# DRAFT ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION FOR NICKEL OXIDE

**Substance name: Nickel oxide**

**EC number: 215-215-7 and 234-323-5**

**CAS number: 1313-99-1 and 11099-02-8**

**Submitted by: FRANCE (Anses - French Mandated National Institute)**

**Date: April 2014**

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Nickel monoxide (NiO) 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 2). 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 intermediates have been excluded at this stage. In a first approach, risk management option analysis (RMOA) are carried out on nickel sulphate ($NiSO_4$) and NiO as both salts cover substantially the majority the uses reported for nickel compounds which may facilitate extrapolation to other compounds in a potential second approach.

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

Amongst the four existing forms of NiO, 3 are chemical grades: green nickel oxide, green nickel oxide with cobaltous oxide impurity, and black nickel oxide with impurities. Nickel oxide sinter is not considered by the registrant as a chemical form: it is of less purity and is a raw material for the stainless steel industry (see section 2.3 for discussion). Main impurities reported in the different forms of NiO include cobaltous oxide, copper, iron, sulfur, nickel hydroxide, and/or cobalt.

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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

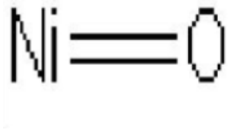
Table 1: Substance identity

| | |
|---|---|
| **Public Name** | nickel oxide |
| **EC number** | 215-215-7 and 234-323-5 |
| **EC name** | nickel oxide / nickel monoxide |
| **CAS number (in the EC inventory)** | 1313-99-1 and 11099-02-8 |
| **CAS name** | nickel oxide |
| **IUPAC name** | oxonickel |
| **Index number in Annex VI of the CLP Regulation** | 028-003-00-2 |
| **Molecular formula** | NiO |
| **Molecular weight range** | 74.6928 |
| **Synonyms** | nickel oxide (NiO), black nickel oxide, green nickel oxide, mononickel oxide, nickel monoxide, nickelous oxide, nickel (II) oxide, nickel (2+) oxide, Bunsenite |

The black nickel oxide and the green nickel oxide correspond of the allotropic forms of the nickel oxide. The registrant reported only the name and other identifiers of nickel monoxide. However, nickel oxide also exists in other forms which are nickel dioxide ($Ni_2O$, CAS n°12035-36-8) and dinickel trioxide ($Ni_2O_3$, CAS n°1314-06-3). Both are not registered under REACH neither reported in the current registration. This is a potential substance identification issue that may be assessed under dossier or substance evaluation.

In the registration dossier, all physical-chemical properties were performed on green nickel oxide except the water solubility which was performed on both green and black allotropic forms. Most physical-chemical properties tested can be considered similar for green and black nickel oxide, except the granulometry that has not been performed for the black nickel oxide.

**Structural formula:**



## 1.2 Classification and labelling

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

Table 2. Harmonized classification of NiO 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) | | |
| 028-003-00-2 | Nickel oxide | 215-215-7 | 1313-99-1 | Skin Sens. 1<br>Carc. 1A<br>STOT RE 1<br>Aquatic chronic 4 | H317<br>H350i<br>H372<br>H413 | none | none |

NiO is not classified for any physical-chemical properties.

## 1.3 Information on the REACH registration status

### 1.3.1 Registration status

NiO is registered in accordance with Article 10 (i.e. full registration dossier), with article 17 (i.e. registration of on-site isolated intermediates - OSII) and also with Article 18 (i.e. registration of transported isolated intermediates - TII): [confidential] full dossiers, [confidential] TII dossiers and [confidential] OSII dossiers are registered under REACH, with a total of 54 registered dossiers all together as a joint submission (last check dated January 2014). 3 registrants have registered both a full dossier and a dossier of transported isolated intermediate. The enclosed risk assessment has been carried out on the last available update from the lead registrant, dated 10 May 2013. Indeed a common chemical safety assessment has been carried out between all registrants and the related chemical safety report (CSR) is only available on the registration dossier of the lead registrant.

Nickel oxide is registered with a public tonnage band of 10,000 to 100,000 tons 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:

A.M.P.E.R.E. ALLOYS 12 Mail Joliot Curie, 95310, SAINT-OUEN-L'AUMONE VAL D'OISE, France

A.M.P.I.S.r.l. Strada Anulare Torre 4, 20090, San Felice - Segrate Milan, Italy

Advanced Refining Technologies GmbH In der Hollerhecke 1, 67547, Worms, Germany

ALBEMARLE CATALYSTS COMPANY B.V. Nieuwendammerkade 1-3 PO Box 37650, 1030 BE, Amsterdam, Netherlands

Avantor Performance Materials B.V. - OR Teugseweg 20, 7418 AM, Deventer, Netherlands

AXENS SA 89, boulevard Franklin Roosevelt B.P. 50802, F-92508, Rueil-Malmaison Cedex France, France

BASF Nederland B.V. Groningensingel 1 Postbus 1019, 6801, MC Arnhem, Netherlands

BASF SE Carl-Bosch-Str. 38, 67056, Ludwigshafen am Rhein Rheinland-Pfalz, Germany

Bootman Chemical Safety Ltd Diss Business Centre, IP214HD, Diss Norfolk, United Kingdom

Cambridge Environmental Assessments Battlegate Road Boxworth, CB23 4NN, Cambridge Cambridgeshire, United Kingdom

CATALYST RECOVERY EUROPE S.A. 420, Route de Longwy, 4832, Rodange, Luxembourg

Chemieservice Dr. Stoeber (N) Kefersteinstrasse 6, D-06110, Halle, Germany

Chemservice S.A. (H5P7) 5, an de Laengten, 6776, Grevenmacher, Luxembourg

Chevron Phillips Chemicals International N.V. - OR CPC Brusselsesteenweg 355, 3090, Overijse, Belgium

Clariant Produkte (Deutschland) GmbH Am Unisys-Park 1, 65843, Sulzbach am Taunus, Germany

colorobbia italia spa via Pietramarina 53 via Pietamarina 123, 50053, Sovigliana - Vinci Firenze, Italy

CRI Catalyst Company Belgium NV Ringvaartweg-Wondelgem, 4, B-9032, Wondelgem, Belgium

CRI Catalyst Leuna GmbH Gebaude 8322 Am Haupttor, D-06237 Leuna, Leuna, Germany

DHI (OR17) Agern Allé 5, 2970, Horsholm, Denmark

Dr. Knoell Consult -OR- A1 Dynamostr. 19, 68165, Mannheim, Germany

EPCOS OHG Siemensstrasse 43, 8530, Deutschlandsberg, Austria

EURECAT FRANCE SAS 121 ave Marie Curie ZI Jean Jaurès, 07800, La Voulte sur Rhône, France

Euro Support Manufacturing Czechia, s.r.o. Záluží 1, 436 70, Litvínov, Czech Republic

Evonik Degussa GmbH Rellinghauser Straße 1 - 11, 45128, Essen, Germany

Ferro (Great Britain) Limited Nile Street Burslem, ST6 2BQ, Stoke-on-Trent, United Kingdom

G.Vogler BV Lentedans 51a, 2907AX, Capelle a/d IJssel, Netherlands

GE thermometrics (UK) Limited CROWN INDUSTRIAL ESTATE, PRIORSWOOD ROAD, TA2 8QY, Taunton SOMERSET, United Kingdom

GRACE GmbH & Co. KG In der Hollerhecke 1, 67545, Worms, Germany

GRACE GmbH & Co. KG (OR 4) In der Hollerhecke 1, 67547, Worms, Germany

H.C. Starck GmbH Im Schleeke 78-91, 38642, Goslar, Germany

Haldor Topsoe A/S Nymøllevej 50, DK28000, Lyngby, Denmark

Harlan Laboratories Ltd 24 Shardlow Business Park London Road, DE72 2GD, Shardlow Derbyshire, United Kingdom

Hellenic Petroleum S.A. 8A Chimarras St, GR 151 25, Maroussi Attica, Greece

INCO Industria Colori spa via Montebonello 19/21, 41026, Pavullo n/F (MO), Italy

INEOS Commercial Services UK Ltd Hawkslease Chapel Lane, SO437FG, Lyndhurst Hampshire, United Kingdom

Instytut Nawozów Sztucznych Aleja Tysiąclecia Państwa Polskiego 13A, 24-110, Puławy, Poland

Jemmtec Ltd T/A Magma Ceramics Low Road Earlsheaton, WF12 8BU, Dewsbury W Yorks, United Kingdom

Johnson Matthey Chemicals GmbH Wardstrasse 17, D-46446, Emmerich, Germany

Johnson Matthey PLC 5th Floor, 25 Farringdon Street , EC4A 4AB, London, United Kingdom

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

REPSOL S.A. Méndez Álvaro, 44, 28045, Madrid Madrid, Spain

Rivendell International Rivendell House, Co. Meath, Stamullen Co. Meath, Ireland

Rivendell International Rivendell House, Co. Meath, Stamullen, Ireland

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

Todini GmbH Dr. Alfred-Herrhausen-Allee 12, 47228, Duisburg, Germany

TRICAT GmbH Catalyst Service Bitterfeld Tricatstrasse, 06803, Bitterfeld-Wolfen Saxonia-Anhalt, Germany

TSGE Concordia House, St James Business Park Grimbald Crag Court, HG5 8QB, Knaresborough North Yorkshire, United Kingdom

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

Univar BV Blaak 333, 3011 GB Rotterdam, Rotterdam, Netherlands

UOP N.V. Noorderlaan 147, B-2030, Antwerp, Belgium

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

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

Xstrata Nikkelverk AS Vesterveien 31, 4606, Kristiansand, Norway.

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

No previous risk assessment has been specifically carried out on nickel oxide.

### 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 (nickel metal, nickel sulphate, nickel dichloride, nickel dinitrate and nickel carbonate) but not for nickel oxide specifically. For further information on this risk assessment, please refer to the RMOA on nickel sulphate or the risk assessment report (RAR) itself.

However some pieces of information can be found on NiO in the available RAR dated May 2009 since several of the five covered compounds were at that time also involved in uses that are reported for nickel oxide, for instance catalysts manufacturing.

Moreover the following statements / conclusions from the RAR, that cover all nickel compounds because of their similar classification under Anne VI of the CLP regulation, are relevant for NiO. The main risks identified by the risk assessment reports that need to be addressed are occupational inhalation exposure. Catalyst production which is the main use of nickel oxide in term of used volume was one of the scenario considered to be at risk for nickel compounds in the RAR.

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:

- 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.

### 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 identified in the risk assessment report, 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 nickel sulphate and nickel chloride 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 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. As for the RAR dedicated to human health, this assessment does not cover especially NiO. However, several of the five covered compounds were at that time also involved in uses that are reported for nickel oxide, for instance catalysts manufacturing. Some information and conclusion could be applied to NiO.

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.

- 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 $EQS_{\text{freshwater sediment}}$ 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.

Anses 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 and focuses only on direct exposure and and human health.

## 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 for some of them. Therefore a number of general and targeted legislative controls are currently in place in the EU. Only those that explicitly cover nickel oxide 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 nickel oxide is provided in section 4 of this document.

### 1.5.1 EU general legislations on dangerous chemicals

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 NiO 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 NiO 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 $\mu g/cm^2$/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 $\mu g/cm^2$ / 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.

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, 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.

The following environmental legislations may directly or indirectly cover Ni compounds including NiO.

- 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)[2].
- Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (Ground water Directive).
- 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.

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[2] 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

### 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 2001 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 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.

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.

#### 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, which take into account not only risk assessment, but also socio-economic and technical feasibility 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 3 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 3. Informal Occupational Exposure Limits (OEL) for nickel compounds in various countries[3]

| **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**[4] | 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 dust | nickel compounds |
| | 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) |

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[3] 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

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

| | | |
|---|---|---|
| **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**[5] | 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 reports shared by the Nickel Institute and its members in the frame of a consultation carried out by France. Registrants of nickel oxide are members of the Nickel Institute and have thus contributed to the consultation.

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 and thus to be 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

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[5] 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.

for authorisation dossier in case that would be required for the uses of nickel oxide (NiO). Four socioeconomic analysis (SEA) have been carried out and shared with France for the purpose of this RMOA; they cover the production and use of pigments, frits, glass and catalysts. Other documents have also been shared on uses description, volumes estimations, etc.

The International Nickel Study Group reports that global primary nickel usage in 2012 in the EU27 was 331,000 tons. 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 in 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 tons (Reck et al. 2008)[6]. However no specific information on the tonnage of NiO is reported. This total tonnage is significantly greater than the value of 22,165 tons (all forms included) of nickel that was reported in the RAR and which is based on 1994 data.

The volumes estimated for NiO 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 4 in order to translate a GES in one "industrial" generic use that is further described in this chapter.

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[6] 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

Table 4. Correlation table between the GES denomination provided in the registration dossiers and the uses discussed in this document.

| **Generic Exposure Scenario** | **Uses discussed in the RMOA** |
|---|---|
| Manufacture of nickel oxide | |
| GES 1. Production of NiO-containing catalysts and catalyst precursors | Production and use of NiO catalyst precursors |
| Downstream uses of nickel oxide | |
| GES 2. Industrial use of powdered and shaped nickel oxide containing catalysts and catalyst precursors (A) | Production and use of NiO catalyst precursors |
| GES 3. Industrial use of nickel oxide-containing catalysts precursors for the production of catalysts containing other nickel compounds (B) | |
| GES 4. Production of nickel based powders from nickel oxide containing materials | (not further developed in section 2)* |
| GES 5. Production of nickel-containing electronic and thermally functioning ceramics | (not further developed in section 2)* |
| GES 6. Production of nickel-containing enamel frits | Production of nickel-containing enamel frits |
| GES 7. Production of nickel-containing pigments | Production of nickel-containing pigments |
| GES 8. Production of nickel-containing glass | Production of nickel-containing glass |
| GES 9. Stainless, special steels and special alloys manufacturing (SA4) | (not further developed in section 2)* |
| GES 10. Production of NiZn cores and solids from NiO powder | (not further developed in section 2)* |

* No information has been provided in the frame of the consultation, therefore the use description is not fully developed in section 2 of this document. However those uses are covered by the risk assessment in section 3 and the discussion on the potential risk management measures in section 4.

In the CSR, GES 1 is described as a manufacture step in the life cycle of the substance described with the following free short title "Production of nickel oxide -containing catalysts and catalyst precursors from precursors prepared by impregnation with or precipitation of Ni compounds, and by regeneration of nickel oxide and/or (sub)sulphide containing catalysts". It is also further described as "production of powdered catalysts or production of shaped catalysts (extrudates, pellets, tablets, spheres, encapsulated powders) from powdered raw materials". In the CSR, GES 2 and GES 3 are described as a use (intermediate use) in the life cycle of the substance with the titles reported in table 3 without additional explanation. Contrary to Industry's view, Anses doesn't consider NiO catalyst precursors as end-products but as an intermediate step in the production process of the Ni containing catalyst which is considered as the final end-product that provides the catalytic property.

In the SEA document provided by Industry, information is given on the manufacture of a NiO (containing) catalyst precursor and its subsequent use that is to say the preparation of the final end product which is the Ni containing catalyst. From Anses interpretation, this covers GES 1 and GES 2 but no information is provided so far in any available document to explain what GES 3 is really; one may understand that other catalysts could associate other metal oxides to NiO (such as molybdenum, cobalt , etc.) but no clear difference has been made between those types in the SEA. Therefore GES 1, 2 and 3 have been grouped in section 2.3 under the same use "production and use of NiO catalyst precursors" in order to provide the most consistent explanation available.

## 2.1 Volumes manufactured and used in the EU

### 2.1.1 The data quality issue

Due to a small amount of European producers, confidentiality issues were raised on volumes used making the Nickel Institute unable to find reliable data on NiO production and uses in the EU. 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[7] (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 as downstream users often buy a nickel chemical as an intermediate to produce another nickel chemical, as is the case in particular in the catalyst industry and the batteries' sector, were some nickel chemicals are produced in-house, from another nickel containing chemical.

### 2.1.2 Estimated volumes

Information on NiO 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). Note that NiO is not manufactured in the EU in order to be sold as such on the market.

Based on Eurostat data (mass flows), the Nickel Institute tried to estimate tonnages imported, exported and used within the EU but highlighted the difficulty of the exercise according the data quality issue stated above. It is estimated that 317 t/y are imported, 1,119 t/y are exported and 2,823 t/y are used in catalytic, frits-pigments-glass sectors plus 1,648 t/y used to manufacture other nickel salts (chloride, sulphate, sulphamate) (in total 4,471 t/y are used within the EU). Thus 4,154 t/y would be manufactured within the

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[7] 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)

EU. Being incomplete and seen not reliable, those data are not considered further in this document.

Each registration dossier of NiO 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 5): on a total volume of 69,840 tons NiO per year expected to be used within EU, 7,921 tons are manufactured in the EU (i.e. 11,3%) and 61,919 are imported (i.e. 88,7%). No exportation 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[8].

Table 5. Data on NiO aggregated volumes from the registration dossiers (t/y)

| | Registrations | | |
|---|---|---|---|
| Type | Full<br>Art. 10 | Intermediate<br>Art. 18 | Total |
| Total number | [confidential] | [confidential] | 54 |
| Tonnage band | 10,000 – 100,000 | | |
| Tonnage total (actual) | 12,560 | 57,280 | 69,840 |
| Tonnage manufactured | 2,570 | 5,351 | 7,921 |
| Tonnage imported | 9,990 | 51,929 | 61,919 |
| 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 NiO registrants and only one CSR is provided by the lead registrant; this CSR reports that [confidential] NiO would be manufactured per year in the EU considering only GES 1 ([confidential] tons taking into account GES 1, 2 and 3 as proposed by Industry) and [confidential] tons NiO would be used. Those data are not seen relevant enough to be further considered in this RMOA.

By comparing both sources from the registration dossiers (Iuclid file part and CSR part), volumes manufactured in the EU are not consistent ([confidential] tons in the CSR versus 7,921 tons in the Iuclid file) whereas volumes used in the EU appear to be closer ([confidential] tons in the CSR versus 69,840 tons in the Iuclid file).

In conclusion and as illustrated by table 6, it is not possible to get a clear picture of the real volumes of NiO imported, manufactured, exported and used within the EU. Available data are not consistent together. The high tonnage reported in the registration dossiers may probably cover the important but unknown volume of nickel sinter oxide used for stainless steel and special alloys manufacturing (see introductive part of section 2) and may partly explain the observed difference between sources.

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

Table 6. Overall comparison of available data on NiO volumes manufactured, exported and used within the EU (t/y)

| | Eurostat | Registration dossiers |
|---|---|---|
| Volumes manufactured within the EU | 4,154 | 7,921 |
| Volumes used within the EU | 4,471 | 69,840 |
| Volumes exported | 1,119 | 0 |
| Volumes imported | 317 | 61,919 |

In the following section, only the volumes provided by Industry in the available SEA are considered (~6,000 tones used per year); It should be kept in mind that they don't cover all the uses. In particular, the use of NiO for stainless steel and special alloys manufacturing, which is expected to be very high, is not included.

## 2.2 Production of nickel oxide

Chemical grade of NiO is not produced in Europe but imported, especially from Canada, China and Philippines. For that reason the registrants didn't provide any corresponding GES in the registration dossiers except GES 1 "Production of NiO-containing catalysts and catalyst precursors".

As this NiO production within GES 1 is seen by Industry as an intermediate use (i.e. produced from other salts and consumed within the whole process of catalyst manufacturing), it may be not interpreted by registrants as a "formal" NiO production under REACH and thus not reported in NiO manufacturing data. Depending on the interpretation of the intermediate status, this would also apply for NiO that is produced by chemical reaction from nickel hydroxycarbonate and then used in the manufacturing of pigments, frits and glass. This gap may partly explain the large differences of volumes observed between sources in section 2.1.

For clarity reasons, these specific NiO productions are considered and explained in the relevant uses descriptions in section 2.3.

## 2.3 Downstream uses of nickel oxide

### 2.3.1 Distinction made between chemical and metallurgical nickel oxide grades

The NiO registrants distinguish the chemical grade and the metallurgic grade (nickel sinter oxide).

NiO chemical grade is relatively pure material for specialty applications (catalysts for instance) and has a wide range of applications in diverse industrial sectors. The metallurgical grade is a less pure material that is mainly used for the production of alloys and NiZn cores and solids (see GES 9 and 10). The registrants' point of view on nickel sinter oxide is not clear and the proposed distinction is not sufficiently argued. Indeed on one side registrants consider nickel sinter oxide as a non-chemical grade that may not be covered by the REACH regulation, but on the other side provide the registration dossiers with the uses of nickel sinter oxide (i.e. GES 9 and 10). From a quick literature's review, it appears that powder nickel sinter oxide is pressured and heated just below the melting temperature in order to produce a particular NiO containing material which exhibits similar physicochemical and mechanical properties as nickel metal and may then be used for alloy production by adding other metals. Even if no chemical reaction occurs during this process (molecular reorganisation), Anses considers that no distinction appears relevant under REACH between the two NiO grades and that nickel sinter oxide should be fully covered in the registration dossiers; this has been done by precaution by the registrants (GES 9 covered in the CSR).

#### 2.3.1.1 Reported uses of black and green nickel oxide

Reported uses of the NiO chemical grade are the following: nickel based powders, nickel-containing electronics and thermally functioning ceramics (ceramics for solid oxide fuel cells and thermistor products), nickel-containing frits, pigments and glass, nickel zinc cores and solids produced from nickel oxide powder, metallic nickel as pellets or powder via carbonyl refining, other nickel chemicals.

