to control dermal exposure
CES 2.4		
OCs affecting worker exposure		The crystals are transferred from the drier in an enclosed conveyor to the packaging station where they are packed in 25 kg bags on an automated bagging line and into big bags (1000 kg) on an enclosed manually operated bagging unit. Filling big bags (1000 kg) is manually operated but largely enclosed (securing the spout of the empty big bag over the fill point, initiating/terminating the automatic filling of the bag, removing the spout of the big bag from the filling nozzle and manually closing the full bag). The powder is allowed to settle in the big bags before removing them from the filling nozzle. Big bags are then driven to the warehouse
RMM	**LEV**	The filling nozzles shall be fitted with LEV
	Enclosure conditions	**None**
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection)
	Dermal	Rigger gloves are required for all activities
CES 2.5		
OCs affecting		Cleaning of premises typically includes wet cleaning of floors and cleaning of plant and equipment by dry (vacuuming) and wet (power washing) methods. Maintenance includes opening of pipes and reactors and can occasionally include

worker exposure		opening of equipment in order to inspect for blockages, leaks and damage and carry out repairs.
RMM	**LEV**	LEV is required to control inhalation exposure to fumes, particulate and liquid aerosols generated
	Enclosure conditions	None
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) and rigger gloves are required for all activities. (Unspecified) masks are required for certain (unspecified) tasks.
	Dermal	Gloves are required to control dermal exposure to particulate and liquid splashes to the skin.

Table 3: GES 3: Crystallisation from a purified nickel sulphate leachate

CES 3.1		
OCs affecting worker exposure		All activities are largely run from control room when operators are not required to directly observe or intervene in the process. The reactor is charged by piping purified NiSO4 solution into the reactor
RMM	**LEV/ Enclosure conditions**	None given
	Training to reinforce good practice and hygiene issues and exposure and biological monitoring of operators is regularly performed	
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) and rigger gloves are required for all activities.
	Dermal	Gloves are required to control dermal exposure when charging the reactor
CES 3.2		
OCs affecting worker exposure		All activities are largely run from control room when operators are not required to directly observe or intervene in the process. The NiSO4 solution is vaporated under reduced pressure, the hydrated nickel sulphate, NiSO46H2O, crystallises out of the concentrated solution in the crystalliser and is separated from the solution by centrifugation. This activity is automated and enclosed.
RMM	**LEV**	LEV ishall be used to extract the gases and vapours generated during heating and evaporating the solution
	Enclosure conditions	Leaching, evaporation/crystallisation/centrifugation shall be enclosed with high level of containment. Evaporation shall be carried out under negative pressure
	Training to reinforce good practice and hygiene issues and exposure and biological monitoring of operators is regularly performed	
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection)
	Dermal	Rigger gloves are required for all activities
CES 3.3		

Operational conditions affecting worker exposure		All activities are largely run from control room when operators are not required to directly observe or intervene in the process. The crystals are dried using a vacuum belt filter and transferred in an enclosed conveyor to intermediate storage silos.
RMM	**LEV / Enclosure conditions**	LEV is required to control inhalation exposure to particulates during release from the filter and packaging. LEV is also used to extract the gases and vapours generated during drying of the NiSO46H2O Filtering of leachate is carried out using open filter presses
	Training to reinforce good practice and hygiene issues and exposure and biological monitoring of operators is regularly performed	
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection)
	Dermal	Rigger gloves are required for all activities.
CES 3.4		
OCs affecting worker exposure		All activities are largely run from control room when operators are not required to directly observe or intervene in the process. There is automated packaging of NiSO4.6H2O crystals small jet bags (25 kg) and stacking the full jet bags onto and shrink wrapping filled pallets. Filling big bags (1000 kg) is manually operated but largely enclosed (securing the spout of the empty big bag over the fill point, initiating/terminating the automatic filling of the bag, removing the spout of the big bag from the filling nozzle and manually closing the full bag). The powder is allowed to settle in the big bags before removing them form the filling nozzle which are fitted with LEV. Pallets and big bags are then driven to the warehouse.
RMM	**LEV**	LEV is required to control inhalation exposure to particulates during release from the filter and packaging. LEV shall be installed on bagging lines and units in the packaging area at the end of the production process (Reduction factor = 0.1). Fixed capturing hoods shall be located in close proximity of and directed at the source of emission for belt filters and packaging units. The design shall enable that the work is performed in the capture zone of the ventilation system and the capture zone shall be indicated at the workplace
	Enclosure conditions	Packaging and transfer systems shall be enclosed and the level of containment high.
	Training to reinforce good practice and hygiene issues and exposure and biological monitoring of operators is regularly performed	

PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection)
	Dermal	rigger gloves are required for all activities.
CES 3.5		
OCs affecting worker exposure		Unspecified instructions for cleaning, maintenance and emergency procedures are followed
RMM	**LEV**	None given
	Enclosure conditions	None given
	Training to reinforce good practice and hygiene issues and exposure and biological monitoring of operators is regularly performed.	
PPE	**Inhalation**	Air-assisted filtering visor with P3 filter element (Willson Turbovisor) **APF = 20** (based on use of powered respirator meeting EN12492 requirement or equivalent suitable P3 level protection) and rigger gloves are required for all activities. Inhalation to vapours, mists and particulates and skin exposure to mists, liquids splashes and particulates shall be controlled by RPE
	Dermal	gloves when undertaking maintenance and cleaning work

Table 4: GES 4: Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating

CES 4.1		
OCs affecting worker exposure		Ni plating solutions are often used hot and this can cause mist emissions from the solution surface. Manual solution make-up and replenishment with NiSO4 solution can lead to solution splashes to the skin and generate spray in the atmosphere.
RMM	**LEV**	LEV shall be used to extract the mist and particulate during the solution mixing, dipping and transferring operations which are not fully enclosed.
	Enclosure conditions	Treatment solutions contain a fume suppressant and/or are covered with a layer of plastic balls floating on the solution surface to seal heat and mist inside plating tank where this barrier will allow easy immersion and removal of items and access to other tank fitments. Treatment solutions not in use are sealed with tank covers. The NiSO4 solution is carefully added to the tank solution where the process is not automated, in order to avoid throwing the NiSO4 along the length of the tanks and creating liquid splashes and solution spray.
PPE	**Inhalation**	Air-assisted filtering visor, masks or hood with P3 filter element (**Assigned Protection Factor ~20** based on use of powered respirator meeting EN12492 requirement or FFP3 (EN149) or equivalent suitable respirator) is required for emergencies and non-routine tasks where exposure to NiSO4 containing mist or dust is possible.
	Dermal	Chemical gloves with EN 374, protection level 6 are required to control dermal exposure when carrying out and process operations on the line.
CES 4.2		
OCs affecting worker exposure		The NiSO4.6H20 powder is carefully added to the tank solution where the process is not automated, in order to avoid throwing the NiSO4.6H20 powder along the length of the tanks and creating liquid splashes and powder becoming airborne.
RMM	**LEV / other conditions**	Local (where appropriate) and general exhaust ventilation. Vacuuming or suitable wet removal methods for cleaning settled dust etc. from plant and premises. Avoid inappropriate cleaning methods such as dry brushing

PPE	Inhalation to mists and particulates and skin exposure to mists, liquids splashes and particulates shall be controlled by RPE and gloves when undertaking maintenance and cleaning work.	
	Inhalation	Use of air-assisted filtering visor, masks or hood with P3 filter element for plant or premises heavily contaminated with nickel-containing dust or spills {**APF ~20** based on use of powered respirator meeting EN12492 requirement or FFP3 (EN149) or equivalent suitable respirator}. RPE with a lower **APF of 10** {air-assisted filtering visor, masks or hood with P2 filter element including powered respirators meeting the EN12492 TM1 or EN 12941 TH1 requirement or the FFP2 (EN149) or equivalent suitable respirator} may be used for cleaning and maintenance work where the plant or premises is less heavily contaminated with nickel-containing dust or spills.
	Dermal	Use of chemical gloves with EN 374, protection level 6, is required to control dermal exposure

Table 6: GES 6: Production of Ni salts from Ni sulphate

CES 6.1		
OCs affecting worker exposure		Maintain clean workplace to prevent accumulation of powders and dusts on surfaces. Use of water or vacuum cleaner with HEPA filter to remove dust from workplace during cleaning and maintenance.
RMM	**LEV**	LEV is required at work stations where dry powders are handled
	Other conditions	Processes shall be automated and enclosed. Enclosure of reaction, filtration and drying systems, automation and enclosure of packing dry product is required.
PPE	**Inhalation**	RPE is required for cleaning and maintenance operations and where exposure to dry powders and/or dust and/or spray solution is possible.
	Dermal	For contact with Ni sulphate solution, gloves and other appropriate protective clothing suitable for working with aqueous solutions and acids are required. For dermal contact with dried product, gloves and other suitable protective clothing suitable for handling powders are required

Table 7: GES 9: Selective plating

CES 9.1		
OCs affecting worker exposure		Manual use of Ni plating solutions can lead to skin contact with and inhalation of mist and fume from the newly applied plating solution. Manual solution filling of the wand dip container or the pump feeding system can lead to solution splashes to the skin and emission to the atmosphere
RMM	**LEV / other conditions**	Plating solutions incorporate a fume suppressant ingredient to limit emissions to the atmosphere during plating. The brush plating wand dipping reservoir and wand mouth feeding system are sealed when not in use. Wands which are dipped in reservoirs of the NiSO4 electrolyte are replaced by wands where the NiSO4 is pumped to the mouth via a closed feeding system. Computer-driven brush plating will be used wherever possible to replace the manual operation. Otherwise 1) portable LEV shall be used to extract mist and particulate during the wand reservoir filling and plating operations where there is limited space for the operator to carry out manual plating in-situ or there are other workplace situations which might lead to over exposure and 2) where possible, individual workpieces will be mounted under the brush plating system and the plating solution applied by moving the workpiece under the wand using a remote or hand held control panel. The operator is likely to be moving for one workplace situation to another so the LEV will have to be mobile.
PPE	**Inhalation**	Use of air-assisted filtering visor, masks or hood with P3 filter element (Assigned Protection Factor ~20 based on use of powered respirator meeting EN12492 requirement or FFP3 (EN149) or appropriate suitable respirator) is required for emergencies and non-routine tasks where exposure to NiSO4 containing mist or dust is possible.
	Dermal	Use of chemical gloves with EN 374, protection level 6, with a good quality disposable glove underneath is required to control dermal exposure when carrying out selective plating operations
CES 9.2		
OCs affecting worker exposure		
RMM	**LEV / other conditions**	Local (where appropriate) and general exhaust ventilation. Vacuuming or suitable wet removal methods for cleaning settled dust etc. from plant and premises. Avoid inappropriate cleaning methods such as dry brushing.

PPE	Inhalation to mists and particulates and skin exposure to mists, liquids splashes and particulates shall be controlled by RPE and gloves when undertaking maintenance and cleaning work.	
	Inhalation	Use of air-assisted filtering visor, masks or hood with P3 filter element for plant or premises heavily contaminated with nickel-containing dust or spills **{APF ~20** based on use of powered respirator meeting EN12492 requirement or FFP3 (EN149) or equivalent suitable respirator}. RPE with a lower **APF of 10** {air-assisted filtering visor, masks or hood with P2 filter element including powered respirators meeting the EN12492 TM1 or EN 12941 TH1 requirement or the FFP2 (EN149) or equivalent suitable respirator} may be used for cleaning and maintenance work where the plant or premises is less heavily contaminated with nickel-containing dust or spills.
	Dermal	Use of suitable chemical gloves (EN 374, protection level 6, PVC or equivalent) goggles and special safety clothing is required to control dermal exposure Protective equipment should be chosen based on activities being undertaken, potential for exposure to airborne NiSO4 and other relevant workplace hazards and may include protective suit with hood (conforming to EN13982-1 Type 5) and safety shoes (*e.g.* according to EN 20346).

Appendix 4: Summary of the $NiSO_4$ risk assessment

Legend :

Green: Acceptable risk (RCR < 1 and level of protection (RPE) consistent with Registrant proposals)

Red: Inacceptable risk (RCR > 1 and/or level of protection (RPE) consistent with the Registrant proposals)

Purple: Non conclusive (RCR with a high level of uncertainty)