The primary use of black nickel oxide, due to its purity, is for high quality nickel zinc cores, used in ferrite manufacturing. It is used in electronic and thermally functioning ceramics like varistors and thermistors which are used in high quality electronic materials. Others include the use as component of catalysts for steam reforming, hydroprocessing, amination and sulfur trapping, but the production of this catalyst doesn’t occur in Europe. Black nickel oxide is also used in inorganic colour pigments to colour enamels, ceramic glazes, paints or plastics and frits for steel enamelling, glass colouring and ceramic glazes.

Green nickel oxide is used in a variety of electronic applications including ferrites and electronic and thermally functioning ceramics (thermistors, varistors and solid oxide fuel cells). Also like the black nickel oxide, it is used extensively as colourants in glass, in frits and pigments (to produce blues, violet, greens, browns, and yellows). Green nickel oxide is also used as for the production of nickel catalysts more specific in the preparation of oxidation and reduction catalysts.

In this document the use of NiO in catalysts is referred to as NiO containing catalyst precursors or NiO catalyst precursor and no difference is made between black and green NiO as uses are similar.

#### 2.3.1.2 Used volumes provided by Industry in SEA

The Nickel Institute provided, from internal consultation, the following estimation of the used volumes for four main industrial applications of NiO (see table 7). The intermediate status is the Anses interpretation (see the relevant subsections below), based on the description of uses given by the nickel institute.

Table 7. NiO uses and volumes (t/y) by main application (source: Nickel Institute), and volumes possibly with the interpreted intermediate status (Anses view)

| **Use** | **Full tonnage** | **Tonnage as non-intermediate** | **Tonnage as intermediate** |
|---|---|---|---|
| Production and use of NiO catalyst precursors | 5,400 | 0 | 5,400 |
| Use of nickel oxide for the production of nickel based powders | Not known | | |
| Use of nickel oxide for the production of nickel-containing electronics and thermally functioning ceramics | Not known | | |
| Use of nickel oxide for the production of nickel-containing enamel frits | 450 | 450 | 0 |
| Use of nickel oxide for the production of nickel-containing pigments | 350 | 175* | 175* |
| Use of nickel oxide for the production of nickel-containing glass | [confidential] | [confidential] | 0 |
| Use of nickel oxide for the production of stainless steel, special steels and special alloy | Not known, expected high | | |
| Use of nickel oxide for the production of NiZn cores and solids from NiO powder | Not known | | |
| **Total tonnage** | 6,215 | 640 | 5,575 |

* as no information is available on the intermediate and non-intermediate tonnage, the provided volume has been equally divided between both status, arbitrarily.

Therefore the Nickel Institute reports an approximate total used volume of ~6,000 tons per year within the EU for 4 uses over 8, without considering the tonnage used for stainless steel and special alloys manufacturing which is expected very high.

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

### 2.3.2 Production and use of nickel oxide catalyst precursors

An extensive industry consultation has been carried out by the Nickel Institute with the European Catalyst Manufacturers Association (ECMA) and their members in order to cover this main use of NiO. Consultation consisted of a combination of written questionnaires and meetings with both groups of companies and individual companies. A representativeness of about 75% of total NiO catalyst precursor production (EU27 and Norway) was represented in the responses.

In this section, NiO refers to "NiO catalyst precursor". NiO is produced during the manufacture of nickel compound containing catalyst precursors and catalysts. The final catalytically active species is in many cases nickel metal or nickel sulfide or subsulfide.

The catalyst applications (steam reforming, hydroprocessing, amination, sulfur trapping) determine the production route and the raw materials to be used. Depending on the various applications, catalysts are produced in different ways but one similarity is that NiO is always used, not as a starting material but it arises along the production process. This means that NiO is never used as a pure substance, but in combination with other substances in the catalyst or catalyst precursor. NiO is present as one of the components of the catalyst mixture.

NiO can be used in automobile catalysts to control the smell from $H_2S$ in fuel (NiO reacts with $H_2S$ to give NiS which further reacts with $O_2$ to give NiO and $SO_2$ which has significantly lower odour than $H_2S$) however the production of this type of catalyst is not carried out within Europe.

All nickel substances used in catalyst industry and consequently the NiO present in catalyst precursors, are only used within chemical or refinery industry conditions. Nickel substances are not present in consumer end-products. No information is available on the number of workers potentially exposed via the downstream use.

The worldwide use of nickel (all compounds included) for catalysts is about 15,000 t/y Ni, of which 29% is used in Europe by downstream users (4,350 t/y). According to an internal study based on the mass flow analysis, the Nickel Institute considers the nickel used for catalyst production in Europe twice as high (59% of the worldwide estimation) i.e. 8,850 t/y.

The raw nickel chemicals used in the process are transformed into NiO during the catalyst manufacturing process and are considered as an intermediate by Industry. Nickel nitrate is the main nickel compound used in Europe to manufacture nickel containing catalysts (52.6% of the total use, ~4,600 t/y). The four other nickel compounds are nickel/aluminium alloy (18.8%, i.e. ~1,600 t/y), nickel hydroxycarbonate and nickel oxide (16.8%, i.e. ~1,400 t/y) and nickel chloride (11.6%, i.e. ~1,000 t/y). This volume estimation of NiO is not taken into account as a further refined calculation (5,400 t/y) has been provided in the frame of a SEA and considered more relevant.

#### 2.3.2.1 The manufacture of nickel oxide catalyst precursors

Catalyst formulation is normally closely held proprietary technology. Catalysts can be produced metalurgically, by melting nickel with other metals and casting the mixture (no need for nickel salts and thus nickel oxide). Alternatively, catalysts can be produced chemically either by precipitation and calcinations and depositing a thin coating onto a substrate, often a ceramic substrate, either by impregnation of a support substrate (contacting a solution with a solid) and subsequent calcinations (impregnation is only possible with soluble nickel compound solutions).

The catalyst applications (steam reforming, hydroprocessing, amination, sulfur trapping) determines the production route and the raw materials to be employed. Depending on the various applications, catalysts are produced in different ways that are tailored to yield the optimal product for a particular service. Hence, depending on whether impurities need to be removed from the gas stream, or what function is required from the catalyst, either a precipitated or an impregnated catalyst will be used.

Figure 1 illustrates and synthesizes the whole manufacturing process which is a complex sequence of various chemical reactions including transformation reactions from substances to other substances and several redox reactions depending on the final uses and customers' needs. The whole description process of catalyst manufacturing is provided in the SEA made available by the Nickel Institute; the current document only reports the main reasoning elements that are needed for the understanding of the NiO functionalities and the RMOA purpose.

Whatever the production route is, the main important point is that NiO is never used as a starting material in the production process, but arises along the production process and, depending on the case, is further converted to sulfides and subsulfides (refinery catalysts) or reduced to nickel metal. That is why NiO is used to manufacture "catalyst precursors" that are then used as catalysts at the plant sites of the catalyst precursors' customers. Indeed only nickel metal provides the catalyst property that is required for the application. NiO as such is always connected to nickel metal containing catalysts, as it plays a key role in ensuring safe transport and handling (passivation) as well as for attachment of the metal particles to the catalyst support (enabling high surface area materials ensuring limited use of raw materials).

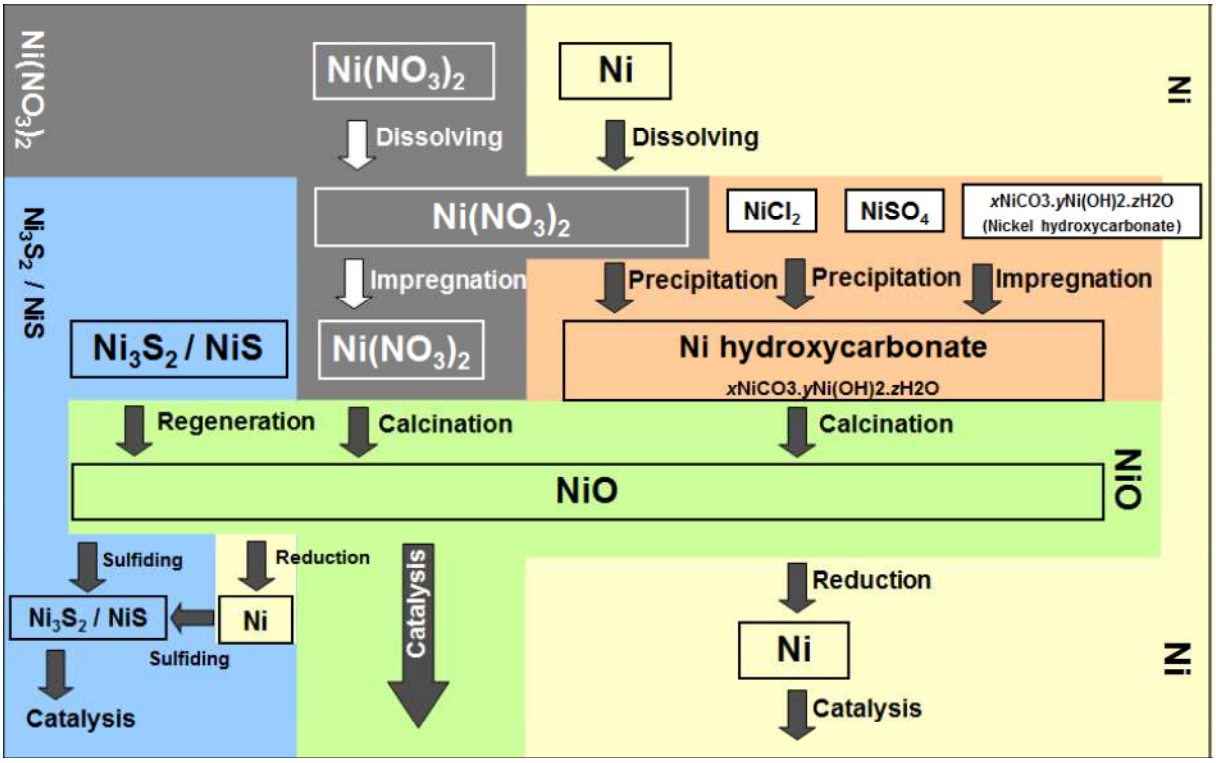

Figure 1. Illustration of the chemical routes for manufacturing Ni containing catalysts (Source: Industry SEA report 2013)

The precipitation route uses nickel hydroxycarbonate which is a solid material (hydroxycarbonate route); a precipitated catalyst has a higher nickel surface area and is therefore a more active catalyst than an impregnated one, which has a lower nickel surface area.

Either nickel metal (Ni), e.g. briquettes, is used as a raw material and this can be transformed into nickel dinitrate or nickel dichloride or nickel sulfate by dissolving into the relevant acids (nitric acid, hydrochloric acid, sulfuric acid). Or either these salts (nickel dinitrate, nickel dichloride and nickel sulfate) are bought as raw materials. Another possible starting material is nickel hydroxycarbonate, it is either bought in as a raw material (i.e. powder) or it is generated in-situ by precipitation from a nickel solution, i.e., usually the nitrate, chloride or sulfate with a basic solution (containing salts such as sodium carbonate with or without sodium hydroxide).

Nickel metal needs first to be dissolved to produce nickel salts (nickel dinitrate, nickel sulfate, nickel dichloride) that are then use within the process. Nickel dinitrate is directly used within the process by impregnation onto a support substrate and then calcinated in order to transform into NiO or precipitated with a basic solution to produce nickel hydroxycarbonate. Nickel dichloride and nickel sulfate are used to produce nickel hydroxycarbonate. The support substrates used for impregnation or precipitation are either an oxide such as amorphous silicon dioxide (kieselguhr) either aluminium oxide (hydrated alumina). Once deposited on/in the substrate, nickel hydroxycarbonate is calcinated in order to be transformed into NiO.

At the end of this process step, NiO is present as a component of the catalyst mixture. NiO catalyst precursors are well established and fairly mature, but there remains scope for improvement. This might be by formulation (e.g. to control particle size, enhance tolerance, improve selectivity etc.). Other developments can include the physical form of the catalyst e.g. pellet size and shape, pore structures or the use of structured packings using wash coat formulations.

NiO containing catalyst precursors contain between 1–95% NiO whereas shaped NiO containing catalyst precursors contain 1–35% NiO, depending on the catalyst specifications required by the downstream user.

#### 2.3.2.2 Preparation for downstream use of the nickel oxide containing catalyst

NiO doesn’t provide any catalytic properties. In order to transform the nickel oxide catalyst precursors into the active catalyst, NiO needs:

- either to be reduced to nickel metal (this is done for steam reforming catalysts) at the catalyst manufacturing site (ex situ) or in the reactor of the chemical industry, i.e. at the downstream user site (in situ),
- either to be sulfided to NiS or $Ni_3S_2$ (this is done for the hydroprocessing catalysts) in the reactor of the chemical industry or refinery of the downstream user or at a catalyst service company site.

Reduction step: ex-situ at the catalyst manufacturing site plus passivation for transport

In this case the NiO is totally reduced to Ni metal at the catalyst manufacturer or service company site. The resulting catalyst is potentially self-heating and must be stabilised in order to prevent catalyst deterioration and ensure safe transportation. This is done by forming a thin surface layer of NiO on the Ni (by reaction with oxygen). This process is called passivation.

The passivated catalyst precursor is then transported to the customer/downstream user and loaded into the reactor. Then the NiO passivation layer is reduced with hydrogen to Ni metal. The final Ni metal catalyst is normally used for several years in the closed downstream user reactor.

Reduction step: in-situ at the customer/downstream users’ site

The NiO containing catalyst precursor is usually transported to the customer/downstream user (chemical or refinery industry site) who loads it into the catalytic reactor, which is typically done by specialised loading companies (subcontractors). Within the closed reactor, the NiO containing catalyst precursor is transformed by a reduction step (activation step) by reaction with hydrogen at elevated temperature to the final nickel metal containing catalyst. The final nickel metal catalyst is normally used for several years in the closed downstream user reactor before the catalyst is unloaded.

Sulfiding step

The NiO containing catalyst precursor is usually transported to the customer/downstream user who loads it into the catalytic reactor, which is typically done by specialised loading companies (subcontractors). This operation appears to be usually subcontracted. NiO is either directly sulfided or first reduced to nickel metal which is then sulfided with hydrogen sulfide at elevated temperature to NiS or $Ni_3S_2$ either in the reactor of the chemical industry or refinery of the downstream user or at a catalyst service company site. At catalyst service company NiO can be directly sulfided into NiS or $Ni_3S_2$ with various sulphur compounds.

### 2.3.2.3 Intermediate status of the manufacturing of catalyst (precursors) use

The intermediate status of the involved nickel species in the whole process can be interpreted as follow according to REACH articles 3(3), article 3(15) and also to the ECHA document on the clarification on the concept of intermediates under REACH[9].

REACH article 3(15) stipulates that an intermediate is "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance". According to the ECHA clarification document, as soon as the main aim of the involved chemical process is not to transform a substance into another one or the substance is not used for this main aim but rather to achieve another function or a specific property, the substances used for this activity should not be regarded as intermediates under REACH.

In the production process of NiO catalyst precursors, nickel dinitrate, dichloride and/or hydroxycarbonate are produced for and consumed in chemical processing in order to be transformed into other substances and at the end into NiO. Their use is therefore considered as an intermediate use according to REACH article 3(15).

Then when the NiO catalyst precursor is used as a nickel containing catalyst, NiO (which has been "manufactured for") is consumed in chemical processing in order to be transformed into another substance (Ni metal or NiS or $Ni_3S_2$); this reaction is intended to be complete. In first approach, this NiO use would therefore be considered as an intermediate use according to REACH article 3(15), especially as a transported isolated intermediate given that the catalyst can be transported safely only in the NiO form.

The remaining question is the interpretation of the catalyst itself (both the NiO catalyst precursor and, in the subsequent step, the nickel containing catalyst) as a substance or as an article. REACH Article 3(3) stipulates that an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. The main function of a nickel containing catalyst is the catalytic property (i.e. to activate and increase the rate of the expected chemical reaction) which is rather ensured by its chemical composition (here

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[9] 4th CARACAL meeting, 2-4 February 2010, meeting document, http://inforeach.gencat.cat/pdf/ECHA_Clarification_concept_intermediates.pdf

the nickel metal or nickel sulphide obtained from nickel oxide) than to its shape, surface or design which are also of great importance as the shape ensures the efficiency of the catalyst by optimizing the contact surface between the catalyst and the material to be treated. Indeed the “catalyst” is the substance or the composition of substances that are fixed/coated on a substrate (see figures 2 and 3) and not the substrate itself that can be interpreted as an article because its shape provides its main function. This catalyst is however not consumed during the reaction but regenerated later on. Therefore, a nickel containing catalyst may be considered as a substance or a multi-constituents substance, depending on the case and not as an article.

On this basis, the use of NiO in the manufacturing and the subsequent use of NiO catalyst precursors may be considered as an intermediate use under REACH.

Figure 2. Picture of a catalyst[10]

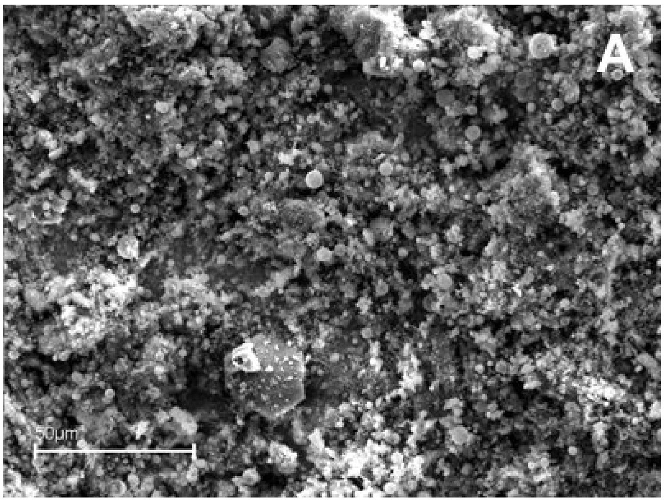

Figure 3. Picture of an alumina-magnesia based support catalyst[11]

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[10] Source http://www.ifpenergiesnouvelles.fr

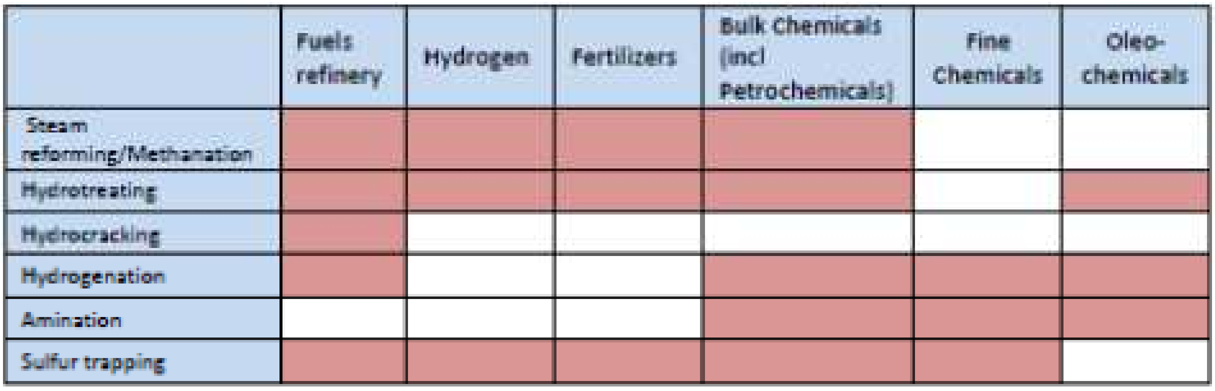
[11] Source: http://www.amiagus.com/products-7/EN/metal-based-honeycomb-structure-catalytic-unit-18.html

### 2.3.2.4 The downstream applications of nickel oxide catalyst precursors

The description of the end uses is important to illustrate the industrial applications and the related markets that rely on the use of NiO containing catalysts precursors. Such knowledge is also required for the analysis of alternatives.

Table 8 provides the main catalysts applications where nickel compounds (and therefore NiO) are involved and the sectors where these types of catalyst are used.

Table 8. Nickel catalyst technologies by end user sector/application[12]



| | Fuels refinery | Hydrogen | Fertilizers | Bulk Chemicals (incl Petrochemicals) | Fine Chemicals | Oleo-chemicals |
|---|---|---|---|---|---|---|
| Steam reforming/Methanation | 🟥 | 🟥 | 🟥 | 🟥 | | |
| Hydrotreating | 🟥 | 🟥 | 🟥 | 🟥 | | 🟥 |
| Hydrocracking | 🟥 | | | | | |
| Hydrogenation | 🟥 | | | 🟥 | 🟥 | 🟥 |
| Amination | | | | 🟥 | 🟥 | 🟥 |
| Sulfur trapping | 🟥 | 🟥 | 🟥 | 🟥 | 🟥 | |

Source: Industry SEA 2013 report (from DHI 2012 report)

During industry consultation it was indicated that there are other miscellaneous uses (applications) for NiO catalyst precursors to produce chemicals (as the styrene polymerisation by nickel catalysts, which involve a dehydrogenation process or the copolymerisation of styrene and ethylene). There are some very high tech applications used or under development such as nickel oxide additives to catalysts in fuel cells or the synthesis of multi-branched carbon fibers by a chemical vapour deposition using a nickel catalyst precursor. Such uses are not covered in this document.

Hydrogenation

Hydrogenation is the biggest use of NiO catalysts. Hydrogenation processes are used to saturate aromatic compounds and olefenic bonds. For illustrative purposes, oleochemical industry uses 400 tons Ni catalysts per year. NiO catalyst precursor is preferred for hydrogenating a wide variety of functional groups. A NiO catalyst precursor is mostly used for the hydrogenation of aromatic nitro compounds to aromatic amines, nitriles to amines, benzene to cyclohexane, olefins to paraffin, ketones to alcohols (polishing) while copper is better for esters to alcohols. Palladium is used commercially for phenol to cyclohexanone, acetylene to ethylene and for many fine chemicals applications. Edible oil hydrogenation is exclusively done with NiO catalyst precursors. Hydrogenation is a growing market, expected to keep on increasing in the future in the perspective of global energy transition.

Steam reforming/methanation

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[12] Source: DHI report 2012, carried out for the Nickel Institute. Nickel catalysts; application and possible alternatives

According to the Nickel Institute, steam reforming and methanation catalysts stand for the second biggest use of NiO catalysts and the market counts 1,400 plants worldwide. Steam reforming is one of the most basic and critically important processes relevant for producing food (hydrogenation of oils), fuel and chemicals. Steam reforming is a process in which hydrocarbon molecules (such as methane from natural gas or coal, naphtha or biofeed) react with steam at very high temperatures of 700-1000°C to synthesis gas, a mixture of carbon monoxide (syngas) and hydrogen.

The carbon monoxide can be used as such, or transformed to produce an additional molecule of hydrogen by reaction with steam in the water-gas-shift process using a nickel, iron and copper catalysts. Thus, steam reforming is the main industrial process for producing hydrogen. It is applied at very large scale and the hydrogen produced is used in hydrogenation processes in the refinery and in the chemical industry, amongst others in the synthesis of ammonia (for production of nitric acid, fertilizers, etc.) and methanol (a bulk chemical). While many metals can act as catalyst in the transformation of hydrocarbons into synthesis gas, a NiO catalyst precursor has proven to be the most efficient catalyst. It is relatively cheap and, in contrast to noble metals, is widely available.

The most common method for large hydrogen consumers is on-site production of hydrogen at the consumption site. This is mainly done for refineries, fertilizer plants (ammonia), methanol, and hydrogen peroxide production plants.

Refineries not only consume, but also produce hydrogen at different stages of cracking and reformulating crude oil.

In fertilizer production, hydrogen is always used for ammonia production and other nitrogen-based fertilizers, urea, ammonium nitrate, ammonium sulfate, ammonium phosphate, calcium ammonium nitrate and UAN (a solution of urea and ammonium nitrate in water). All fertilizers composed with a nitrogen atom use ammonia and thus hydrogen, which requires the use of a NiO precursor catalyst. These fertilizers are extensively used in agriculture and associated with an important market.

From communication with a producer of fertilizers, Nickel Institute learnt that there are 35 ammonia plants in Europe producing ammonia for the fertilizer industry (75%) and for other industrial chemicals (25%) like caprolactam, acrylonitrile, etc. Except for a few plants, natural gas is used as the feedstock for ammonia production. The natural gas used as raw material to produce ammonia undergoes several chemical reactions (desulfurization, hydrogen removing, methane conversion, methanation, etc.) and each step requires the use of a NiO catalyst. More than 95 % of all ammonia is produced by this process.

There is today growing interest in the development of much smaller units based on similar technologies to produce hydrogen as a feedstock for fuel cells and small-scale steam reforming units to supply fuel cells are currently the subject of research and development.

### Hydrotreating

Hydrotreating is the third biggest use of NiO catalysts. It is a hydroprocessing catalyst used in oil refineries (587 Ni t/y) to pre-treat oil fractions and remove nitrogen (HDN), sulfur (HDS), oxygen (HDO) and metal atoms from molecules containing such atom. Without this removal the atoms would lead to environmentally unacceptable gases such as $SO_2$ and NOx when the oil fractions are used as fuel. Also, the oil fractions need to be processed for quality improvement and the catalysts involved in such processes would be poisoned by the S, N and metal atoms. Typically, hydrotreating is done prior to processes such as catalytic reforming so that the catalyst is not contaminated by untreated feedstock. Hydrotreating is also used prior to catalytic cracking to reduce sulfur and improve product yields, and to upgrade middle-distillate petroleum fractions into finished kerosene, diesel fuel, and heating fuel oils.

Hydrotreating is using the hydrogen produced during the steam reforming process in order to remove the sulfur components; the S, N, O and metal atoms are removed in reactions in which C-S, C-N, C-O and C-M bonds are hydrogenated and broken.

Light oil fractions and less difficult heavier fractions are often treated over a sulfided Co-Mo on alumina catalyst. Bonds of molecules in heavier, more aromatic oil fractions can only be broken with the help of a stronger catalyst such as NiO catalysts (Ni-Mo and Ni-W) that are partly sulfided to NiS.

## Hydrocracking

Hydrocracking is a process that effectively combines catalytic cracking and hydrotreating in a single step. It is used to upgrade heavy residual feeds high in aromatics to high-octane gasoline and middle distillates. It is used in the oil refineries and bulk chemistry to break large molecules (which have only value as fuel) into smaller ones. Hydrocracking is catalytic cracking that occurs in the presence of hydrogen, which both optimizes the types of products formed, and simultaneously removes unwanted sulfur and nitrogen contaminates. The cracking of the large molecules occurs in reactions over acidic and metallic catalytic sites at the catalyst surface.

Hydrocracking is therefore always preceded by a hydrotreating unit to remove S, N and O atoms. Usually a sulfided Ni-Mo catalyst is used in the hydrotreating reactor. Depending on the quality of this pre-treating process step, a Ni-Mo on solid acid or a platinum on solid acid catalyst is used in the hydrocracking unit proper.

However hydrocracking units cost more to construct and run, which limits their attractiveness to refiners and are only used where diesel demand and emissions standards are both high, and spare capacity is low (North America and Europe).

## Amination

Amination involves the catalytic reaction of ammonia or alkylamines with reactants like alcohols or aldehydes in which the reactive group replaces one or more hydrogens in the ammonia molecule. NiO catalyst precursors, ethanol and ammonia react to produce ethylamine. Further reaction leads to diethylamine and triethylamine. The amines find use in the synthesis of pharmaceuticals, agricultural chemicals, and surfactants.

## Sulfur trapping

Because sulfur is a poison for most catalysts, it needs to be removed upstream, at the beginning of the process. Therefore "nickel-based sulfur guards" are very effective in virtually absorbing all of the sulfur compounds from the feedstream. These guards are commonly used to polish the remaining sulfur species left after a hydrotreater and are used for pre-treatment of steam reforming feedstocks, protection of fuel cells.

## End of life of catalysts

After use, a catalyst can be sent either to a regenerator company which prepares it for reuse either to a reclamation company. When the production unit at the downstream user is shut down, the spent catalyst is unloaded from the reactor, which is usually done by contractors hired by the downstream user. As a general rule, if at least 75% of its original catalyst activity can no longer be regenerated, it is reclaimed or disposed. The spent catalyst contains the elements it is composed of (alumina, sometimes silica, molybdenum, nickel and phosphorus) and the elements captured during the chemical or refining process (sulfur, carbon, hydrocarbons, nickel, vanadium, arsenic, etc.).

Hydroprocessing catalyst which operates in the sulfided form is almost the only type of catalysts that can be sent to a regenerator company and are again prepared for re-use. Spent catalysts containing NiS or $Ni_3S_2$ are re-oxidized into NiO. The main reason is that hydroprocessing catalysts have a relative short life cycle (few years), which makes regeneration from an economic point of view less expensive than installing a new catalyst. About 85-90% of the world's regenerated catalysts are hydroprocessing catalysts (hence, based on nickel).

It is estimated that among the regenerated hydroprocessing catalysts, 60% are from hydrotreating units and 15% from hydro-cracking units. Moreover, 25% of the other regenerated catalysts are from specialty applications, which include reforming and petrochemical operations. Steam reforming/methanation catalysts are typically not regenerated and are sent directly to reclamation. Hydrogenation catalysts are mostly irreversibly poisoned by sulfur and thus sent to metal reclamation.

As a whole, regenerated catalysts stand for 16% of the world market of catalysts (and 416 tons per year).

Catalysts that are deactivated or cannot be used anymore, are reclaimed by specialized companies. The reclamation company will transform the metal content into metal compounds, the latter will be sold again on the market. Spent NiO catalysts of more than 10% nickel are quite valuable and, therefore, are mostly sent to specialist companies for nickel reclamation. NiO catalysts are recycled by nickel smelters and the nickel becomes part of a larger nickel pool supplied to various industries.

#### 2.3.2.5 Catalysts producers, users and volumes of nickel compounds used (including NiO)

Supply chain: Producers and Catalyst service companies

Producers of NiO catalysts precursors are members of the European Catalyst Manufacturers Association (ECMA) which has twenty members most of them located in Western Europe (UK, Germany, France, Belgium, The Netherlands, Denmark). [additional text confidential]

Volumes

As NiO is not purchased as such but manufactured then consumed and finally regenerated within the whole process, the estimation of NiO quantities used is a difficult exercise. Most of the available data are expressed in equivalent nickel (content of nickel) per year and not directly as NiO.

Lok & Prins (2012)[13] applied a top-down methodology in order to estimate the catalyst production worldwide and in Europe and to make the difference between Ni and NiO content in catalysts and catalysts precursors. The European catalyst production is estimated at 8,700 t Ni/y and the European catalyst use at 4,269 t Ni/y (over 14,658 t Ni/y worldwide). In Europe, this figure (8,700 t Ni/y) consists of 4,080 t Ni/y (for NiO catalyst precursor) and 4,622 t Ni/y (for Ni metal catalysts). Considering that a typical

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[13] Lok, M., Prins, R., (2012b) "Production and application of Nickel Catalysts in Europe and the world"

NiO catalyst precursor contains 3% of Ni pro rata to 4% of NiO (as an average), a recalculation estimates the production at 5,440 t NiO/y.

Besides, an industry consultation has been organized with the European Catalyst Manufacturers Association (ECMA), which has twenty members, most of them located in Western Europe (UK, Germany, France, Belgium, The Netherlands, Denmark) in order to get a picture of the NiO volumes in the catalyst sector. On the 13 respondents representing 75% of the total European catalyst manufacturing industry, a figure of ~4,000 t NiO/y manufactured is estimated, which would be roughly extrapolated at 5,333 t NiO/y manufactured for the whole European production.

Both results are consistent and one can therefore estimate the European production of NiO around 5,400 t/y in the catalyst manufacturing sector.

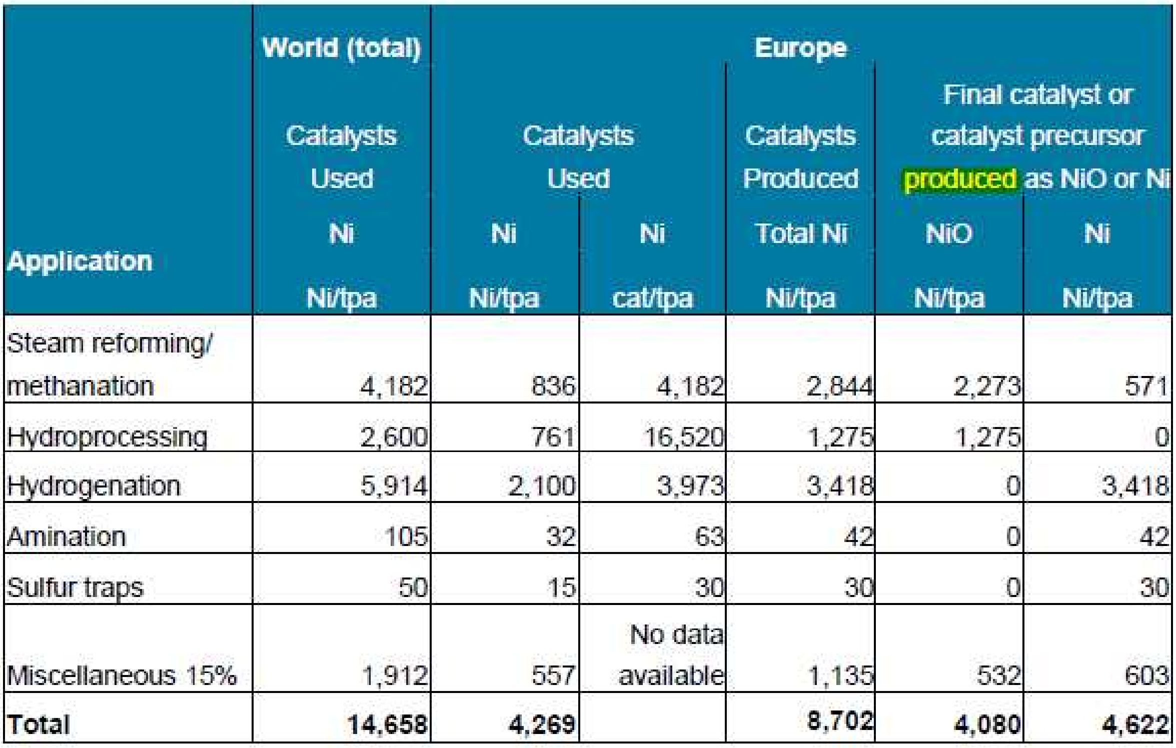
### Downstream applications

Communication with catalyst manufacturers suggests that approximately 50-75% of the NiO catalyst precursors are used outside Europe especially, hydrogenation type catalysts for petrochemicals and petroleum hydrotreatment, corresponding to a use of 2,100 t Ni/y (demand for catalyst amounts to 3,973 t/y of catalyst). Second largest use of NiO catalyst precursors, is in steam reforming and methanation catalysts with around 836 t Ni/y (demand for catalyst amounts to 4,182 t/y of catalyst). The third largest industrial use of NiO catalyst precursors is in hydrotreating processes with around 761 t Ni/y (demand for catalyst amounts to 13,050 t/y of catalyst).

From the top-down industry consultation and based on the European market data, it appears that 689 t NiO/y are sold to the refinery sector by European manufacturers (the demand of the refinery industry being around 900 t/y), 381 t/y to the bulk & fine chemicals and oleochemicals, 62 to the hydrogen sector and 57 to the fertilizers sector.

Compared to fresh NiMo catalysts (hydroprocessing catalysts), regenerated catalysts account for about 16% of the world market or 416 Ni t/y. Based on the world regeneration capacity which is about 30,000 t/y of which 8,000 t/y is NiMo (4,5% Ni), one can calculate that about 360 t Ni /y is regenerated as NiMo catalysts. The average for the two calculations (416+360/2) is 388 t Ni/y Ni which is only 2.6% of all Ni used in the world for production of nickel catalysts.

Table 9. Tonnages in all catalyst applications in 2011



| Application | World (total) | Europe | | | | |
|---|---|---|---|---|---|---|
| | Catalysts Used | Catalysts Used | | Catalysts Produced | Final catalyst or catalyst precursor produced as NiO or Ni | |
| | Ni | Ni | Ni | Total Ni | NiO | Ni |
| | Ni/tpa | Ni/tpa | cat/tpa | Ni/tpa | Ni/tpa | Ni/tpa |
| Steam reforming/ methanation | 4,182 | 836 | 4,182 | 2,844 | 2,273 | 571 |
| Hydroprocessing | 2,600 | 761 | 16,520 | 1,275 | 1,275 | 0 |
| Hydrogenation | 5,914 | 2,100 | 3,973 | 3,418 | 0 | 3,418 |
| Amination | 105 | 32 | 63 | 42 | 0 | 42 |
| Sulfur traps | 50 | 15 | 30 | 30 | 0 | 30 |
| Miscellaneous 15% | 1,912 | 557 | No data available | 1,135 | 532 | 603 |
| **Total** | **14,658** | **4,269** | | **8,702** | **4,080** | **4,622** |

Source: Industry SEA report 2013; from Prins & Lok, 2012.

### 2.3.2.6 Market trends

Because the world demand for fuels is still increasing and since light crude oils are running out and ever heavier crude oils have to be used, the demand for Ni-Mo (hydrotreating) and Ni-W (hydrocracking) catalysts in the petroleum industry is expected to further increase, both in absolute and relative (to Co-Mo) terms.

The European catalyst market represents over 20% of the world market (around € [confidential]) and is expected to grow at a rate of about 5% per year, with a faster growth expected in Eastern Europe (6%). The main downstream market segments, covering about 90% of worldwide use of nickel in catalysts are hydrogenation (worldwide 5,914 tons/year of nickel), hydrogen production (4,182 tons/year of nickel) and hydroprocessing (2,600 tons/year of nickel).

The whole market analysis is provided in the SEA that has been made available by the Nickel Institute.

### 2.3.2.7 Analysis of alternatives

The purpose of the analysis of alternatives (AoA) is to determine if there are any 'suitable' alternatives to the use of nickel oxide. The AoA presented here focuses on the use of nickel oxide in catalysts and is entirely based on a recent study by DHI (2012)[14]. The AoA makes an assessment of the suitability of the alternatives including the technical feasibility, the economic feasibility and the risk reduction. The availability of the potential alternatives is also considered as far as possible. The conclusions provided by DHI consider all those factors together but may be interpreted differently according to the weight given to them. The AoA has been solely based on publicly available information in order to avoid confidentiality issues.

A lot of research on potential alternatives is already performed, but has not yet yielded viable alternatives that could be tested on an industrial scale.

Regarding steam reforming catalysts, nickel could technically be replaced by ruthenium, and possibly by other platinum group metals (pgm); both are considered less toxic than nickel and lower overall risk to humans and the environment. However, the world metal production would only allow a tiny fraction (<1%) of current estimated 1400 steam reforming plants in the EU to switch over, severely affecting other sectors that rely on NiO including fertilisers production.

Regarding hydrotreating catalysts, a direct "drop-in" replacement for NiO catalyst precursors is considered not feasible, but is nevertheless expected by refineries. The only realistic alternative is cobalt, which requires larger reactors (substantial investment costs) due to characteristics of Co-Mo catalysts (less active). Furthermore a substitution would require acceptance of higher sulfur and nitrogen content in product (downstream refinery processes, European sulfur content limits for e.g. diesel and gasoline). Currently CoMo is already used, according to the industry consultation the use of CoMo increased since 2010, but majority i.e. around 60% uses NiMo. Depending on the Co salt used as raw material and its harmonized classification, a risk reduction may not be expected.

In hydrogenation, the options for substitution are limited to copper and pgm metals that are less hazardous than nickel but entail lower selectivity (copper) and higher cost of production and market availability (pgm). Sub-optimal catalysts (in terms of selectivity) would lead to higher processing costs, increased waste production and a potential loss of quality products. Pgm metals are already widely used in hydrogenation and for a few additional applications these might be used as alternatives to nickel. Large-scale replacement of nickel by pgm metals will result in price increase, deplete world resources and severe competition between sector of uses.

In amination substitution by nickel-free catalysts like solid-acid catalyst (silica-alumina and zeolite) is attractive from a risk reduction point of view, but may lead to much lower yields, increased waste and higher processing costs for higher amines.

Replacement of nickel-based reactive sulfur adsorbents is possible as adsorbents can be based on less hazardous substances such as copper and zinc. Replacement of nickel would, however, result in increased costs because bigger reactors are needed and because of more frequent replacement of down-stream catalysts due to the increased risk of sulfur slipping through.

During industry consultation, other miscellaneous uses of NiO catalyst precursors were identified. For some of these catalysts there are potential non-NiO alternatives, but they are not technically feasible because of lower performance. Other suitable alternatives do not yet exist and more research would be needed in this area.

Although potentially attractive from a risk reduction point of view, the overall conclusion from DHI is that pgm metals like ruthenium, platinum or palladium could only substitute

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[14] Source: DHI report 2012, carried out for the Nickel Institute. Nickel catalysts; application and possible alternatives

NiO in a limited number of mostly niche applications and with increased cost. For example, in the fertilizers industry, the NiO-based catalysts weigh up to [confidential]% of the total production cost and would weigh up to [confidential]% if platinum was used as an alternative metal (to the current price of platinum). Furthermore, pgm metals are among the least abundant of the Earth's elements and world production for wider application is insufficient because of already existing large demands from other sectors (e.g. automotive industry).

While large-scale replacement of NiO catalyst precursors by pgm-based catalysts is not considered feasible, substitution by cobalt might be an alternative to NiO in hydrotreating applications. World production of cobalt appears to be adequate. However, because of the much lower activity of cobalt compared to nickel, substitution would not only lead to increased processing costs but also to investment costs in larger scale installations. Moreover, application of CoMo catalysts will only be technically feasible in small niche markets, as the EU’s legal requirements on content of sulfur in fuel (the largest application for such catalysts) cannot be reached with the current CoMo technology.