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
GES 1: Ni SO4 production from copper refining								
CES 1.1 Electrolyte reception	0.52	0.01	**52**	**1.3****	**MEASE modeling (tier1 model):** - PROC2. - Medium dustiness - Non-direct handling - Closed system without breaches. ** RPE = 40	RCR >1 (MEASE modeling, RPE = 40)	**RPE (APF20 or 40).** **Enclosed, no LEV reported**	RCR > 1 with RPE 40.
CES 1.2 De-copperisation /electrolysis	0.006	0.01	**0.6**	**-**	**Exposure data measurements:** Highest of 2 personal, inhalable exposure measurements for evaporator and filter	N° measure: 2 GSD: not specified	**RPE (APF 20 or 40)** **Enclosed, no**	Minimum of 12 measurements is required to validate the RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
					Operator *RPE = 20	**Insufficient**	**LEV reported**	
CES 1.3 Solution concentration & $NISO_4$ $2H_2O$ or $NiSO_4$ $6H_2O$ crystallisation	0.006	0.01	**0.6**	**-**	**Exposure data measurements:** Single personal, inhalable exposure measurement for 'evaporator and filter' operator *RPE = 20	N° measure: 1 GSD: not specified **Insufficient**	**RPE (APF 20 or 40)** **LEV & enclosed**	Minimum of 12 measurements is required to validate the RCR
CES 1.4 Packaging	0.02	0.01	**2**	**0.1***	**Exposure data measurements:** 2 personal, respirable Measurements taken during filling and loading to containers. Inhalable value estimated as twice the respirable exposure level *RPE = 20	N° measure: 2 GSD: not specified **Insufficient**	**RPE (APF 20 or 40)** **LEV & enclosed**	Minimum of 12 measurements is required to validate the RCR
CES 1.5 Cleaning & Maintenance	0.08	0.01	**8**	**0.4***	**Exposure data measurements:** Inhalable value estimated as twice the respirable exposure level (personal, respirable value was the maximum result of 4 measurement ranges for evaporators and crystalliser service)	N° measure: not specified only 4 ranges (min and max values) available GSD: not	**RPE (APF 20 or 40)** **No RMMs and conditions reported**	Minimum of 12 measurements is required to validate the RCR No information on the number of measurement (only

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
					*RPE = 20 ** RPE = 40	specified		ranges available)
GES 2: Ni SO4 production: solvent extraction of NiSO4 leachate								
CES 2.1: Charging *Crude NiSO4 6H2O and NiCO3 reception & leaching*	1.32	0.01	**132**	**3.3****	**MEASE modeling (tier1 model):** - PROC 4. - solid, Medium dustiness - Non-direct handling - LEV assumed. -**RPE = 40	RCR >1 (MEASE modeling, RPE = 40)	**RPE (APF 20)** **LEV & Enclosed**	RCR > 1 with RPE 40
CES 2.2: Purification of leachate to make NiSO4 solution	0.02	0.01	**2**	**0.1***	**MEASE modeling (tier1 model):** - PROC 2. - solution - Non-direct handling - LEV assumed.	RCR <1 (MEASE modeling, RPE 20)	**RPE (APF 20)** **LEV & enclosed**	RCR < 1 with RPE 20 Consistent with the RPE reported by the Registrant

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
					- * RPE = 20			
CES 2.3: solvent extraction *Further solution purification, concentration & NiSO46H2O crystallisation*	0.12	0.01	**12**	**0.6***	**MEASE modeling (tier1 model):** - PROC 2. - solid, Medium dustiness - Non-direct handling - LEV assumed. - * RPE = 20 **RPE = 40	RCR < 1 (MEASE modeling, RPE 20)	**RPE (APF 20)** **LEV & enclosed**	Consistent with the RPE reported by the Registrant
CES 2.4: Packaging of NiSO46H2O into bags	0.01	0.01	**1**	**0.05 ***	**Exposure data measurements:** 75th percentile value of personal exposure measurements (n=12) aggregated over all activities *RPE = 20 (RCR tier 2)	N° measure: 12 GSD: not specified	**RPE (APF 20)** **LEV**	The RCR could be validated if data are of good quality (GSD < 2) but no information is available.
CES 2.5: Cleaning & Maintenance	0.66	0.01	**66**	**3.3*** **1.65 ****	**MEASE modeling (tier1 model):** - PROC 10.	RCR > 1 (MEASE modeling, RPE 40)	**RPE (APF 20)** **LEV**	RCR > 1 with RPE 40

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
					- solid, Medium dustiness - Non-direct handling - <240 min - LEV assumed. - * RPE = 20 **RPE = 40	🟥		
GES 3: Crystallisation from a purified nickel sulphate leachate								
CES 3.1 Purified leachate reception & charge into reactor	0.02	**0.01**	**2**	**0.1***	**MEASE modeling (tier1 model):** - PROC 1 -medium dustiness solid, - > 25% concentration, - non-direct use, - intermittent exposure for more than 4 hours. - * RPE = 20 (RCR tier 2)	RCR < 1 (MEASE modeling)	**-RPE (APF 20)** **-No LEV reported**	RCR < 1 with RPE 20 Consistent with the RPE reported by the Registrant
CES 3.2 solution concentration, NiSO4 6H2O	0.006	0.01	**0.6**	**-**	**Exposure data measurements:** single measurement taken during 'operating evaporator and filter' during an analogous activity (NiSO4.6H2O recovery (from solution)	N° measure: 1 GSD: not specified	**-RPE (APF 20)** **- LEV** **-Activity**	Minimum of 12 measurements is required to validate the RCR

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
crystallisation & separation					operation for NiSO4.6H2O produced from a purified spent electrolyte) - * RPE = 20 (RCR tier 2)	**Insufficient**	**automated and enclosed.**	
CES 3.3 drying	0.11	0.01	**11**	**0.55 ***	**MEASE modeling (tier1 model):** - PROC 2 - medium dustiness solid, - > 25% concentration, - non-direct use, - intermittent exposure for more than 4 hours. - * RPE = 20 **RPE = 40	RCR < 1 (MEASE modeling, RPE 20)	**-RPE (APF 20)** **-LEV**	Consistent with the RPE reported by the Registrant
CES 3.4 packaging	0.023	0.01	**2.3**	**0.11 ***	**Exposure data measurements:** 75th percentile of personal, inhalable measurements (n=7) for packaging. Packaging value includes NiSO4 and nickel hydroxycarbonate, as the ^packaging was carried out in same area and the operators rotate between both	N° measure: 7 GSD: not specified	**-RPE (APF 20)** **-LEV** **-Enclosed system**	Minimum of 12 measurements is required to validate the RCR. No raw data, only range available

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
CES 3.5 cleaning & maintenance	0.3	0.01	**30**	**1.5*** **0.07****	**MEASE modeling (tier1 model):** - PROC 10 -low dustiness solid, - > 25% concentration, - non-direct handling, non dispersive - intermittent exposure for ≤ 4h. - * RPE = 20 **RPE = 40	RCR < 1 (MEASE modeling, RCR 40)	**-RPE (APF 20)** **-No LEV reported**	RCR < 1 with RPE 40 RPE 20 reported by the Registrant for this task.
GES 4: Metal surface treatment: nickel electroplating, nickel electroforming, electroless nickel plating								
CES 4.1 Nickel electroplating, nickel electroforming & electroless nickel plating	0.0083	0.01	**0.85**	**-**	**Exposure data measurements:** 75th percentile value from 20 personal exposure measurements ranging from 0.0009-0.0235 mg m-3 - * RPE = 20 (RCR tier 2)	N° measure: 20 GSD: 2.7 RCR < 1 (no RPE)	**RPE (APF 20)** **LEV**	N° measure: 20 and GSD: 2.7 (moderate) => 20 à 30 measures required to validate the RCR. Consistent with the RPE reported by the Registrant

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
CES 4.2 Cleaning and Maintenance	0.342	0.01	34.2	3.4° 1.7* 0.17 **	**MEASE modeling (tier1 model):** - PROC 10 - medium dustiness solid, - 5-25% concentration - non-direct handling, non dispersive use - 1h duration exposure - GV - ° RPE = 10 * RPE = 20 ** RPE= 40	RCR < 1 (MEASE modeling, RPE 40)	**RPE (APF 10 or 20)** **Local (where appropriate) and general exhaust ventilation (GV)**	RCR < 1 with RPE 40 RPE of 10 or 20 maximum reported by the Registrant.
GES 5: Production of batteries								
CES 5.1 NiSO4 6H2O & Ni briquettes reception (raw material handling)	NA	0.01	NA	-	**Exposure data measurements:** The higher of 2 static exposure values for the unbagging of NiSO46H2O (=0.082). LEV is assumed to be in Place ⇨ For calculation of acute systemic exposure inhalation only	Not applicable (NA)	**No RPE reported** **LEV**	No long-term systemic inhalation exposure was considered : this operation is not of long term duration Frequency and duration of use/exposure: Unbagging 20 kg of

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
								NiSO46H2O takes between 10 and 20 minutes once per month.
CES 5.2 Manufacture of the NiSO4 solution	[confidential]	0.01	>1	<1*	**Exposure data measurements:** The highest of 3 personal inhalable nickel exposure measurements -* RPE = 20	N° measure: 3 GSD: not specified insufficient	**No RPE reported** **LEV**	Minimum of 12 measurements is required to validate the RCR
CES 5.3 Manufacture of positive (Ni(OH)2 based) active mass	[confidential]	0.01	>1	<1*	**Exposure data measurements:** The highest of 3 personal inhalable nickel exposure measurements -* RPE = 20	N° measure: 3 GSD: not specified insufficient	**No RPE reported** **LEV**	Minimum of 12 measurements is required to validate the RCR
CES 5.4 Manufacture of negative (Cd(OH)2/Ni(OH)	[confidential]	0.01	<1		**Exposure data measurements:** The highest of 2 personal inhalable nickel exposure measurements	N° measure: 3 GSD: not specified	**No RPE reported** **LEV**	Minimum of 12 measurements is required to validate the RCR