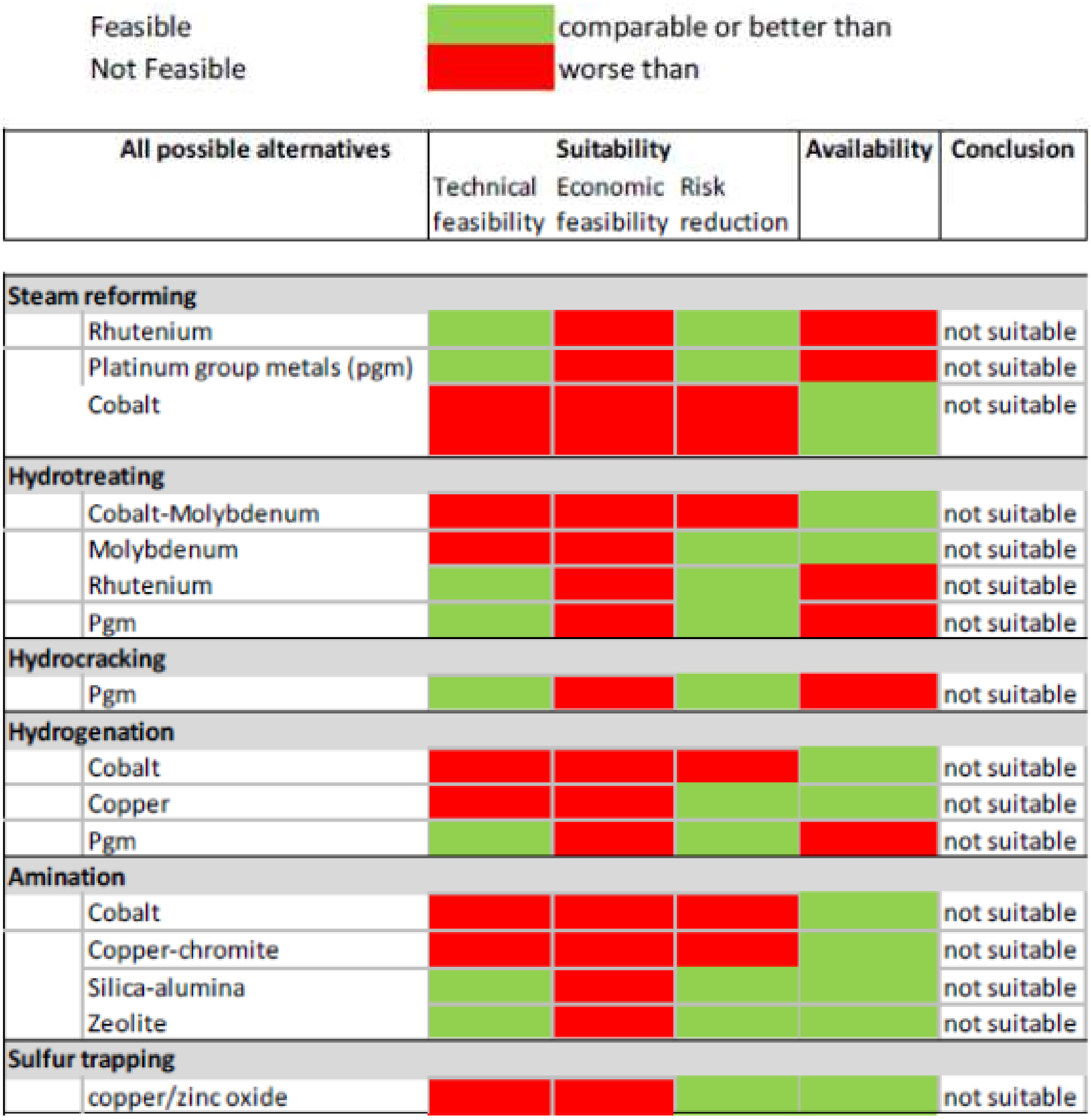
The DHI conclusions are summarized in table 10 but remain questionable depending on the weight given to each individual factor and shall thus be interpreted with caution. The DHI report also assessed the raw material used (as intermediate) for manufacturing the alternative catalyst and no risk reduction may thus be expected even if the end substance (the oxide form) may appear less toxic based on its current classification.

Without cost and yield consideration, suitable alternatives may be identified in a first approach for amination, sulphur trapping, hydrotreating (however with the sulphur issue) and some targeted applications on a case by case basis. The main activity sectors using Ni based catalysts do not benefit from suitable alternatives for the time being.

Apart from drop-in alternatives and alternative substances or combinations of substances, alternative processes/technologies have not been considered yet.

Regarding the steam reforming / methanation sector, there is the possibility to use an alternative technology than catalysts in order to generate hydrogen from the electrolysis of water without using nickel compounds. However such technology is yet not economically feasible because of high energy input and current energy cost; however the trends in renewable energies may change the context in the future.

Table 10. Suitability of possible alternatives to NiO in catalysts (note that the risk reduction column is based on the substances' hazard CLP classification dated 2013 that may have changed since that time)



| | | |
|---|---|---|
| Feasible | 🟩 | comparable or better than |
| Not Feasible | 🟥 | worse than |

| All possible alternatives | Suitability | | | Availability | Conclusion |
|---|---|---|---|---|---|
| | Technical feasibility | Economic feasibility | Risk reduction | | |
| **Steam reforming** | | | | | |
| Rhutenium | 🟩 | 🟥 | 🟩 | 🟥 | not suitable |
| Platinum group metals (pgm) | 🟩 | 🟥 | 🟩 | 🟥 | not suitable |
| Cobalt | 🟥 | 🟥 | 🟥 | 🟩 | not suitable |
| **Hydrotreating** | | | | | |
| Cobalt-Molybdenum | 🟥 | 🟥 | 🟥 | 🟩 | not suitable |
| Molybdenum | 🟥 | 🟥 | 🟩 | 🟩 | not suitable |
| Rhutenium | 🟩 | 🟥 | 🟩 | 🟥 | not suitable |
| Pgm | 🟩 | 🟥 | 🟩 | 🟥 | not suitable |
| **Hydrocracking** | | | | | |
| Pgm | 🟩 | 🟥 | 🟩 | 🟥 | not suitable |
| **Hydrogenation** | | | | | |
| Cobalt | 🟥 | 🟥 | 🟥 | 🟩 | not suitable |
| Copper | 🟥 | 🟥 | 🟩 | 🟩 | not suitable |
| Pgm | 🟩 | 🟥 | 🟩 | 🟥 | not suitable |
| **Amination** | | | | | |
| Cobalt | 🟥 | 🟥 | 🟥 | 🟩 | not suitable |
| Copper-chromite | 🟥 | 🟥 | 🟥 | 🟩 | not suitable |
| Silica-alumina | 🟩 | 🟥 | 🟩 | 🟩 | not suitable |
| Zeolite | 🟩 | 🟥 | 🟩 | 🟩 | not suitable |
| **Sulfur trapping** | | | | | |
| copper/zinc oxide | 🟥 | 🟥 | 🟩 | 🟩 | not suitable |

Source: DHI 2012 report.

In conclusion, the overview of alternatives carried out by industry is rather pessimistic: the substitution by other finished products or by alternative processes does not seem feasible at large-scale and the chemical drop-in substitution could be developed by R&D activities but the solutions would anyway be of wide range and would need to be adapted on a use-by-use basis. In conclusion, the substitution in catalysts sector can be considered as impossible today.

### 2.3.3 Use of nickel oxide for the production of nickel based powders

Nickel supplied as NiO in concentrate or pellet or briquette or ferronickel form is used for the production of nickel based powders. NiO is smelted under reducing conditions to nickel metal e.g., by addition of reducing agent such as carbon. The reduced molten nickel metal is then atomized to produce nickel pellets and powder. No more information is available on this use.

### 2.3.4 Use of nickel oxide for the production of nickel-containing electronics and thermally functioning ceramics

The primary use of black nickel oxide, due to its purity, is for high quality nickel zinc cores, used in ferrite manufacturing. It is used in electronic and thermally functioning ceramics like varistors and thermistors which are use in high quality electronic materials and for solid oxide fuel cells manufacturing.

A thermistor (see figure 4) is a type of resistor whose resistance varies significantly with temperature, more so than in standard resistors. They are widely used as inrush current limiters, temperature sensors, self-resetting overcurrent protectors, and self-regulating heating elements. Thermistors differ from resistance temperature detectors (RTD) in that the material used in a thermistor is generally a ceramic or polymer, while RTDs use pure metals.

Figure 4. Illustration of a thermistor[15]

A fuel cell (see figure 5) is a device that converts the chemical energy from a fuel into electricity through a chemical reaction with oxygen or another oxidizing agent. Hydrogen is the most common fuel, but hydrocarbons such as natural gas and alcohols are sometimes used. Fuel cells are different from batteries in that they require a constant source of fuel and oxygen/air to sustain the chemical reaction; however fuel cells can produce electricity continually for as long as these inputs are supplied.

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[15] http://en.wikipedia.org/wiki/Thermistor

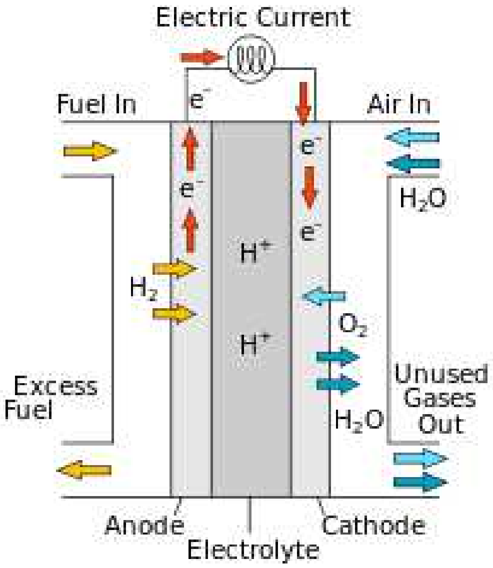

Figure 5. Illustration of a fuel cell[16]

The NiO is processed in an industrial setting through a conventional ceramics processing route involving mixing and processing with other materials to form intermediate materials. This is followed by surface application or forming of the intermediate materials and sintering at high temperatures which leads to the formation of semi-conducting ceramic materials. These ceramic materials are then used to produce solid oxide fuel cells and thermistor products.

As regards to the thermistor production, NiO is milled and then mixed with other ingredients including cobalt oxide and manganese oxide then calcined in a furnace. The calcined powder is then mixed with deionised water and additives, formed and sintered to produce the semiconducting ceramic that is cut into 'chips' of sintered ceramic. Those thermistors are then assembled into the temperature sensing probe and packed.

As regard to fuel cell production, anodes for solid oxide fuel cells are made of either a nickel/yttria-stabilised zirconia (NiYSZ) or of nickel oxide/yttria-stabilised zirconia (NiO-YSZ). These anodes are produced by using powder technology methods in one of three ways: a nickel slurry is applied to the cell substrate and yttria-stabilised zirconia is deposited by electrochemical vapour deposition and sintered; or Ni-YSZ slurry is applied to the cell substrate and sintered; or NiO-YSZ paste is applied to the cell substrate by screen-printing and sintered. During cell application in stack environment NiO is reduced to particulate nickel.

No more data has been provided by Industry on this use. Since the function of NiO is not described, its intermediate status cannot be assessed.

### 2.3.5 Use of nickel oxide for the production of nickel-containing frits

A clear distinction should be made between the use of NiO in frits manufacturing and the use of frits containing NiO. The following information only addresses the former use but also give some explanations on how NiO containing frits are used later on in order to illustrate the market sector and to allow a better understanding on the NiO specificity.

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[16] http://en.wikipedia.org/wiki/Fuel_cell

For the purpose of the conducted SEA by Industry, an extensive industry consultation has been organised with the Frits Consortium and those of their members, which use NiO for the manufacturing of frits.

### 2.3.5.1 What are frits and what are nickel oxide containing frits used for?

Frits are used as constituents in alkali borosilicate enamels for iron and steel (pipes and bathroom fittings) and in ceramic glazes for pottery and porcelain (tiles). They are also reported as being used in paints, plastic, and construction materials such as concrete.

Frits are technically speaking very similar to glass, but with one key difference in the glass manufacturing process being that the glass melt is often transformed into an article in an on-line process whilst frits are not. Figure 6 provides an illustration of coloured frits.

Figure 6. Illustration of frits[17]

The melting process makes that the elements become inert, transforming the original mix in a 'glass', often considered without risks for the human health or the environment. Indeed potential hazardous chemicals such as nickel compounds cannot be released under reasonable conditions.

Actually, one can distinguish two processes in frits manufacturing: the manufacture of the frits (melt is cooled down) and the application of the frits onto a substrate to produce the article (frits are mixed with other ingredients into a glaze).

Two types of frits are distinguished: enamel frits and glass frits.

Enamel frits are used in the manufacture of enamel glazes to coat metal surfaces in order to manufacture sanitary articles (steel bathtubs and shower, sanitary ware as hot water tanks, boilers, stove and stove pipe producers), cooking equipments (steel pots and frying pans, metal oven trays and walls, white ware, and casings for kitchen and

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[17] Source: http://ceramicolor.federchimica.it/LeNostreProduzioni/Fritte.aspx

domestic appliances) and also industrial applications (storage tanks, silos, chemical reactors, dryers, closed tanks, etc.). The principal application of enamel frits is the coating of metal surfaces to provide a chemically and physically resistant covering.

Glass frits are used by the ceramic industry mainly for decorative purposes. They are used to produce ceramic glazes, applied to the surface of ceramic bodies; end products are tiles and tableware, decorative ceramics [pottery], sanitary ware) and by the glass industry for colouring sodalime glass applications (end articles are perfume bottles, decorative vases and other container glasses (jars, bottles), glass sculptures, beads and jewellery, smoked architectural glass, etc. The glazes (mixture of raw materials, frits and pigments) give the ceramic tiles their characteristic colour and image. Frits may be sold in their pure form to the ceramic ware manufacturers who create their own glazes, or the frits manufacturers may produce and supply the glazes themselves. Glass frits are also often used by artists in the creation of glass art to embellish art pieces with an infusion of colour or texture.

According to Industry, contact with NiO during the use of the pan is impossible. The NiO that is used in the frit and applied on the outside layer of the frying pan (in the past it was used on the out- and inside, nowadays this is only done for paella pans) is bound into a matrix, which is very resistant. Even in the end-of-use stage, the content of NiO that can be released is below the limits of the European Waste Directive (Directive 2008/98/EC).

### 2.3.5.2 Functionalities of nickel oxide in frits manufacturing

Table 11 provides information on the NiO functionality in frits. Not all frits produced use NiO as a raw material. NiO is introduced in enamel frits or glass frits for a specific purpose: NiO is needed for adherence properties in ground coat enamel frits (adhesion to metallic substrate like steel) and for colouring properties in glass colouring frits and ceramic glazes. Some manufacturers also indicated to use a nickel pigment (chrome-iron-nickel spinel, CAS 71631-15-2, EC 275-738-1) to introduce NiO into the frit.

Enamel frits

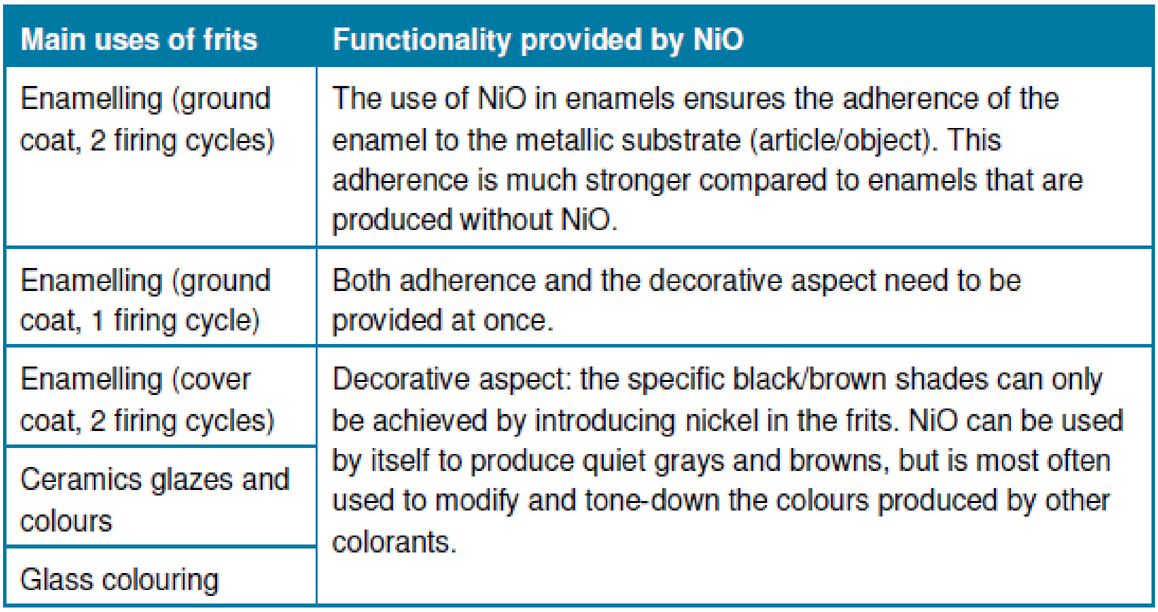
The specific property of NiO in porcelain/vitrous enamelling of steel is to provide adherence to the metallic substrate. All adhesion agents are metal oxides, like nickel oxide. The metal oxides are involved in chemical redox reactions to promote adhesion between the steel surface and the enamel coating. The use of NiO in enamels is generally in the ground coat, in which it is often used in combination with cobalt and manganese oxide. Leaving one of the two components (NiO or CoO) out of the frits is technically possible, but a frit without both of these components will not provide a good adherence. The International Enamellers Institute established that the highest enamel adherence with steel was reached with the following content of adhesion agents: 2% cobalt oxide, 2.5% nickel oxide and 3.6% copper oxide.

NiO gives a brown-black tone to the frit and subsequent mixtures (enamels) and products but in this application, the colour of the ground coat is of minor importance; nickel oxide is only used in minor quantities for coloured cover coat enamels.

Glass frits for ceramic glazes and glass colouring

Frits and ceramic glazes are applied to protect the article/object by an impervious layer that protects the article against water, fire, etc. Frits are also the main component of nearly all ceramic glazes in ceramic floor and wall tiles, dishes, pottery and sanitary ware. Frits are present in many compositions of different materials where a glass phase is needed, even if only as a binder. Indeed, most ceramic colors are the result of metallic oxides being dispersed in the fabric of the glaze. Adding NiO to ceramic glazes provides a smokey grey, black or brown colour to the glaze; the basic colour can be adapted when other materials and pigments are added (colouring agents are often metal oxides like e.g. manganese, iron, nickel, cobalt, chromium, copper and vanadium; all metal oxides have specific colours).

Table 11. Functionality of NiO in enamelling, ceramic glazes and glass colouring



| Main uses of frits | Functionality provided by NiO |
|---|---|
| Enamelling (ground coat, 2 firing cycles) | The use of NiO in enamels ensures the adherence of the enamel to the metallic substrate (article/object). This adherence is much stronger compared to enamels that are produced without NiO. |
| Enamelling (ground coat, 1 firing cycle) | Both adherence and the decorative aspect need to be provided at once. |
| Enamelling (cover coat, 2 firing cycles) | Decorative aspect: the specific black/brown shades can only be achieved by introducing nickel in the frits. NiO can be used by itself to produce quiet grays and browns, but is most often used to modify and tone-down the colours produced by other colorants. |
| Ceramics glazes and colours | |
| Glass colouring | |

Frits with a low NiO content (0.7-2%), this type of frits is mostly referred to as a ground coat, whereby the main functionality is to provide adherence. However, stakeholders indicate that for certain applications a content up to 12% can be required by customers. The same range of 0.7-2% is required when NiO is used for colouring purposes in frits for ceramic glazes. Other adhesion agents (metal oxides), up to an additional content of 5%, are sometimes added as well if this is required by the application of the frit.

Frits with a high NiO content (10-15%) are used in glass manufacturing for colouring purposes.

### 2.3.5.3 Frits producers and nickel oxide volumes used

Producers

On the 50 installations that manufacture frits in Europe, around 80% are located in Spain (see Table 12). In the frame of the conducted survey, 7 companies representing 10 facilities were identified using nickel oxide for the production of frits. Two out of 7 frits manufacturers are only producing this type of frits for internal use. The others sell their frits to their downstream users (enamellers, ceramic or glass industry).

Table 12. Distribution of frits installations in the EU using NiO

| Location of facilities | |
|---|---|
| Spain | 2 |
| France | 2 |
| Italy | 2 |
| Belgium | 1 |
| Germany | 1 |
| The Czech Republic | 1 |
| The Netherlands | 1 |
| TOTAL | 10 |

However, when looking at the consumption data of NiO (individual data are confidential and have not been provided), the ranking is changing. Spain is far in front, followed by Belgium and France. Together, these top-three countries are using about 90% of the NiO annually consumed by the European frit manufacturers. Thus, these three countries represent a consumption of around 405 t/y (on a retained total tonnage of 450 t/y).

Almost all companies are globally oriented, with multiple facilities around the world. Only one SME is represented among these global frits manufacturers. Typically frits manufacturers are medium to large sized companies, there are a few small sized companies but these have not reported to use NiO. The NiO-frits industry counts for about 600 jobs in the EU.

<u>Volumes</u>

Over 600,000 tons of frits manufactured yearly within the EU27, around 25,000 tons are estimated to be produced using NiO as a raw material. The total use of NiO for frits manufacturing within the EU27 is estimated to be around 400 t/y. But the consultant stipulated that not all manufacturers contributed to the internal survey and that the SEA at hand represents less than 30% of the estimated total consumption of NiO in the EU frits industry.

Given that some glass manufacturers have reported to produce also frits for colouring purposes of the glass, this tonnage may be slightly underestimated but Industry assumes that the use of NiO for frits production is not higher than 450 t/y. This quantity has been retained in this document rather than 400 t/y.

The majority of NiO is used in frits production for enamelling purposes i.e. 382 t/y (85% of 450 t/y); 60 t/y (i.e. 15% of 450 t/y) of NiO is used for glass colouring purposes. Only 0.6% of NiO used in frits manufacturing is destined for the ceramic sector i.e. 2.7 t/y; none of the ceramic manufacturers claimed to use nickel oxide directly in their production process, meaning that they all purchase NiO containing frits from frits manufacturers; few of them use directly nickel oxide as a substance in the production process of technical ceramics (high voltage applications, electric elements for conducting and insulating, etc.) but volumes are not available.

#### 2.3.5.4 Process summary

NiO is received either as nickel oxide powder automatically (no operator contact) fed into an intermediate storage silo from a delivery tanker or received in bags. The raw materials are then weighed out, mixed and transferred to the kiln for melting. There are automated and manual options for dosing, mixing with other ingredients and charging the kiln, i.e., 1) NiO powder is transferred from the silo by screw or (open) belt conveyor to the balance cone where a charge is automatically weighed, then mixed with other ingredients and sent to the kiln; 2) NiO in bags are manually fed directly into the kiln.

Raw materials including NiO are melted together. The 'frit' melt may then pass between rollers to adjust the thickness. Then the melt is turned into small glass frits by quenching (rapidly cooled and shattered by pouring into water, spraying with water or passing through air cooled rollers). Frits not undergoing further processing are automatically recovered from the quenching bath, dried and sent to packaging. Frits undergoing milling are automatically recovered from the quenching bath and transferred (probably by vehicle) (intermediate packaging) or automatically (conveyor belt and via storage).

Frits and additives are then milled in a ball mill to the powder product and dried in a hot air drier after wetmilling. The powder and 'quenched-only' frits are conveyed, directly or via intermediate storage, to the bagging line and big-bagging unit. Once filled, big bags are decoupled from the feeder, closed by hand and transferred to the storage area. Bags are closed automatically. Powdered frits and intact frits are packed into bags or big (bulk container) bags. The bagging unit is manually operated (hanging the empty bag in the unit, securing the bag sock or spout to the feeder, initiating/terminating the automatic filling of the bag, manually decoupling and closing the full bag and driving it to the warehouse).

#### 2.3.5.5 Intermediate status of nickel oxide in frits manufacturing

According to Article 3(3) of REACH, an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

Therefore frits cannot be considered as an article under REACH because their shape, surface or design does not determine the function to a greater degree than their chemical composition. Frits are rather considered as a complex substance with a composition similar to a multiconstituents or UVCB substance.

In accordance with Article 3(15) of the REACH Regulation, an intermediate is "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance." The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing.

The ECHA document on the clarification on the concept of intermediates under REACH[18] states the following. The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing. The definition of an intermediate is therefore the definition of an intermediate use of a substance. As soon as the main aim of the involved chemical process is not to transform a substance into another one or the substance is not used for this main aim but rather to achieve another function or a specific property, the substances used for this activity should not be regarded as intermediates under REACH.

Basic raw materials or substances (silica, fluorspar, soda ash, borax, etc.) are used to produce frits. In the frits, these materials and/or substances are bonded in a vitreous matrix, ensuring their stability and behaviour as a homogeneous solid; the materials react at a high temperature to form a complex meta-stable structure wherein the matrix elements are interacting within the matrix via a combination of covalent and ionic bonds. The raw substances are "used for chemical processing" (cf. Article 3(3) definition) in the

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[18] 4th CARACAL meeting, 2-4 February 2010, meeting document, http://inforeach.gencat.cat/pdf/ECHA_Clarification_concept_intermediates.pdf

frits manufacturing but it is not possible to know if they are consumed or not as they may either react with other substances or remain and be bonded within the matrix. The involved chemical reaction used raw substances to produce another substance (complex substance) that is frit. In this way the use of these raw substances in frits manufacturing can therefore be considered as an intermediate use according to REACH Article 3(15); these substances can meet the definition of an intermediate, especially transported isolated intermediates since they are generally produced elsewhere and transformed at the frits manufacturers' site.

Similarly to other raw substances, NiO cannot be traced as such in frits as it is embedded in the new matrix structure; it is bonded with other elements besides oxygen, without being able to make a clear distinction between the other elements as frits has a glass structure (amorphous) and it is not possible to distinguish the various compounds to which nickel is attached. Despite that, NiO is not a basic raw substance for frits manufacturing as it is not always used and considered not necessary to produce frits. Indeed the main aim of NiO is to provide a special function and physicochemical property to the frits (colour and/or adhesion property to the substrate).

Therefore Anses considers the NiO use in frits manufacturing as a non-intermediate use under REACH.

#### 2.3.5.6 Frits regulatory status under REACH

According to REACH Annex V and as for glass and ceramics, frits are exempted from registration and evaluation, unless they meet the criteria for classification under the CLP Regulation because of the presence of 0.1% of already classified hazardous substances such as NiO for instance. Given that all NiO containing frits manufactured in Europe have a NiO content over 0.1%, all should be registered under REACH and be labelled as well. Note that some manufacturers have delisted some frits products from their product range due to the new labelling of Ni containing frits. Several manufacturers have made efforts to meet the limits, for certain type of frits it was possible to lower the content of NiO without quality loss for enamelled products or glass products and for others types it was not possible.

#### 2.3.5.7 Market trends

Generally, half of the frits manufacturers consider the frits market as mature and stable. More than 60% of European frits production is exported to non-European countries (i.e. Egypt, Portugal, Morocco, Germany, Poland, Russia, Indonesia and Algeria). The main reason for the observed shrinking market of frits is that other technologies gain interest with respect to enamelling and consumers' preferences are changing.

#### 2.3.5.8 Analysis of alternatives

An extensive and detailed analysis of alternatives has been carried out by Industry that cannot be reported in this document, especially regarding the complex analysis of the technical and economical feasibility. Therefore only the main ideas and conclusions are reported hereafter. Over the 10 facilities manufacturing frits within the EU, 7 have been selected but one major manufacturer and 2 medium size producers didn't answer the survey. Indeed such information on alternative is often considered as confidential business information.

In theory several possible types of alternatives can be envisaged:

- ‘drop-in’ substances that directly replace NiO, but not nickel, 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

The same enamel frits and glass frits can be produced when NiO is replaced by nickel hydroxycarbonate but 60% more hydroxycarbonate is needed compared to NiO to obtain same level of nickel compounds. The nickel hydroxycarbonate is transformed into NiO by calcinations directly in the production process and no change in the process would be needed. Nickel hydroxycarbonate is therefore an intermediate in the production of NiO without any advantage under REACH. Some manufacturers are reluctant to use nickel hydroxycarbonate because there is a chance that nickel carbonyl will be released, which is poisonous.

Regarding enamel frits, adhesion agents are only present in ground-coat enamel and cobalt is known to be a good adhesion agent, especially in combination with NiO, but according to the Frit Consortium, nickel is the best available metal providing adhesion to frits for enamelling purposes, given its redox potential which provides excellent properties in terms of oxidation reduction. Cobalt is the only element that provides similar yet not so good properties to frits, compared to those that can be obtained by using nickel. Other metal oxides are also considered to be good adhesion agents amongst which manganese oxide, copper oxide are seen absolutely qualified for the purpose and perhaps antimony oxide too. However in case of substitution, a new combination of metals will need to be developed depending on the application the frits are used for, probably a combination of cobalt oxide, manganese oxide, copper oxide and perhaps antimony oxide. Also potentially a new combination of other raw materials in the frits formula (silica, alumina, soda ash, potash, borax, titanium oxides, zirconium oxides, fluorine compounds or colouring agents) or the enamel formula (clay, silica, borax, sodium nitrate and water) will be needed too. Some manufacturers already produce nickel free frit by replacing the NiO by nearly 100% CoO and some other minor adhesion agents. This is however not possible for each application and research is still on-going.

Regarding glaze frits used for ceramic glazes and glass production, cobalt oxide and a new combination of metal oxides are not seen as a good alternative as none of them will provide the same colour to the glaze or glass instead of brown–grey. Thus Industry considers that no suitable alternative is identified that could potentially replace NiO as a colouring agent in glass and ceramic colouring frits.

The hazard profile of these substitutes indicates a potential for a reduction in cancer risk considering that none are classified carcinogen under Annex VI of the CLP contrary to NiO. However a potential for respiratory sensitization could be anticipated for workers exposed to cobalt oxide and manganese dioxide.

### Alternative technologies

A potential alternative technology is the use of a nickel dip in the production process of steel. A very thin nickel layer at the steel/enamel phase boundary accelerates the formation of strong adhesion between the two materials and thereby allows for shorter firing time that is a necessary supposition for industrial enamelling. Consequently, nickel must either be introduced by the ground coat enamel or it must be deposited on the pickled steel sheet by the so-called nickel dip. The nickel treatment offers the following advantages: greater reliability through improved enamel adherence including an improved resistance to fish scaling; more opportunities for the use of coloured direct-on enamels or enamels with special properties (e.g. self-cleaning enamels); lower firing temperatures for ground coat or direct-on enamels (reduction of 20°C is possible with nickel dip); fixation or transformation of harmful iron salts.

Alternative materials

Instead of using an alternative substance or technology, alternative materials (i.e. surface finishes) can be used such as industrial varnish, silicone resin or aluminium enamel. But all these materials do not show the same advantages as enamels regarding heat resistance, abrasion resistance and resistance to chemical attacks. Plastics and resins are also alternative materials to enamels for certain applications only (sanitary articles for instance) but do not show equivalent 'luxury' appearance. Crystal glass may also be identified for very limited applications but does not provide the same properties as soda-lime glass and is more brilliant and definitely up-market.

Conclusion on the alternatives

In conclusion, some alternatives seem to be available on the market, in particular alternative finished products composed of alternative materials although the decorative properties may be different. With some adjustments for enamelling frits, the chemical substitution might be (at least theoretically) possible as well. However, from the industry feedback, it is not clear today which alternative combination would be the most suitable and in which proportion for a specific type of frit. It is expected that the majority of manufacturers will thus continue the on-going R&D activities in order to identify a potential alternative combination for their ground coat enamel frits process, test it and possibly adopt the alternative.

If R&D cannot be shared yet, there are however indications from communication with industry that alternatives are available (besides the drop-in substances mentioned in the current report) or could become available within a certain time period.

As a whole, the substitution of NiO in frits sector can be considered as possible.

### 2.3.6 Use of nickel oxide for the production of nickel-containing pigments

In the frame of the SEA exercise conducted by the Nickel Institute, an extensive industry consultation was organised with the Inorganic Pigment Consortium and their members using NiO for the manufacturing of pigments.

#### 2.3.6.1 What are pigments and nickel oxide containing pigments?

Colourants can be either inorganic or organic compounds and also natural or synthetic. However today many natural colourants are produced synthetically. Colourants are either dyes or pigments.

Dyes are applied to various substrates (textile, leather, paper, hairs etc.) from a liquid in which they are completely or at least partly soluble. In contrast to pigments, dyes must possess a specific affinity to a given substrate.

Pigments consist of small molecules that are practically insoluble in water and in the media in which they are applied; they need to be attached to a substrate by means of additional compounds (binder) like e.g. polymers in paints, plastics, or melts. Pigments do not dissolve like dyes, but are dispersed onto the substrate, meaning that particle size remains in the final end product and even determines to a certain degree the colour induced to the substrate.

Nearly all inorganic pigments are oxides, sulfides, oxide hydroxides, silicates, sulfates or carbonates. They generally consist of particles with uniform chemical composition. White pigments are zinc sulfide pigments (i.e. pure zinc sulfide and Lithopone – composed of barium sulfate and zinc sulfide), barium sulphate and zinc oxide. Coloured pigments are iron oxides (red, orange, yellow, brown), cobalt blue, cadmium sulfide, chromium yellow, Complex Inorganic Coloured (CIC) pigments, bismuth vanadate pigments; some iron oxides and CIC are manufactured using NiO that induces the colours yellow and purple. Black pigments are black iron oxide, iron chromium black. Metallic oxide pigments are very sensitive to firing conditions: indeed oxides are characterised by different states of oxidation and environment conditions and temperature affect the redox balance, changing the tone of the colour.

NiO is not used by all manufacturers and not for all types of pigments. NiO is only used in the manufacture of CIC pigments (see below, C.I. Pigments Yellow 53, CI Pigment Yellow 153, Black 25, Brown 34 and Black 30) and few iron oxides.

Each inorganic pigment is differentiated by the elements constituting it and the crystalline structures that are generated after the chemical reaction; CIC pigments are not a mixture, but consist of a stable crystal lattice of different metal cations. "Doped substances" is the term used to characterize a crystal lattice of CIC with some NiO inside the crystallographic phase. In other words, the CIC has a classification on its own resulting from tests performed with the CIC itself, not with the constituents.

### 2.3.6.2 Functionalities of nickel oxide in pigments manufacturing

NiO is a colouring agent that is used either as a main constituent (see Table 13) either as a modifier agent in the pigment manufacturing (see Table 14).

The main functionality of pigments manufactured with NiO is the provision of a specific colour tonality to articles. This is not limited to simply one colour, but to a wide variety of differences in the brown/grey/black colours. NiO is a main constituent used only in two pigments: "antimony nickel titanium oxide yellow" and "nickel iron chromite black spinel" which specifically require nickel oxide.

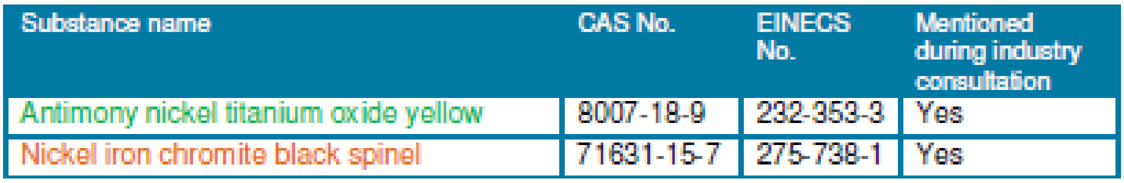
It is also used as a modifier in 41 pigments that are not based on NiO, including 36 CIC pigments. Modifiers are often metals that are not part of the name of the substance but which may play a key role in the final properties. They are introduced in the calcination reaction with the purpose of replacing a limited proportion of the main constituents in the structure, in order to give a specific shade or subtle tone which cannot be achieved otherwise. A structural action takes place: nickel replaces the position of another metal.

In case NiO is a main constituent, it is not possible to manufacture the pigment without using NiO. On the contrary, in case NiO is used as a modifier, it is possible to make the pigment without NiO.

However indirectly, the properties of NiO containing pigments go beyond their colour tonality in the downstream supply chain. For example "antimony nickel titanium oxide yellow" (rutile structure) is essentially used in plastics applications and not for ceramic uses, because of technical properties making the pigment easily dispersed in plastic substrates, but not in ceramic ones. These properties are indirectly related to NiO; indeed if the dispersion is strongly linked to the structure of the pigment (rutile) and not to the NiO used. Hence, the disperse characteristic is indirectly provided by NiO.

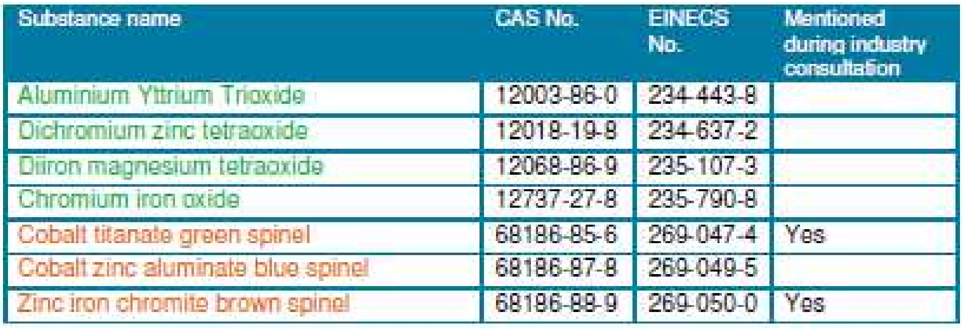
The content of NiO differs according to the type of pigment. For example, in the main constituent pigment "nickel iron chromite black spinel", the content can be as high as 27%. For other pigments, where nickel is used as a modifier, lower percentages of NiO are used. In those cases, typical ranges of NiO are 6-9%, or even lower in specific cases. For the pigments "zinc iron chromite brown spinel" and "iron cobalt chromite black spinel", NiO is typically used at low levels (e.g. <10%). Therefore, even though these values have to be used as approximations, one can say that when nickel is a main constituent, ranges can be between 10 and 27%, and when used as modifier, a range of 1-10% can be assumed.

Table 13. List of pigments for which NiO is used as main constituent (pigments marked in orange are CIC pigments)

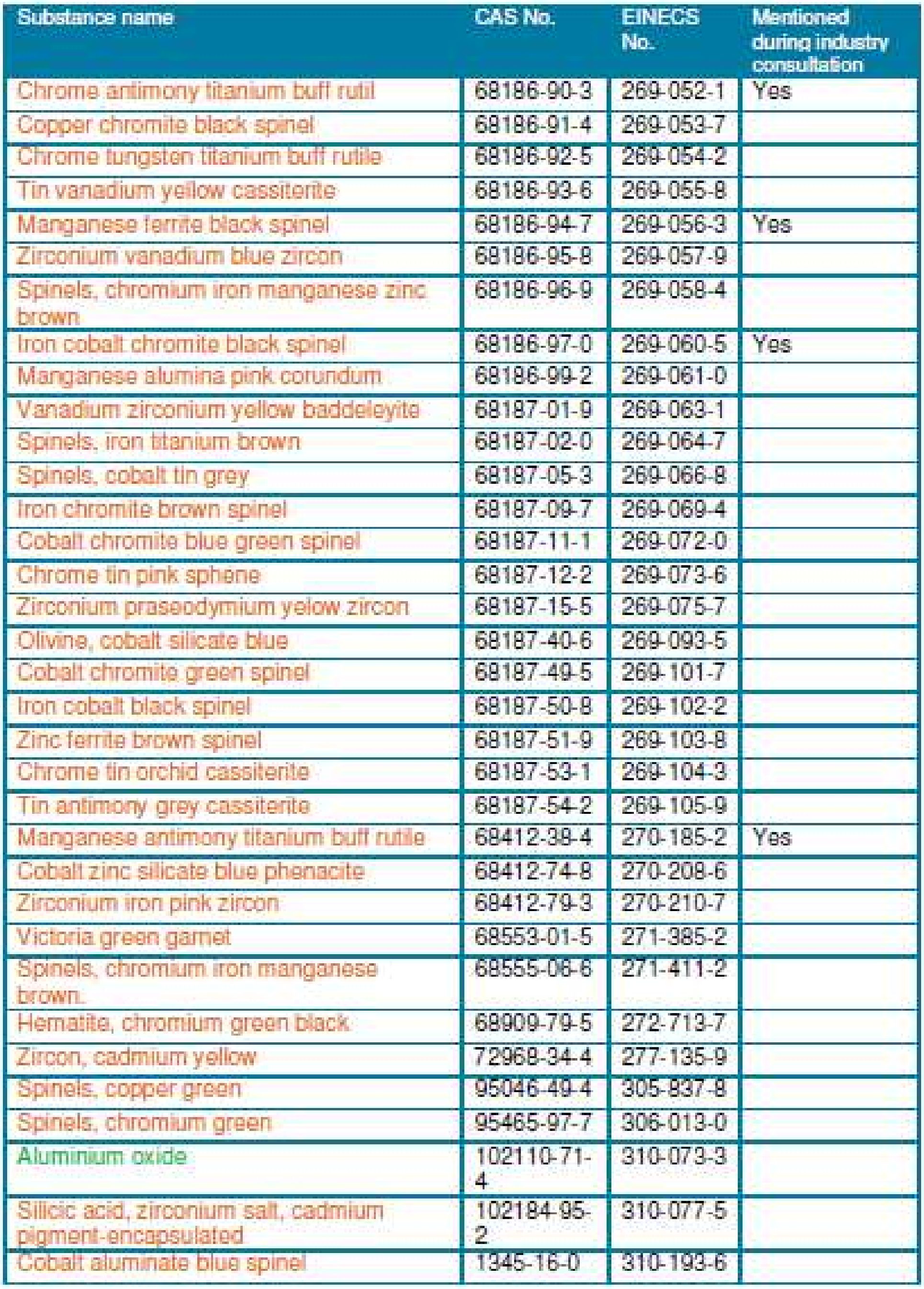


| Substance name | CAS No. | EINECS No. | Mentioned during industry consultation |
|---|---|---|---|
| Antimony nickel titanium oxide yellow | 8007-18-9 | 232-353-3 | Yes |
| Nickel iron chromite black spinel | 71631-15-7 | 275-738-1 | Yes |

Table 14. List of pigments for which NiO is used as modifier (pigments marked in orange are CIC pigments)



| Substance name | CAS No. | EINECS No. | Mentioned during industry consultation |
|---|---|---|---|
| Aluminium Yttrium Trioxide | 12003-86-0 | 234-443-8 | |
| Dichromium zinc tetraoxide | 12018-19-8 | 234-637-2 | |
| Diiron magnesium tetraoxide | 12068-86-9 | 235-107-3 | |
| Chromium iron oxide | 12737-27-8 | 235-790-8 | |
| Cobalt titanate green spinel | 68186-85-6 | 269-047-4 | Yes |
| Cobalt zinc aluminate blue spinel | 68186-87-8 | 269-049-5 | |
| Zinc iron chromite brown spinel | 68186-88-9 | 269-050-0 | Yes |