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
2 based) active mass						insufficient		
CES 5.5 Manufacture of electrodes as pocket plate electrodes	Not applicable	0.01	Not applicable	**-**	Exposure to NiSO4 is not relevant for this process/activity. Ni is only in the form of Ni dihydroxide	Not applicable	Not relevant	Not relevant
CES 5.6 Nickel electroplating (strips)	[confidential]	0.01	**>1**	**<1***	**Exposure data measurements:** The highest of 5 static exposure measurements for nickel electroplating from a NiSO4 rich solution -* RPE = 20	N° measure: 5 GSD: not specified insufficient	**RPE (no APF reported)** **LEV**	Minimum of 12 measurements is required to validate the RCR
CES 5.7 Cleaning and maintenance	[confidential]	0.01	**>1**	**>1*** **<1****	**Exposure data measurements:** 75th percentile personal, inhalable for raw materials handling in analogous process. 3 measurements. -* RPE = 20 - ** RPE= 40	N° measure: 3 GSD: not specified insufficient	**RPE (no APF reported)** **General ventilation provision to the premises**	Minimum of 12 measurements is required to validate the RCR.
GES 6: Production of Ni salts from Ni sulphate								

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
Production of Ni salts from Ni sulphate	**0.1**	**0.01**	**10**	**0.5*** (With enclosure and automation)	**Exposure data measurements:** Reasonable worst case shift mean concentration based on expert judgement and experience in other industrial settings where powders are handled. LEV is assumed rather than enclosure and automation. Exposures would be 10 x lower for entirely automated and enclosed handling of powders -* RPE = 20	RCR < 1 With RPE 20	**- RPE (no APF reported)** **- LEV**	Exposure estimation not referenced. No information available concerning the process.
GES 7: Use of nickel sulphate in the manufacturing of micronutrient additives for biogas production								
CES 7.1 nickel sulphate reception	1.026	0.01	**102.5**	**2.55 ****	**MEASE modeling (tier1 model):** -PROC8b -incidental expo -duration 4 hrs - GV -**RPE=40	RCR > 1 (MEASE modelling, RPE 40)	-**RPE (APF = 40)** **- No LEV**	RCR > 1 with RPE 40

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
CES 7.2 preparing the additive (for biogas production) powder or solutions	0.047	0.01	**4.7**	**0.23 ***	**MEASE modeling (tier1 model):** -PROC 3 -incidental expo -duration 4 hrs - LEV -**RPE=40	RCR < 1 With RPE 20	**-RPE (APF = 20)** **- LEV**	RCR < 1 with RPE 20 RPE 40 reported by the Registrant in case of emergency or inspection tasks
CES 7.3 packaging the additive product	0.023	0.01	**2.3**	**0.11 ***	Read across 75th percentile for personal exposure measurement (face) reported for an analogous operation for packaging of NiSO46H2O and nickel hydroxycarbonate-* RPE = 20	N° measure: 7 GSD: not specified	**-No RPE** **- LEV**	Minimum of 12 measurements is required to validate the RCR No RPE reported by the Registrant for this task.
CES 7.4 palletising the packaged additive	0.023	0.01	**2.3**	**0.11 ***	**MEASE modeling (tier1 model):** -PROC 3 -incidental expo -duration less than 1 hr - GV	RCR < 1 (MEASE modelling, RPE 20)	**-RPE (APF ~20)** **-No LEV**	RCR < 1 with RPE 20 Consistent with the RPE reported by the Registrant

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
					-*RPE=20			
CES 7.5 cleaning & maintenance	0.0324	0.01	**32.5**	**1.6** **0.8****	**MEASE modeling (tier1 model):** -PROC 10 -incidental expo -duration less than 1 hr - GV -*RPE=20 **RPE=40	RCR < 1 (MEASE modelling, RPE 40)	**-RPE (APF ~20)** **-No LEV**	RCR < 1 with RPE 40. Only RPE 20 reported by the Registrant for this task.
GES 8: Production of nickel-containing pigments from nickel sulfate								
CES 8.1 Raw materials handling- *reception and dissolution of NiSO4*	0.006	0.01	**0.6**	**-**	**Exposure data measurements:** Based on 7 personal exposure measurements for dosing and mixing -*RPE=20	N° measure: 7 GSD: not specified *Not clear how the average was calculated and a full data*	**- RPE (FFP 1) {approved with regard to EN 149}** **- LEV**	Minimum of 12 measurements is required to validate the RCR. High level of uncertainty associated with the exposure estimates