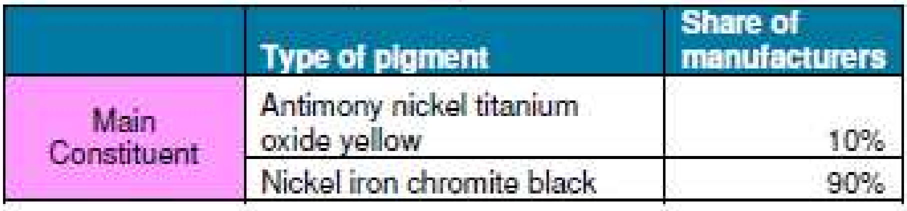
| Substance name | CAS No. | EINECS No. | Mentioned during industry consultation |
|---|---|---|---|
| Chrome antimony titanium buff rutil | 68186-90-3 | 269-052-1 | Yes |
| Copper chromite black spinel | 68186-91-4 | 269-053-7 | |
| Chrome tungsten titanium buff rutile | 68186-92-5 | 269-054-2 | |
| Tin vanadium yellow cassiterite | 68186-93-6 | 269-055-8 | |
| Manganese ferrite black spinel | 68186-94-7 | 269-056-3 | Yes |
| Zirconium vanadium blue zircon | 68186-95-8 | 269-057-9 | |
| Spinels, chromium iron manganese zinc brown | 68186-96-9 | 269-058-4 | |
| Iron cobalt chromite black spinel | 68186-97-0 | 269-060-5 | Yes |
| Manganese alumina pink corundum | 68186-99-2 | 269-061-0 | |
| Vanadium zirconium yellow baddeleyite | 68187-01-9 | 269-063-1 | |
| Spinels, iron titanium brown | 68187-02-0 | 269-064-7 | |
| Spinels, cobalt tin grey | 68187-05-3 | 269-066-8 | |
| Iron chromite brown spinel | 68187-09-7 | 269-069-4 | |
| Cobalt chromite blue green spinel | 68187-11-1 | 269-072-0 | |
| Chrome tin pink sphene | 68187-12-2 | 269-073-6 | |
| Zirconium praseodymium yelow zircon | 68187-15-5 | 269-075-7 | |
| Olivine, cobalt silicate blue | 68187-40-6 | 269-093-5 | |
| Cobalt chromite green spinel | 68187-49-5 | 269-101-7 | |
| Iron cobalt black spinel | 68187-50-8 | 269-102-2 | |
| Zinc ferrite brown spinel | 68187-51-9 | 269-103-8 | |
| Chrome tin orchid cassiterite | 68187-53-1 | 269-104-3 | |
| Tin antimony grey cassiterite | 68187-54-2 | 269-105-9 | |
| Manganese antimony titanium buff rutile | 68412-38-4 | 270-185-2 | Yes |
| Cobalt zinc silicate blue phenacite | 68412-74-8 | 270-208-6 | |
| Zirconium iron pink zircon | 68412-79-3 | 270-210-7 | |
| Victoria green garnet | 68553-01-5 | 271-385-2 | |
| Spinels, chromium iron manganese brown. | 68555-06-6 | 271-411-2 | |
| Hematite, chromium green black | 68909-79-5 | 272-713-7 | |
| Zircon, cadmium yellow | 72968-34-4 | 277-135-9 | |
| Spinels, copper green | 95046-49-4 | 305-837-8 | |
| Spinels, chromium green | 95465-97-7 | 306-013-0 | |
| Aluminium oxide | 102110-71-4 | 310-073-3 | |
| Silicic acid, zirconium salt, cadmium pigment-encapsulated | 102184-95-2 | 310-077-5 | |
| Cobalt aluminate blue spinel | 1345-16-0 | 310-193-6 | |

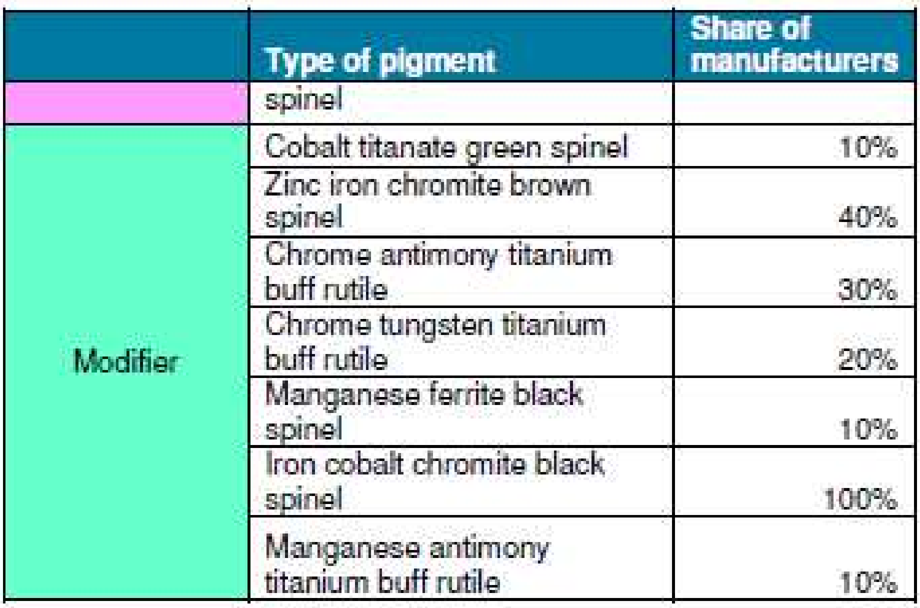
### 2.3.6.3 Pigments producers and nickel oxide volumes used

Within the survey, 10 companies representing 11 facilities were identified using NiO in the production of pigments. Together, these 10 companies consume around 350 t NiO/y which is the actual use of NiO in the EU27, and no extrapolation was needed since all manufacturers using NiO contributed to this part of the consultation. Many pigments manufacturers also produce frits. This volume is then used to produce between 1,000 and 35,000 t/y of NiO-based pigments.

The pigment "nickel iron chromite black spinel" for which NiO is used as main constituent and the pigment "iron cobalt chromite black spinel" for which NiO is used as modifier are produced by all otherwise almost all EU manufacturers (see Table 15).

Table 15. Share of manufacturers producing main constituents and modifiers based pigments





| | Type of pigment | Share of manufacturers |
|---|---|---|
| Main Constituent | Antimony nickel titanium oxide yellow | 10% |
| | Nickel iron chromite black spinel | 90% |
| Modifier | Cobalt titanate green spinel | 10% |
| | Zinc iron chromite brown spinel | 40% |
| | Chrome antimony titanium buff rutile | 30% |
| | Chrome tungsten titanium buff rutile | 20% |
| | Manganese ferrite black spinel | 10% |
| | Iron cobalt chromite black spinel | 100% |
| | Manganese antimony titanium buff rutile | 10% |

According to the BREF 2007[19], the main worldwide inorganic pigment producers are located in the USA and in Europe (each representing about 30% of worldwide production). Regarding the production of inorganic pigments in Europe, installations are mainly located in Spain, Italy and Germany. Production of pigments is also reported in France, Portugal, the United Kingdom and the Netherlands. The geographical distribution of pigments installations using NiO is presented in Table 16.

Spain is far way out in front, with more than 90% of yearly NiO consumption (315 t/y), followed by Italy with between 5 and 10% of yearly NiO consumption (17.5 to 35 t/y).

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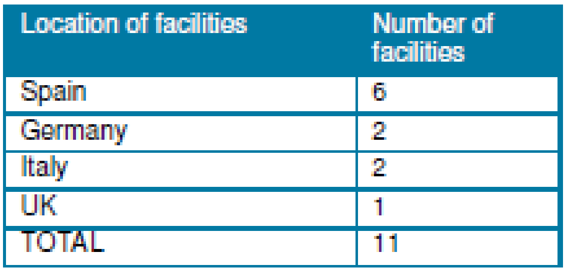
[19] Integrated Pollution Prevention and Control, Reference Document on Best Available Techniques for the Production of Speciality Inorganic Chemicals, August 2007

The use of NiO in pigment manufacturing in Germany and the UK is almost negligible, together these countries represent less than 5% of yearly NiO consumption in the EU (less than 17 t/y).

Table 16. Distribution of pigments installations in the EU using NiO



| Location of facilities | Number of facilities |
|---|---|
| Spain | 6 |
| Germany | 2 |
| Italy | 2 |
| UK | 1 |
| TOTAL | 11 |

The BREF 2007 also indicates that in Europe, large enterprises (over 250 employees), medium sized enterprises (between 50 and 249 employees) and small companies (below 50 employees) manufacture speciality inorganic pigments. Within these companies, the workforce employed to run a pigments production facility is generally below 50. From industry consultation it was learnt that 8 over 10 companies are globally oriented with multiple facilities around the world; only two SMEs are represented among the pigments manufacturers using NiO. As a whole, the EU NiO-based pigments market represents a production value of about €50 million and counts for 1,800 jobs.

#### 2.3.6.4 Downstream uses of nickel oxide containing pigments

The principal market for the NiO containing pigments is for colouring glaze mixtures, applied by the ceramics industry; only minor tonnages of the pigments output are sold to downstream users in plastics industry and painting, coating industry but exact figures are missing (only 2 European manufacturers are concerned); NiO containing pigments are not used in the textile industry and the potential use in building materials has not been confirmed. NiO containing pigments may also be used in enamelling glazes.

NiO is specifically used as an inorganic colour pigment for ceramic colours and ceramic glazes (both products are based on frits) used to colour ceramic floor and wall tiles. Adding NiO to ceramic colours and glazes provides a grey, black or brown colour to the glaze. The basic colour can be switched when other materials and pigments are added. Nickel containing pigments can be added to the glaze mixture in concentrations ranging from 0.1 to 5%. When glazes are applied onto the surface of the ceramic tile and afterwards fired, they give an impermeable, protective and decorative layer to the tile, providing the ceramics their aesthetic and their inner technical characteristics.

All pigment manufacturers use to sell ceramic colours and glazes to the ceramics industry. None of the members of the Cerame-Unie representing the European Ceramic Industy claimed to use NiO directly in their production process; there were only few responses stating the use of NiO as a substance in the production process of technical ceramics (high voltage applications, electric elements for conducting and insulating…).

There are several possibilities for selling the pigment to the ceramic industry: the pigment manufacturer produces the ceramic glaze with the inorganic pigments and other materials and sells to ceramic producers; the ceramic industry buys the pigments and creates their own glazes; pigments are sold to a frits manufacturer who produces and supplies the glazes themselves to the ceramic industry. It is often the case that the pigments and frits are produced within the same company.

#### 2.3.6.5 Market of nickel oxide containing pigments and market trends

Based on the concentration of NiO in the pigment, which can range from 1 to 27%, and the total yearly use of NiO in the pigment industry (350 t/y), output of pigment production can be roughly estimated in a broad range of 1,000 to 35,000 t/y. Given that not all pigments are produced at a concentration of 1% or 27%, it is reasonable to assume that an average of 18,000 t/y could be regarded as a representation of the EU pigment production (estimated between 1,000 and 35,000 t/y as mentioned above). Taking into account total EU pigment production of nearly 1 million t/y, this would mean that only approximately 0.02% requires the use of nickel oxide.

According to the BREF (2007), the significant increase of manufactured coloured products has led to a similar growth in demand of colourants in the last few decades. As natural (mined) pigments have not been able to satisfy this demand, the production of inorganic pigments has steadily increased. However many manufacturers indicated observing a stabilising or shrinking market and expect a depressed market in the short term due to severe competition from outside the EU and the current economic downturn. Consultation of pigment manufacturers showed that many downstream users are nowadays shifting outside the EU to the developing markets of Asia, particularly China and India that compete Europe with cheap low-end tile production. The downstream users in the ceramics industry are also subject to this shift; indeed there is a lot of competition from cheap low-end tile production coming from Asia, supplied by pigment manufacturers located nearby.

#### 2.3.6.6 Pigments manufacturing process summary

The first step in the production process involves manual opening of NiO bags and manual tipping or automatic discharge of NiO powders and other ingredients, including water, into a reactor for mixing. Mixing can be performed in dry or wet mixers involving water in a closed reactor. If mixed with water (i.e. wet mixing), the mixture of raw materials is dried using specific equipments (such as atomizers, jet driers). This is followed by continuous and automated drying and calcining operation in tunnel ovens or rotary kilns. During operation of the ‘discontinuous’ drying and calcining processes, the mixture of raw materials is (manually or automatically) loaded into crucibles and conveyed through the oven on wagons.

The resulting calcined product is unloaded (manually or automatically) from the crucible and transferred to milling. The dry calcined product is then ground in an enclosed ball mill and conveyed to packaging. On the other hand, calcined NiO products containing salts are ground wet, washed to eliminate excess of soluble salts and dried. Finally, the calcined powder product is blended with additives and packed specific containers (bags or big bags).

#### 2.3.6.7 Intermediate status of nickel oxide in pigments manufacturing

According to Article 3(3) of REACH, an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

Therefore pigments cannot be considered as an article under REACH because their shape, surface or design does not determine the function to a greater degree than their chemical composition, but rather as a substance with a composition similar to as a multiconstituents or UVCB substance. Contrary to glass, ceramics and frits, pigments shall be registered under REACH (cf. REACH annex V).

In accordance with Article 3(15) of the REACH Regulation, an intermediate is "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance." The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing.

The ECHA document on the clarification on the concept of intermediates under REACH[20] states the following. The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing. The definition of an intermediate is therefore the definition of an intermediate use of a substance. As soon as the main aim of the involved chemical process is not to transform a substance into another one or the substance is not used for this main aim but rather to achieve another function or a specific property, the substances used for this activity should not be regarded as intermediates under REACH.

According to Industry, in the manufacture of rutile pigments, the rutile lattice of titanium dioxide can absorb for example nickel oxide, chromium oxide, manganese oxide or vanadium oxide as colouring components and antimony oxide, niobium oxide or tungsten oxide as a modifier to maintain an average cation valency of four, similar to titanium. Incorporation of metal oxides including NiO in the complex inorganic coloured pigment (CIC) results in the loss of their chemical identity and consequently of their original chemical, physical and physiological properties. Therefore, these rutile pigments are not considered as e.g. nickel, chromium or antimony compounds, but as titanium compounds. This means that NiO is one of the main constituents of the pigment but it doesn't mean necessarily that NiO still exists as such in it.

In case NiO is a main constituent of the pigment it seems that NiO is "used for chemical processing" (REACH article 3(3) definition) in order to be transformed or modified in another substance which is the pigment. The expected pigment property (i.e. colour) depends only on NiO; indeed it is not possible to manufacture the pigment without using NiO. Therefore Anses considers the use of NiO as main constituent in pigments manufacturing as an intermediate use under REACH which would thus be exempted from authorisation.

The situation may be different when NiO is used as a modifier in the pigment. According to Industry, modifiers are used as an additional compound to play a key role in the final properties of the pigment. Modifiers are introduced in the calcination reaction with the purpose of replacing a limited proportion of the main constituents in the structure, in order to give a specific shade or subtle tone which cannot be achieved otherwise; a structural action takes place: nickel replaces the position of another metal. In this case; NiO is not a basic raw substance for the pigment manufacturing as it is not always used and not necessary to produce it. Indeed it is added in order to provide a specific shade or subtle tone. Therefore Anses considers the use of NiO as modifier in pigments manufacturing as a non-intermediate use under REACH.

It is not possible to calculate the tonnage of NiO used as main constituent (intermediate status) and as modifier (non intermediate status). Indeed, despite the known lower concentration of NiO in pigments when used as modifier (1-10%) than when used as main constituent (10-27%), no distinction is made in the total pigment manufacturing (i.e. average of 18,000 t/y of NiO containing pigments) between both categories.

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[20] 4th CARACAL meeting, 2-4 February 2010, meeting document, http://inforeach.gencat.cat/pdf/ECHA_Clarification_concept_intermediates.pdf

Therefore the provided tonnage (i.e. 350 t/y) has been arbitrary split equally between both uses for the purpose of the RMOA. This may not illustrate the real tonnage used.

### 2.3.6.8 Analysis of alternatives

Only 5 over 10 manufacturers contributed to the AoA, representing around 30% of the total tonnage of NiO used in the EU. The main reason is that most of the production processes have been developed individually using the specific in-house know-how that is considered confidential business information.

Many research departments within companies are looking for an alternative, and it seems that there are indications of alternatives that cannot be fully delivered due to confidentiality issues.

As already explained, recall that NiO is required for specific colouring purposes. Only nickel can provide specific colour tonality to articles and objects. This is not limited to simply one colour, but to a wide variety of differences in the brown/grey/black colours. Besides nickel as a main constituent of the pigment, NiO can also be used as a modifier which allows for the earlier mentioned differences in tonality and detailed decorations. These specific colour shades cannot be obtained by any other metals.

Each end-user of pigments is expecting a certain level of performance which is the main driver to purchase this pigment for their application. The provided AoA has only focused on the colour provided by the pigment as such whatever the applications (end-uses) are.

In theory several possible types of alternative can be envisaged

- ‘drop-in’ substances that directly replace nickel oxide, but not nickel, 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

Drop-in substances are substances for which no major change in the production process of the pigment (i.e. the same pigments) is required.

It is indicated by the manufacturers that there are yet no possible substitutes for NiO that are technically and economically feasible to produce pigments where nickel is a main constituent: the produced specific colour tonality cannot exist without the use of nickel compounds. For pigments where NiO is used as a modifier, the specific properties of colour tonality cannot be achieved with any other substance.

Nickel hydroxycarbonate is also used by some manufacturers as well it is transformed into NiO by calcination directly in the production process and has to be regarded as an intermediate in the production of NiO. Nickel hydroxycarbonate differs from nickel oxide in the fact that larger quantities of material are needed because during calcination $CO_2$ is emitted and in the end the same product needs to be obtained. Some manufacturers are reluctant to use nickel hydroxycarbonate because there is a chance that nickel carbonyl will be released, which is poisonous. Only one manufacturer of pigments and frits estimated that about 95% of his production depends on nickel hydroxycarbonate for frits and pigments. Nickel hydroxycarbonate is not seen as an alternative as NiO is finally produced during the process.

### Alternatives substances or combinations of substances

The replacement of “iron cobalt chromite black spinel” where NiO is a modifier (by far the most important pigment) is sometimes possible by “copper chromite black spinel” or “chromium green black hematite”, but only for low temperatures applications (700-1,000°C) and not all applications. Another alternative for NiO containing “iron cobalt chromite black spinel” is the use of the same pigment but without the addition of NiO; the lifetime of the ceramic article is not affected by leaving out the NiO, but the colour is changed. The use of the pigment without NiO would completely change the colours observed for this pigment. Therefore, this alternative does not fulfil the same functionality. It is not known if a risk reduction can be expected from such substitution, especially for copper chromite black spinel which is not yet registered under reach.

Copper chromite black spinel is a weak scattering pigment with strong absorption across the entire solar spectrum compared to iron cobalt chromite black spinel that doesn’t allow the same thermal properties of the tile surface and limit the insulation capacity, that is an important issue for construction materials for which it is the intention to avoid heating of certain objects to avoid excessive energy costs for cooling. “Chromium green black hematite” appears more brown than black and same issues are reported when used in paints and coatings where pigment helps to keep buildings/houses/etc. cooler and saves on energy (cooling) costs. The unit prices for each alternative are in the same order of magnitude as “iron cobalt chromite black spinel”, however “copper chromite black spinel” is 16% more expensive and chromium green black hematite is 75% cheaper.

Industry concluded that no alternatives substances are available at the moment but that there are indications of alternatives under R&D; hence it is possible that contra types (i.e. new combination of pigments) can become available within a certain time period. Industry highlights that a new combination of pigments is not going to behave in exactly the same way compared to the original pigment based on NiO and the colour characteristics and colour tonalities on the final product (roof tiles, paints…) will be different. Therefore Industry concluded that these alternatives are technically unsuitable.

### Alternative processes/technologies

A potential alternative technology is the use of an inkjet technology for the enamelling and plastics industry. The application of colours with the inkjet system, without contact between printer and tile and with high resolution, opens new prospects for tiles decoration. Ink jet technology is widely used for paper printers but it is still under development for tiles. While the cost of inks and equipment are high, the method guarantees large flexibility. However, it seems that the machines use inks that are similar to those traditionally used for applying ceramic glazes, suggesting that the same type of pigments (based on NiO) still need to be used. Therefore Industry doesn’t consider this process as an alternative technology.

Another technology consists of tintometric systems, which is automatic equipment to prepare printing pastes and allows for better management of the inks (often experienced as difficult by many ceramic manufacturers). A tintometric system is able to prepare a coloured ink on the basis of a colourimetric measurement in the lab and using a limited number of pigments. In that way, a reduction in pigments is obtained by 10-15%. This system can help the downstream users in achieving the appropriate colours during quality control. However, again these machines use inks that are similar to those traditionally used for applying ceramic glazes, indicating that the same type of pigments (based on NiO) still need to be used. Therefore Industry doesn’t consider this process as an alternative technology.

Conclusion of the AoA

For some low firing applications (e.g. roof tiles) NiO pigments can be replaced by "copper chromite black spinel" or "chromium green black hematite". For other applications it is likely that research will be done in order to find and introduce an alternative contra type.

Industry however considers such alternatives technically not feasible because the same colour can not exactly be obtained compared with NiO and none of the alternatives behaves in exactly the same way as the original NiO based pigment; all alternatives will behave in a different way depending on the type of light absorbed. Even close, the colour tonalities of the final product will be different. Moreover, besides the colour function, the functionalities of the end-products ceramics may change.