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
						set was not available		
CES 8.2 mixing raw materials *(preparation of granular pigment precursor)*	0.003	0.01	**0.3**	**-**	**Exposure data measurements:** Based on 8 personal exposure measurements for dosing and mixing (range) -*RPE=20	N° measure: 8 GSD: not specified	**- RPE (FFP1, 2 or 3) {approved with regard to EN 149}** **- LEV**	Minimum of 12 measurements is required to validate the RCR. No information on the distribution of the data (GSD)
CES 8.3 Drying and calcining of product	0.02	0.01	**2**	**0.1***	**Exposure data measurements:** Based on 8 personal exposure measurements assigned to charging the crucibles. -*RPE=20	N° measure: 8 GSD: not specified *Not clear how the average was calculated and a full data set was not*	**- RPE none** **- LEV**	Minimum of 12 measurements is required to validate the RCR. High level of uncertainty associated with the exposure estimates

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
						available		
CES 8.4 Dry milling	0.04	0.01	4	**0.2***	**Exposure data measurements:** Based on a single personal exposure measurement, reported for milling. Assumed to be inhalable fraction. -*RPE=20	N° measure: 1 GSD: not specified **<u>Insufficient</u>**	**RPE (FFP1 and FFP2) {approved with regard to EN 149}** **- LEV**	Minimum of 12 measurements is required to validate the RCR.
CES 8.5 Wet milling, Washing and Drying	0.004	0.01	**0.4**	**-**	**Exposure data measurements:** Based on a single personal exposure measurement for drying final product -*RPE=20	N° measure: 1 GSD: not specified **<u>Insufficient</u>**	**-RPE (FFP1 and FFP2) {approved with regard to EN 149} minimum** **- LEV**	Minimum of 12 measurements is required to validate the RCR.
CES 8.6 Blending and	0.03	0.01	**3**	**0.15 ***	**Exposure data measurements:** The highest of 5 personal exposure	N° measure: 5 GSD: not	**RPE: RPE (FFP1, 2 or 3)) {approved with regard to EN**	Minimum of 12 measurements is required to validate

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
packaging					measurements for mixing and/or Packaging -*RPE=20	specified	**149}** **- LEV**	the RCR.
CES 8.7 Cleaning and maintenance	0.34	0.01	**34**	**0.85 ***	**Exposure data measurements:** Based on a read across from a solution/suspension preparation operation in the catalyst industry. 3 personal measurements for solution make up. Range: 0,027-0,46 -*RPE=20 **RPE=40	N° measure: 3 GSD: not specified **Insufficient**	**- RPE (RPE {half face mask (HEPA filter) or FFP 1, 2 or 3}** **- Local and general exhaust ventilation**	Minimum of 12 measurements is required to validate the RCR.
GES 9: Selective Plating with Nickel Sulphate								
CES 9.1 Use of nickel sulphate in selective plating	0.047	0.01	**4.7**	**0.23 ***	**Exposure data measurements:** Highest of three personal exposure Measurements. Represent exposure to Ni from a NiSO4 selective plating system -*RPE=20	N° measure: 3 GSD = 4.3 **Insufficient**	**RPE: (APF 20)** - Computer-driven brush plating will be used wherever possible to replace the manual operation. Otherwise	Minimum of 12 measurements is required to validate the RCR.

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
							portable LEV.	
CES 9.2 Cleaning and Maintenance Industrial use	0.342	0.01	**34.2**	**0.85** **	**MEASE modeling (tier1 model):** -PROC 10 -Industrial use -Ni content 5-25% -non dispersive use -incidental -duration 1h -GV -*RPE=20 -**RPE=40	RCR < 1 (MEASE modelling, RPE 40)	**RPE (APF 10 or 20)** **- Local and general exhaust ventilation.**	RCR < 1 with RPE 40 Only RPE 20 proposed by the Registrant for this task.