Industry therefore concludes that there are currently no suitable alternatives to the use of NiO which is, again, to achieve a special tone of the pigment and therefore to the final article. However, as a whole, since some alternative pigments still exist and although some difference in tone and colour would appear, the substitution of NiO in frits sector can be considered somehow possible.

### 2.3.7 Use of nickel oxide for the production of nickel-containing glass

For the purpose of SEA drafting, the Nickel Institute has organised an extensive consultation with the sector association Glass Alliance Europe (formerly CPIV) and their member associations FEVE (glass packaging and machine-made glass tableware), Glass for Europe (flat glass), ESGA (special glass), EDG (domestic glass), Glass Fibre Europe and APFE (glass fibre).

Glass is a collective term for a range of materials of different elemental compositions in a glassy state. Glass is an inorganic material obtained from different inorganic materials (sand, soda, potassium oxide, lead oxide, nickel oxide, etc.) which react at a high temperature to form a random network, where different elements are bonded together by oxygen bridges. The various base materials form a vitreous structure. Although conventionally glass compositions are expressed as oxides of the different components, the end product is a substance that does not contain these oxides as such. Glass is rigid like a solid, but its molecules are not arranged in repeating crystals; it is amorphous like a liquid and energetically unstable in comparison with a crystal of the same chemical composition. Glass is an inorganic product of fusion that has cooled to a rigid condition without crystallization (definition adopted in various national and international standards). The molecular structure of glass is in the form of $Si_mNa_nPb_oK_pNi_r…O_s$. Therefore glass industry is regarding glass as a substance itself similar to a UVCB substance.

The physico-chemical properties of the substance glass (chemical resistance, mechanical resistance, transmittance, colour, etc.) are a function of the network formed. Different elemental compositions lead to different glass chemical structures and consequently different physico-chemical properties of the final material.

The addition of modifiers in the glass network changes the bonding relationships and structural groupings, resulting in changes in the physical and chemical properties of the glass. Sodium sulphate and nitrate as well as potassium nitrate are glass oxidants and refining agents.

The fact that there is a large variety of end products, implies a large variety of production technologies. Each type of glass and end use requires specific technologies, different raw materials, different size of furnaces, defining the physical properties of the end products.

NiO is used neither by all manufacturers nor in all types of glass. NiO is both a glass colouring and decolouring agent. NiO is only used to manufacture crystal glass, ophthalmic glass and Black Light Blue glass (BLB glass). These three uses are detailed hereafter. Crystal glass belongs to the category of domestic glass manufacturing. The two others belong to the category of special glass manufacturing. Flat glass, container glass, glass fibre and glass wool are not manufactured from NiO.

NiO can be used in the production of tinted glazing produced for the automotive industry in order to achieve the required colour and optical properties; however, this type of glass is not manufactured in the EU.

Other nickel compounds (nickel sulphate) can be used to manufacture the same type of flat glass. However this use has been covered by the REACH registration dossier of nickel sulphate and is therefore considered as non-existent within the EU.

Frits are also commonly used in soda-lime glasses for colouring purposes (see section 2.2.5). The only difference is that frits are added in the forehearth, meaning that only minor parts of the glass batch are coloured instead of the addition of NiO in the batch at furnace level.

In 2010, total European (EU27) glass production reached a volume of more than 34 million tons, making Europe the largest glass producer in the world. The industry employs around 11,000 people.

#### 2.3.7.1 Regulatory status of glass and its nickel oxide constituent under REACH

In accordance with Article 3(15) of the REACH Regulation, an intermediate is "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance".

The ECHA document on the clarification on the concept of intermediates under REACH[21] states the following. The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing. The definition of an intermediate is therefore the definition of an intermediate use of a substance. As soon as the main aim of the involved chemical process is not to transform a substance into another one or the substance is not used for this main aim but rather to achieve another function or a specific property, the substances used for this activity should not be regarded as intermediates under REACH.

Following this analysis, Anses doesn't consider NiO as a raw substance for glass manufacturing as it is not always used and not necessary to produce primary glass. Even if it is added to the raw materials in the melt, the main aim of NiO is to provide a special function (colouring or decolouring effect) and physicochemical property to the glass (colour, transparency). In this point of view and following ECHA clarifications, Anses considers the use of NiO for glass manufacturing as a non-intermediate under REACH.

#### 2.3.7.2 Process summary of glass manufacturing (common approach)

NiO raw material, supplied in the form of sealed palletised bags/sacks/drums is manually or automatically (using conveyer) tipped into intermediate (flow) bins, which are sealed

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[21] 4th CARACAL meeting, 2-4 February 2010, meeting document, http://inforeach.gencat.cat/pdf/ECHA_Clarification_concept_intermediates.pdf

off and transported (fork lift truck, FLT) to the mixing area. NiO fines recovered in the ventilation are returned to the silos or flow bins, and reused again.

NiO powder, released from flow bins or silos, is (screw or vibratory) conveyed to the balance where the charge is weighed out. Alternatively, because NiO is a minor ingredient it may be manually tipped into the balance from a sack or added last - just before discharge to the furnace. The sack of NiO is added and mixing with the others raw materials just before transferring by truck to the furnace. The NiO containing charge is transferred, along with other ingredients, to the mixer using an enclosed system (closed belt conveyor or pneumatic conveying). The mixed batch is conveyed from the mixer to furnace using an automated (closed belt conveyor or pneumatic conveying) or mechanised ‛repacking’ (into flow bins) and driving (of flow bins) enclosed system. The furnace charge is melted between 1425 and 1600°C using refractory pots (specialized products), day tanks (coloured glass) and continuous tanks (flat and container glass).

This is then followed by forming or shaping of molten glass containing NiO. Glass is shaped or formed by blowing (used for light bulbs, bottles, Christmas tree ornaments and jars), pressing (used for domestic ware, optical and filters), drawing (used for tubes and rods), and casting (for telescope mirrors). In machine pressing and blowing, the discharged melt from the furnace is basically cut into gobs which are pressed or blown into a mould and the finished product taken removed. After the shaping process, finishing techniques such as annealing may be used to further shape the glass. Finished glass products are then inspected and boxed for dispatch.

#### 2.3.7.3 Crystal glass production

Domestic glass accounts for 4% of total glass output (by volume) in the EU and crystal glass only contributes to a minor extent to this figure. It is estimated that total yearly crystal glass production in the EU amounts to around 60,000 tons (i.e. 0.17 % of the total European glass manufacturing), and only a half (i.e. 30,000 tones) is produced using NiO (i.e. 0.085% of the total European glass manufacturing). Around 85-90% of the world crystal glass production is currently produced in the EU. The use of NiO in the EU is estimated at around 3 to 5 t/y for lead crystal glass and crystal glass production.

What is crystal glass?

Lead glass is a variety of glass in which lead(II)oxide replaces the calcium content of a typical glass, which makes that the appearance of lead glass more bright. Lead crystal glassware contains more than 24% of lead oxide and is only produced for decorative properties. Lead-free crystal glass, "crystal", is commonly used to manufacture domestic glassware, it has a similar refractive index to lead crystal. In lead-free crystal glass, barium oxide, zinc oxide, or potassium oxide are used instead of lead oxide.

Crystal glass refers as well to lead crystal glass as crystal glass because NiO is used in both types of glass.

Functionalities of nickel oxide in crystal glass manufacturing

The functionality of NiO in crystal glass is twofold: it is especially needed for colouring and decolouring. Coloured or decoloured glass depends on two factors: the reduction state of the glass and the specific colouring agents used, the recipe usually involves the addition of metal compounds to the glass batch. NiO is also used as processing agent since it induces a structural change in the chemical structure of the glass; but this is not further developed by Industry and therefore not considered as an essential property for crystal glass manufacturing.

Colouring agents are often metal oxides like e.g. manganese, iron, nickel, cobalt, chromium, copper and vanadium. The metal oxides each have specific colours that they produce. Depending on the type of glass and the amount of nickel oxide added, glass can vary from clear to the colours violet, smokey grey and brown. Hence, changing the oxidation state can induce a typical change in colour.

The decolouring process is necessary to cancel iron contamination (yellowish, greenish hue) in the glass batch (see figure 7). Iron contamination is caused by ferrous oxide (FeO) and causes blue-green colour and ferric oxide ($Fe_2O_3$) which causes a yellow-green colour. Even in very small fractions (~0.02%), iron needs to be regarded as a very powerful colouring agent and in making clear glass it is an undesirable impurity. A decolouring process is thus needed. Within it 2 main stages can be distinguished: the chemical process (oxidising agents reduce colour of the iron by transforming $Fe^{2+}$ into $Fe^{3+}$; no need for NiO) and the physical process (a complementary colour, NiO is added to the batch to neutralise the yellow-green colour, it is a masking process; NiO produces a neutral grey tint in the glass that is not seen by the human eye). In order to neutralise this yellowish, greenish hue and to obtain clear crystal glass, the complementary colour purple needs to be added to the batch. It is precisely NiO which provides a purple colour. If more NiO is added to the batch, the resulting glass will darken and a coloured glass is obtained. Depending on the concentration of NiO that is added, a blue or violet or even black crystal glass is produced.

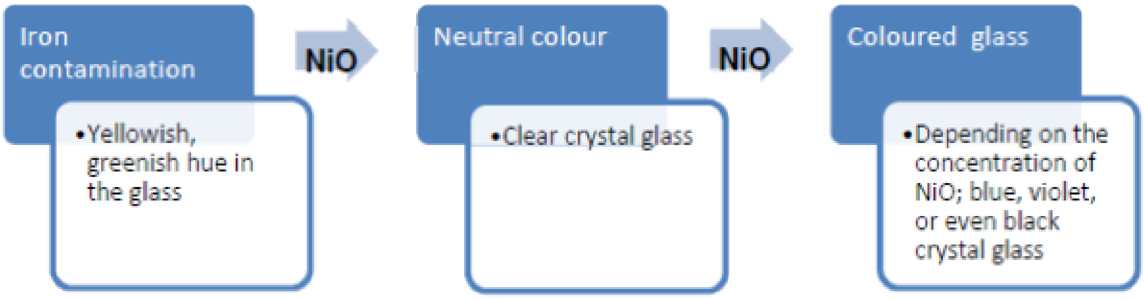

Figure 7. Effect of introducing NiO into the glass batch

More generally, NiO is added in the glass batch recipe to change the optical properties of the glasses, i.e. the light transmission. Proper decolourisation reduces the light transmittance of the glass. The better glass has been decoloured, the less grey colour and the higher brilliance it possesses. NiO is not a simple decolouring or colouring agent, it is a "processing agent" since it induces a structural change in the chemical structure of the glass.

Besides iron contamination introduced by using sand and cullet (recycled glass), the type of electrodes used in an all-electrically-heated furnace can influence the degree of colouring. The industry tries to minimise this effect by using passivated electrodes or by using low-frequency current but this is not 100% effective. As a consequence, manufacturers still have to use decolouring agents like NiO.

Glass decolouring agents are generally used in combination, not separately. For example, nickel oxide is often used in combination with cobalt oxide. There are two types of glass that need to be decoloured. Lead crystal glass is chemically decoloured with arsenic or antimony containing compounds and physically decoloured with NiO (~0.3-0.8 g/100kg of sand); the resulting glass is colourless but less brilliant. Soda-lime crystal glass cannot be physically decolourised by NiO, because in this case it does not provide a complementary colour. Nickel interacts with Na (soda) to give a greyish hue. The batch must contain an oxidiser, such as a nitrate or a combination of selenium compound and neodymium oxide.

### Crystal glass producers and nickel oxide volumes used

#### *Producers*

It is assumed that only 30,000 tons of crystal glass is produced using NiO by presumably 20 to 25 companies, mainly located in France, Italy, Poland, Austria, Slovakia, the Czech Republic and a fewer ones in the UK and Germany. About ten producers are major and lead the EU market. The others are SMEs.

The major EU-based crystal glass producers with a major presence in the EU market are: [confidential]. There are also a lot of SMEs that play a significant role in this high value segment.

Most silos and mixing vessels in modern glass processes are fitted with filter systems which reduce dust emissions. However, a characteristic of the crystal glass sector is that some batch plants are relatively small and due to the specialised nature and lower volumes of some of the products, there is a higher level of manual (and semi-manual) handling and transfer. Where materials containing potentially more toxic compounds (e.g. lead oxide, arsenic, etc.) are handled, there is the potential for emissions of these substances and exposure to them.

#### *Volumes*

The use of NiO in the EU is estimated at around 3 to 5 tonnes for crystal glass production, more specifically clear crystal glass and coloured crystal glass (blue, violet, or black glass). This shows that NiO is only required in small amounts, with the content of NiO in the raw material batch being less than 1%.

### Market trends

The domestic glass sector is one of the smaller sectors of the glass industry with approximately 4% of total output (by production volume). Finished products like glass tableware, cookware and decorative items such as drinking glasses, bowls, plates, cookware, vases and ornaments are produced mainly by SMEs. This domestic sector also covers the production of crystal glass, but crystal glass only contributes to a minor extent to this figure. The following types of downstream users were identified by crystal glass manufacturers: consumers (households), distributors (department stores, architectural firms), drinks and cosmetic industry.

Crystal glass production in the EU is typically characterised by high-value crystal glass requiring specific skills (handmade) and with a market of end users showing a willingness to pay a higher price for a product originating from the EU. End products in the crystal glass industry are mainly for domestic purposes; for example crystal drinking glasses, decanters and other tableware or decorative objects like chandeliers or other architectural objects.

A large part of lead crystal glass production is exported: 85% of global lead crystal glassware output (by volume) is produced in Europe and SMEs play a significant role in this high value segment. According to industry, in recent years this could even amount to 90%. Export is oriented in particular to (in order of importance): Russia, US, Asia and the Middle East.

Manufacturers report an increasing global demand for crystal articles because of a worldwide growing luxury market. However, most of the European manufacturers have a stable production and observe a stabilised market, probably because part of global demand is fulfilled by the increased production in Asia and Turkey.

A few companies produce the majority of the EU output. The smaller SME entities have less capital-intensive installations and are capable of specialising in high-value items and niche markets. The market mainly drives this specialisation, as the crystal glass market is affected by continuously evolving customer tastes and social trends. Therefore, flexibility is an important part of the manufacturing operation. As a consequence, glass formulations must be tailored to specific products and processing requirements. The SMEs produce an extremely diverse range of products, requiring small amounts of glass, most of the time produced in pot furnaces and day tanks (relatively cheap to build and operate). However, SMEs could never compete economically in high volume markets in which manufacturers operate with continuous furnaces and profit from economies of scale (i.e. production of a sufficient volume to secure profit margins).

Analysis of alternatives

To avoid confidentiality issues, the AoA has been solely based on publicly available information, excluding ongoing R&D from individual companies. Feasibility, suitability, availability and costs have been taken into account.

Both colouring and decolouring effects have to be considered. The use of organic pigments is not feasible for colouring purpose because carbon compounds oxidize at a temperature of 1,500°C, which destabilizes the pigments and undoes the colouration functionality.

The subject of decolouring is complicated, because of the various base glass compositions used and the diverse ranges of approaches to decolour. It needs to be stressed that each manufacturer has its own specific production method and has acquired its own optimal batch composition. Optimization takes place, based on the requirements of the product (transmittance of the glass), of the processing properties and of the cost price. The subject of decolouring is complicated because of the various base glass compositions used and the diverse ranges of approaches to decolour.

Years of experience and knowledge of each manufacturer has led to specific glass batch formulations. It is not only the combination and concentration of decolouring agents that is company-specific, but also the combination and concentration of the base materials is important and can influence the appearance of the glass.

A crystal glass manufacturer can distinguish his product in the market by producing an ultra-clear and brilliant glass with an attractive design. The brilliance is the most important parameter of competition between manufacturers as design can easily be changes.

In theory several possible types of alternative can be envisaged

- ‘drop-in’ substances that directly replace NiO, but not nickel, 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*

In decolouring process, that replacement of NiO by other metal oxides is one of the best options. All manufacturers indicate that more research is needed in order to define a new combination of (de)colouring agents and base materials to come to a similar colour or a similar degree of clear crystal glass. Some already used alternatives can potentially work for some manufactures, but cannot be regarded as feasible alternatives for the entire sector.

Only nickel nitrate would act as colouring and decolouring agent but nitrate will also create an oxidizing effect; moreover no decrease in human health risk is expected from this hazardous substance.

The combination of erbium oxide (dierbium trioxide, EC 235-045-7, CAS 12061-16-4) and cobalt oxide is stated by several stakeholders to be a feasible alternative in order to obtain clear crystal glass (decolouring effect). The mixture of erbium and cobalt is already used by many world class crystal glass manufacturers. Regarding decolouring, this combination can provide a similar quality of clear and brilliant crystal glass. If one compares a crystal glass decoloured with nickel and one decoloured with erbium and cobalt, one will only notice a difference if both are compared side by side only. A larger quantity of erbium and cobalt is needed, this can amount up to three times more to obtain a similar clear glass; availability of erbium is critical and low for cobalt (cobalt is only produced as by-product of other mined metals, its cost is high). However using this combination of oxides to colour the glass will give a different colour (colouring effect). Erbium oxide has not harmonised classification and is self-classified as Eye Irrit 2. Cobalt oxide (EC 215-154-6, CAS 1307-96-6) is classified Acute Tox. 4, Skin Sens. 1 Aquatic Acute 1 and Aquatic Chronic 1 under Annex VI of the CLP and is thus considered less harmful than NiO regarding its Carc 1A classification.

During industry consultation the combination of praseodymium, neodymium and/or erbium is mentioned as a technique for decolouring crystal glass. However, none of the stakeholders actually uses praseodymium. Neodymium on the other hand is used, most of the time in combination with other decolouring agents (like nickel oxide). Regarding the decolouring, neodymium can provide a similar quality of clear and brilliant crystal glass. If one compares a crystal glass decoloured with nickel and one decoloured with neodymium, a difference will only be noticed if both are compared side by side. As for erbium oxide, using neodymium to colour the glass will give a different colour (colouring effect). Neodynium oxide (EC 215-214-1, CAS 1313-97-9) is self classified Aquatic Chronic 4, STOT SE 1, Skin Irrit. 2, Eye Irrit. 2 and is thus considered less harmful than NiO. Neodynium is a more abundant element than erbium but its availability remains low.

Note that the reported CLP classifications are dated 2013.

Selenium is also indicated to be a physical decolouring agent, however, as it is reported to be an unstable element in glass production.

### *Alternative substances or combinations of substances*

A potential alternative is the use of the purest raw materials (sand) and in what extent this is able to avoid iron contamination and hence the yellowish hue to obtain crystal glass. As Silica does not provide colour to the glass, this alternative is only investigated as having potential for decolouring purposes.

Nowadays crystal glass manufacturers already use the purest sand available on the market (low iron silica) compared to the lower quality sand that is used for container glass production. There are suppliers like Sibelco (Belgium) that are specialised in delivering high purity silica sand with low iron deposition, which indeed increases the transparency of glass.

There is also more pure sand available on the market, which currently is used in high-end applications like the production of optical fibres. It is indicated that this raw material is up to 20 times more expensive. Industry considers this alternative not viable from an economic point of view.

*Alternative materials*

Amongst all the possible alternatives materials used instead of crystal glass depending of the purpose i.e. drinking glasses, decoration, jewellery, etc (soda-lime glass, metals, soda-lime glass, plastic, wood porcelains, etc.), most likely soda-lime glass is the material which is closest to crystal glass because of its similar weight and transmittance (or colouring possibilities). However, the market for crystal glass products will remain, since it is driven by the consumer's search for a more valuable and luxurious product compared to ordinary glass, seeking for higher aesthetics. Therefore, Industry considers that none of the materials will satisfy the same qualities and characteristics (hence functionality) as are expected from crystal glass.

*Alternative processes/technologies*

Another option to be investigated is the use of alternative production methods. It is known that the type of electrodes used in an all-electrically-heated furnace can influence the degree of colouring. A solution consists of using $SnO_2$-electrodes (tin oxide electrodes) in combination with a special supply system. In this case, provided that good quality silica is used, there is almost no need for discolouration. This means that there is no longer the need to use NiO or other decolouring agents. But a proper decoloured glass cannot be guaranteed yet.

*Conclusion of the analysis of alternatives*

Several drop-in substances or combination of substances are already used by some producers instead of NiO. Based on the currently available hazard information and the classification and labelling, erbium oxide, cobalt oxide and neodymium oxide appear to be good alternatives for NiO. Therefore without cost consideration and element availability, a combination of those oxides can be considered as a suitable and already available alternative to NiO for decolouring crystal glass. All manufacturers would need to perform individual research to find their optimal combination of substances.

Possible combined process improvements i.e. by using alternative furnace electrodes and a more pure silice may help achieving the expected result for high quality crystal glass without NiO use, admittedly with higher costs. In principle, the substitution in crystal glass sector can thus be considered as possible.

#### 2.3.7.4 Ophtalmic glass production

The large variety of special glass formulations produced mainly in small amounts account for 2% of the total glass production in the EU (i.e. 680,000 tones). Within special glass, ophthalmic glass (i.e. sunglasses) only contributes to a minor extent. Only two European manufacturers provide tinted sunglasses, located in Germany and France; both require the use of nickel compounds, either by the direct use of NiO or by calcination of nickel hydroxycarbonate to obtain NiO.

Sunglasses (lenses) are made with darkened, usually tinted lenses to filter the quantity of light reaching the eyes. All types of tinted sunglasses made of glass (yellow-brown) are produced with NiO: tinted, reflective, photochromic and polarizing sunglasses. NiO is thus used as a colouring agent.