CES (Contributing Exposure Scenario)	**Inhalation Exposure** **(mg Ni/m^3)**	**DNEL** **mg Ni/m^3**	**RCR** **Tier 1**	**RCR** **Tier 2**	**Methods for calculation of** **Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
CES 9.2 Cleaning and Maintenance Professional use	0.428	0.01	**43**	**1.07 ****	**MEASE modeling (tier1 model):** -PROC 10 -Professional use -Ni content 5-25% -non dispersive use -incidental -duration 1h -GV -*RPE=20 -**RPE=40	RCR > 1 (MEASE modelling, RPE 40)	**RPE (APF 10 or 20)** **- Local and general exhaust ventilation.**	RCR > 1 with RPE 40
GES 10: Formulation of Products for Surface Treatment of Anodised Aluminium Sheets								
CES 10.1 Preparation of colorant and sealant formulations	0.114	0.01	**11.5**	**0.57 ***	**MEASE modeling (tier1 model):** -PROC 8 -Ni content 5-25% -non dispersive use -incidental -duration 1h	RCR < 1 avec RPE 20 (MEASE modeling)	- **RPE:** (APF 20) - **LEV.**	RCR < 1 with RPE 20 consistent withRPE of 20 reported by the Registrant for this task

CES (Contributing Exposure Scenario)	**Inhalation Exposure (mg Ni/m^3)**	**DNEL mg Ni/m^3**	**RCR Tier 1**	**RCR Tier 2**	**Methods for calculation of Exposure**	**Confidence in the RCR**	**RMM and PPE (Registrant)**	**Remarks**
					-LEV - -° RPE = 10 *RPE=20 **RPE=40			
CES 10.2 Cleaning & Maintenance	0.324	0.01	**32.5**	**3.2°** **1.7*** **0.8****	**MEASE modeling (tier1 model):** -PROC 10 -Ni content 5-25% -non dispersive use -incidental -duration 1h -GV -° RPE = 10-*RPE=20-**RPE=40	RCR < 1 (MEASE modelling, RPE 40)	**-RPE (APF 10 or 20)** **- Local and general exhaust ventilation.**	RCR< 1 with RPE 40. Only RPE of 20 is proposed by the Registrant for this task
GES 11: Surface Treatment of Anodised Aluminium Sheets								
CES 11.1a Surface treatment (cold & hot sealing) as dipping	0.001	0.01	**0.1**	-	**MEASE modeling (tier1 model):** 90th percentile exposure modeled exposure estimate using MEASE for PROC 13 (Ni content 1-5%, incidental exposure, inclusion into matrix, duration 8 hours, LEV)	RCR < 1 (MEASE modelling, no RPE)	**- RPE (APF 20)** **- LEV**	

CES (Contributing Exposure Scenario)	Inhalation Exposure (mg Ni/m^3)	DNEL mg Ni/m^3	RCR Tier 1	RCR Tier 2	Methods for calculation of Exposure	Confidence in the RCR	RMM and PPE (Registrant)	Remarks
CES 11.1b Surface treatment (cold & hot sealing) as topping-up	0.324	0.01	**34.2**	**0.8****	**MEASE modeling (tier1 model):** 90th percentile exposure estimate using MEASE for PROC 10 { Ni content 5- 25%, incidental exposure, nondispersive use, duration 1 hour, general ventilation} ° RPE 10 * RPE 20 **RPE 40	RCR < 1 (MEASE modelling, RPE 40)	**- RPE (APF 20)** **- LEV**	RCR< 1 with RPE 40 Only RPE of 20 is proposed by the Registrant for this task
CES 11.2 Fabrication	0.057	0.01	**5.7**	**0.57°** **0.28***	**MEASE modeling (tier1 model):** 90th percentile exposure modeled exposure estimate using MEASE for PROC 24 (Ni content <1%, incidental exposure, non-dispersive use, duration 8 hours, LEV) ° RPE 10 * RPE 20	RCR < 1 (MEASE modelling, RPE 20)	**- No RPE reported** **- LEV**	no RPE reported by the Registrant
CES 11.3 Cleaning & Maintenance	0.342	0.01	**34.2**	**0.8****	**MEASE modeling (tier1 model):** 90th percentile exposure estimate using MEASE for PROC 10 { Ni content 5-25%, incidental exposure, nondispersive use, duration 1 hour, general ventilation} ° RPE 10 * RPE 20 **RPE 40	RCR < 1 (MEASE modelling, RPE 40)	**- RPE (APF 10 or 20)** **- Local and general exhaust ventilation.**	RCR < 1 with RPE 40. Only RPE of 20 is proposed by the Registrant for this task