### Functionalities of nickel oxide in ophthalmic glass manufacturing

The tint of the glass is determined by the use of NiO that is used to impart colour to silicate glasses. It is used to colour the lens greyish, brown, yellow-gold, amber-brownish, green, purple-rose and blue to violet (depending on the glass matrix and the NiO quantity). Only the visible light between 380 nm and 780 nm will be blocked and small part of UV rays. Other raw materials have their own properties and will block other wave lengths.

Glass lenses are tinted by adding NiO to the glass itself during its manufacture. Many manufacturers employ a process called 'constant density' to tint the lenses. It is the oldest method of creating sunglasses and involves a glass (or polycarbonate mixture) with a uniform colour throughout the material. The tint is built right into the lenses when they are created. Literature also indicates that metallic substances could also be applied on coated lenses, but no manufacturers were identified using this type of process in the European Union.

### Ophtalmic glass producers and nickel oxide volumes used

Only two European manufacturers provide tinted sunglasses, one located in Germany and one located in France. The use of NiO in the EU ophthalmic glass production is estimated at [confidential] for ophthalmic glass production, more precisely in tinted sunglasses (i.e. [confidential] % of the worldwide used NiO for this purpose, estimated around [confidential] t/y by the consulted stakeholders).

### Market description and market trends

According to the BREF (2012)[22], the production of the special glass sector in 2005 was around 2,1% of the glass industry output (by volume), and in terms of tonnage it was the fifth largest sector. Note that sunglasses only contribute to a minor extent to this figure.

Sunglasses are globally distributed to the end consumers. Ophthalmic glass making is a mature business; nevertheless the levels of production in Europe have been maintained reasonably well, due to some technical barriers. The share of ophthalmic polymers (and hence plastic sunglasses) is still progressing. Polycarbonate is the material most often used in the US, while CR-39 (plastic) is mostly sold in the EU. However, in some areas in the EU, a significant part of the market is still covered by glass (especially Eastern Europe). A member of the end use market stated that 95% of sunglasses in the world are produced with plastics or polycarbonate, only 5% is made of glass.

Glass lenses have the best optical clarity and scratch resistance, and therefore they remain the preferred choice of high-end brands, even though they are heavier than plastics. Glass made sunglasses are specifically produced for people with medical eye diseases; in case colour is very important, this cannot be obtained by plastic or other materials in sunglasses. Overall, the ophthalmic sector is very segmented, with small individual tonnages, characterised by several compositions and formulations, with high added value requiring special raw materials often unique for providing characteristics to the glass. This is also the case for the production of sunglass lenses.

Sunglass blanks are produced in small amounts in small, often electric furnaces, and are operated for shorter campaigns. Despite the small scale, these operations usually also

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[22] Best Available Techniques (BAT) Reference Document for the Manufacture of Glass, JRC reference report, 2013 (adopted March 2012) http://eippcb.jrc.ec.europa.eu/reference/gls.html

require substantial long-term investment in high-quality equipment, skilled staff, and extensive research and development work.

There is limited competition on the market of tinted sunglasses as there are only two manufacturers in the EU. One company has several special glass products, of which only 10% of the activities can be connected to the production of sunglass lenses. The other company is specialised in the melting and production of optical glass sunglass lenses.

Like the crystal glass market, the sunglasses are also affected by customer tastes and social trends. For example, in the nineties there was a trend towards blue and pink coloured sunglasses. It is important for the manufacturer to keep ahead of these changes and to respond accordingly and therefore, flexibility is an important part of the manufacturing operation. As a consequence, glass formulations must be tailored to specific products and processing requirements.

Glass, however, is considered as rather outdated, and its safety and durability limitations make it a last-choice nowadays. It is more prone to potentially dangerous breakage, unlike other materials like polycarbonate and plastic. However, as glass remains the preferred material of some luxury sunglass brands, glass remains the preferred material for customers looking for luxurious materials and design. As already said, glass is also the best option for people with certain eye disorders.

### Analysis of alternatives

The AoA was mainly developed through approaching sector organisations and individual companies. The main functionality that is targeted for the AoA is the colouring effect with the related UV filtering. The reported functionality of NiO for eliminating iron contamination in glass (see section on crystal glass) is not discussed in the provided documents.

In theory several possible types of alternative can be envisaged

- 'drop-in' substances that directly replace NiO, but not nickel, 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*

Nickel hydroxycarbonate can be used as a drop-in alternative. It is transformed into NiO by calcination directly in the production process and is thus considered as an intermediate in the production of NiO and no risk reduction is thus expected at all. Some manufacturers are reluctant to use nickel hydroxycarbonate because there is a chance that nickel carbonyl may be released, which is poisonous.

#### *Alternative substances or combinations of substances*

Five alternatives have been identified as possible candidates to replace NiO in ophthalmic glass: Disperse Yellow 3, Disperse Violet 1, Disperse Blue 7, Disperse Brown 1 and Disperse Blue 3. No REACH registration dossier is currently available for those 5 compounds (Table 17).

Table 17. Possible alternative substances to the use of NiO and related classification

| Alternative | CAS number | EC number | Classification[23] |
|---|---|---|---|
| CI Disperse Yellow 3<br>(N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]acetamide) | 2842-40-8 | 220-600-8 | Annex VI of the CLP:<br>Skin sens. 1<br>Carc.2 |
| CI Disperse Violet 1<br>(1,4-diaminoanthraquinone) | 128-95-0 | 204-922-6 | Self classification:<br>Acute Tox. 3<br>Skin Sens 1<br>STOT RE 2 |
| CI Disperse Blue 7<br>(1,4-dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone) | 3179-90-6 | 221-666-0 | Self classification:<br>Acute Tox. 4<br>Skin Irrit 2<br>Eye Irrit 2<br>STOT SE 3 |
| Disperse Brown 1<br>(2,2'-[[3-chloro-4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]imino]bisethanol) | 23355-64-8 | 245-604-7 | Self classification:<br>Acute Tox. 4<br>Eye Dam 1 |
| Disperse Blue 3<br>(9,10-anthracenedione, 1,4-diamino-, N,N'-mixed 2-hydroxyethyl and methyl derivatives) | 2475-46-9 | 219-604-2 | Self classification:<br>Acute Tox. 4<br>Skin sens. 1<br>Aquatic Acute 1 |

Based on the currently available classification only and regarding the expected risk reduction, the identified alternative compounds appear to be good alternatives for NiO, except CI Disperse Yellow 3 which is considered potentially carcinogenic.

*Alternative materials*

Sunglasses (lenses) can also be made with darkened, tinted Plastic (CR-39), High Index, Polycarbonate or Trivex lenses to filter the quantity of light reaching the eyes. Glass in general is the clearest material of all the mediums available for sunglass manufacturing and is more scratch resistant compared to other materials. On the other hand, there are also a number of drawbacks of glass lenses compared to the mentioned alternative materials: glass is thicker hence heavier and it may chip or break.

CR-39 is a plastic made from hard resin that meets optical quality standards. These lenses tend to be lighter and are more impact-resistant compared to glass.

Polycarbonate is a synthetic plastic material that has great strength and is very lightweight. These polycarbonate lenses tend to be lighter and are more impact-resistant compared to glass and plastic. Optical-quality polycarbonate and glass lenses are free of distortions, such as blemishes or waves, and have evenly distributed colour across each lens. Distortion is extremely common in cheap sunglasses. Polycarbonate is the most cost-effective material on the market, it is a light material and inexpensive. Polycarbonate lenses are extremely durable as it is the preferred material used for e.g. space shuttle windows. Polycarbonate is the best choice in environments like construction, sports, or warehouses, where your glasses run a risk of being broken. Moreover, it naturally protects to UV radiations.

High index lenses are the thinnest available medium on the market and have better optics compared to polycarbonate. A disadvantage is that it can create surface reflection

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[23] Note that the reported CLP classifications are dated 2013

and it is not as impact resistant. Thinner, lighter high-index lenses are especially recommended with strong eyeglass prescriptions.

Trivex is a new plastic lens material that is used as a substitute for polycarbonate lenses. Trivex is optically superior to polycarbonate and it is lighter. Like polycarbonate it provides 100% UV protection and it is extremely durable. Most importantly, Trivex is a good substitute for polycarbonate lenses, it is easier to tint compared to polycarbonate.

Many sunglasses are already manufactured using these various types of materials. Each of these alternatives aims at a particular use and market segment. All materials (Glass,CR-39, Polycarbonate, Hi-index and Trivex) protect the eyes from the sun's harmful glare and cut back on part of the UV light. Most likely customers would prefer these materials to glass, each of them for a specific purpose. All alternative materials have their pros and cons. Alternative materials can be made more scratch resistant if an appropriate hard coating is used. Using adjusted techniques and coatings, the alternative materials can give optics similar to glass.

For example, alternative materials overcome some major drawbacks of glass: they are lighter and hence improve the wear comfort, and they cannot break or shatter. For that reason, plastic lenses are the preferred material for active adults, sportswear, and safety wear because the impact resistance is higher.

However glass lenses have the best optical clarity and scratch resistance, and therefore they remain the preferred choice of the high-end brands. Currently, it is indicated by industry that glass made sunglasses are still the preferred option for luxury brands. Glass is also especially recommended and designed for some medical eye diseases. Consumers with eye disorders will probably change to another material because the exact colour required for some disorders cannot be obtained with other materials. Glass is also less expensive than polycarbonate and CR-39. Industry considers therefore that none of these materials can provide the same qualities and characteristics expected from glass.

### *Alternative processes/technologies*

There are several methods and processes to tinting lenses. The most common used tinting method is the heat treated process using specially formulated chemical dyes. A coat of light-absorbing molecules is applied to the surface of clear polycarbonate. This process can be used on most lens materials (Plastic (CR-39), Trivex, High Index, and Polycarbonate lenses) but excluding glass.

### *Conclusion on the AoA*

Industry conclusion states that no suitable alternative is yet identified that can provide the same colour point as NiO and the same functionality of glass lenses. However it appears that alternative substances may become available and suitable even if Industry denies its suitability because of economic and technological issues (the exact tint obtained with NiO cannot be reached with these alternatives). More R&D would thus be needed first for substitution in optical glass manufacturing (made from glass). The main remaining issue that should be investigated further in the AoA is the glass lenses designed for medical eye diseases.

It is considered that the aesthetic and luxury expectations of consumers should not be considered as a relevant driver in the AoA conclusion since such market drivers may probably change once the initial product (and its characteristics) is no longer be available on the European market. In conclusion, the substitution in ophthalmic glass sector can thus be considered as possible.

#### 2.3.7.5 Black Light Blue (BLB) glass production

The large variety of special glass formulations produced mainly in small amounts account for 2% of the total glass production in the EU (i.e. 680,000 tones). Within special glass, BLB glass only contributes to a very minor extent with less than [confidential] t/y in Europe.

The BLB fluorescent type is equipped with a deep-bluish-purple glass called Wood's glass, a NiO doped glass instead of a clear glass envelope (cf. figure 8). The glass locks almost all visible light between 400 and 700nm. The black light blue efficiently emits near ultraviolet rays at 315 to 400nm, this creates strong photochemical and fluorescent effects (the emitted UV light reacts with various external phosphors which glow as long as the UV light is shining on them).

The BLB lamp is a fluorescent lamp emitting long wave UV radiation for detection and analysis purposes in archaeology, money checking, forensic science, food industry, medicine, mineralogy, philately as well for special effects in night clubs, discos, theatres and sign lighting.

There are also incandescent bulbs, mercury vapour black lights on the market that can hold back all light except for a few violet rays of the visible spectrum and ultraviolet wavelengths of about 365nm. These bulbs are also referred to as “blacklite” or “black light blue”.

Fluorescent black lights are typically made in the same fashion as normal fluorescent lights except that a different sort of phosphor coating is used and the normally clear glass envelope of the bulb is replaced by a deep-bluish-purple glass.

Figure 8. Illustration of a fluorescent black light blue[24]

Functionalities of nickel oxide in BLB glass manufacturing

The black light blue lamps are manufactured with NiO to develop a special deep blue filter glass that absorbs visible rays and transmits near ultraviolet rays. The "black" glass tube itself blocks most visible light, so in the end only emitting long-wave UV-A light, along with some blue and violet visible light, passes through.

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[24] Source:

NiO is only needed in small amounts in the glass batch (less than [confidential]). BLB glass production is estimated to be less than 100 t/y. The percentage of NiO used determines the degree in which UV light and visible light is transmitted.

### BLB glass producers and nickel oxide volumes used

Only two manufacturers provide light bulbs worldwide and only one is producing BLB glass and is located in The Netherlands.  The use of NiO in the EU is estimated at less than [confidential] per year.

### Market trends

According to the BREF (2012)[25], the production of the special glass sector in 2005 was around 2.1% of the glass industry output (by volume), and in terms of tonnage it was the fifth largest sector. BREF specifies that 53.5% of this amount is realised by the production of glass tubes but the specific BLB glass only contributes to a minor extent to this figure.

BLB glasses are globally distributed to the lighting industry and then further directly to end consumers or commercial sectors (banks, forensics, food industry, medicine, night clubs, etc.).

There is only one company producing lead free BLB glass in the world, located in the EU, and holding a monopoly position. According to it, the market of black light blue glass is still growing.

### Analysis of alternatives

Contact has been made with the only European manufacturer, which indicated that there are no alternative 'drop-in' substances available to produce the black light blue fluorescent glass. The literature search carried out by the consultants involved in the SEA identified two potential patents that could possibly replace the black light blue glass ("UV light-permeable glass and article comprising it" and "Green luminescent glass for ultraviolet LED") and, from these patents, potential drop-in substances that could replace NiO.

#### *'Drop-in" substances*

Three alternatives have been identified as possible candidates to replace nickel oxide in BLB glass production (Table 18): fluorine, cerium oxide and terbium oxide.

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[25] Best Available Techniques (BAT) Reference Document for the Manufacture of Glass, JRC reference report, 2013 (adopted March 2012) http://eippcb.jrc.ec.europa.eu/reference/gls.html

Table 18. Possible alternative substances to the use of NiO and related classification

| **Alternative** | **CAS number** | **EC number** | **Classification**[26] |
|---|---|---|---|
| Fluorine | 7782-41-4 | 231-954-8 | Self classification:<br>Skin Corr. 1A<br>Acute Tox. 2 |
| Cerium oxide | 1306-38-3 | 215-150-4 | Self classification:<br>Not classified |
| Terbium oxide | 12037-01-3 | 234-856-3 | Self classification:<br>Not classified |

As cerium is the most abundant element compared to other rare earths lithium, neodymium, lead, tin, boron, silver, no issue on cost and availability is raised. On the contrary terbium (metal) has extremely low supply (world production is around 10 t/y) and therefore is very expensive. This could imply that supply is far less than demand would be but the ratio that would be needed to replace NiO is not known as no R&D has been carried out or is available.

Based on the currently available classification only and regarding the expected risk reduction, the identified alternative compounds appear to be good alternatives to NiO.

These alternatives have been discussed with the BLB glass manufacturing company and it was concluded that these alternatives cannot be considered as technically feasible, for the following reasons. The fluorine alternative has radiation in the UV-C area and therefore it is considered as dangerous for the human skin and eyes; indeed as almost all applications of the BLB light are related to the use of the lamp by consumers, the technical feasibility is to be judged not suitable. The second application is considering UV LEDs and is generating green light. These LED lights will mask luminescent properties that are certainly visible in violet near-UV-area (BLB application). Hence, this type of light is emitting totally different wavelengths and thus it is to be considered as a totally different product.

### *Alternative materials*

Patent number 5474589[27] describes an optical glass that is UV light-permeable and consisting of a fluorine-doped synthetic quartz glass, which has a long term reliability. The glass is suited to emit UV light having a wavelength of 155 nm to 400 nm and has a composition of quartz in which a content of fluorine is present of about 1.5 to 3% by weight.

Another patent[28] discloses the composition of a green luminescent glass for ultraviolet LED and the preparation method for the glass. Glass is manufactured from cerium oxide and terbium oxide.

### *Conclusion on the AoA*

No suitable alternative is currently identified for replacing the use of NiO in the BLB glass manufacturing. But R&D should be further developed to investigate possible "drop-in"

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[26] Note that the reported CLP classifications are dated 2013

[27] http://www.google.com/patents/EP2465831A1?cl=en

[28] http://www.google.com/patents/US20120138854

substitution of NiO from the currently identified candidates. The substitution in BLB glass sector is thus considered by industry as impossible today.

### 2.3.8 Use of nickel oxide for the production of of stainless steel, special steels and special alloys

Stainless steel and alloy manufacturing use only the sinter NiO which is not considered by Industry as a chemical form of NiO but as a metallurgic form that would not be covered by REACH. Therefore the registrants didn’t consider further the manufacturing and use of sinter NiO in the current anticipation of a non-use scenario and SEA drafting.

Stainless steel is produced by melting a charge consisting of a variety of different feedstocks (stainless steel and steel scraps, ferroalloys, normal carbon steel scrap) in an electric arc furnace (EAF). Multiple steel products are produced either using the electric arc furnace or the basic oxygen furnace (BOF); the EAF process is similar to that described above for stainless steel. The production process for high nickel alloy production involves melting the alloy, followed by a variety of procedures to manipulate the alloy into shape.

No data on alternatives neither any SEA report has been provided by industry for this specific use of NiO.

### 2.3.9 Use of nickel oxide for the production of NiZn cores and solids from nickel oxide powder

NiO is used to produce Nickel-Zinc cores and solids. NiO raw material, supplied in the powder form is transferred to open vessels in automated processes for milling. Milling involves producing powder from solid materials. Then the powdered form is pressed and sintered to make solid objects at elevated temperature conditions.

NiO is also used to produce metallic nickel as pellets or powder via carbonyl refining. The granular NiO feedstock is fed through a rotating kiln and reduced to the metallic state by hydrogen gas at a temperature of about 450°C. The granular nickel metal then passes through another sealed rotating kiln, where, in the course of 9−10 days, about 90% of the nickel is converted into nickel carbonyl. The nickel carbonyl is subsequently decomposed to nickel pellets or to nickel powder

No data on alternatives neither any SEA report has been provided by industry for this specific use of NiO.

### 2.3.10 Use of nickel oxide for the production of other nickel chemicals

From the EU RAR and IARC, NiO may also be used as an intermediate to produce the following other nickel chemicals: nickel bromide, nickel chloride, nickel sulphate and nickel sulphamate. However those applications are no more used in Europe according to the Nickel Institute and are therefore not reported in the REACH registration dossiers of NiO.

Nickel bromide ($NiBr_2$) can be prepared as the hexahydrate by the reaction of black nickel oxide and HBr. The anhydrous halides can be made by direct reaction of the elements at high temperature or in non-aqueous solution, although the fluoride is better made indirectly. They are also formed by dehydration of the hydrates in a stream of the hydrogen halide gas to prevent formation of NiO.

Nickel chloride hexahydrate can be prepared by the reaction of nickel powder or nickel oxide with hot aqueous hydrochloric acid.

Nickel sulphate hexahydrate can be made by adding nickel powder or black NiO to hot dilute sulphuric acid or by the reaction of nickel carbonate and dilute sulphuric acid.

Nickel sulphamate can be prepared as the tetrahydrate (CAS No.13770-89-3) by dissolving nickel powder in a hot solution of sulphamic acid. Soluble NiO, hydroxide or carbonate can be used as well. Short reaction times are need for the preparation because sulphamic acid hydrolyses readily to form sulphuric acid.

Table 19 below provides a global conclusion on the substitution possibilities per activity sector for which data have been provided by Industry (from analysis of alternatives). This table is also provided in the conclusion of this report (as table 49).

Table 19. Conclusion, based on industry view, on substitution possibilities per activity sector

| **Activity sector** | **Substitution possibility** |
|---|---|
| Catalyst | Very low possibility / Impossibility |
| Frits | Possibility |
| Pigments | Possibility |
| Glass | Possibility<br>Except BLB glass: impossibility |

# 3 RISK ASSESSMENT AND OBJECTIVES FOR FURTHER RISK MANAGEMENT

## 3.1 Hazard identification

Nickel oxide is classified under Annex VI of the CLP Regulation EC No.1272/2008 (see Table 20).

Table 20. Harmonised classification of NiO 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) | | |
| 028-003-00-2 | Nickel oxide<br>/<br>Nickel monoxide | 234-323-5<br>/<br>215-215-7 | 11099-02-8<br>/<br>1313-99-1 | Skin Sens. 1<br>Carc. 1A<br>STOT RE 1<br>Aquatic chronic 4 | H317<br>H350i<br>H360D<br>H372<br>H413 | none | none |

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 REACH registration dossiers

Contrary to other nickel compounds, NiO has not be covered by the European risk assessment 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) and made available in 2009.

A first risk assessment has therefore been carried out by Anses in the frame of this RMOA on the information provided in the registration dossiers (last update dated May 2013). Risk characterisation has used the exposure data provided by the registrants in the chemical safety report of the lead registration dossier. Monitoring data have been provided for almost all exposure scenarios and few modelled exposure data have been used. When no information has been provided, the risk assessment has not been carried out. Risk characterization ratios (RCRs) have been calculated with the DNEL for long term inhalation exposure considered appropriate by Anses (DNEL of 0,01 mg Ni/m$^3$, i.e. inhalable OEL proposed by SCOEL).

Based on the former risk assessment conclusions on other nickel compounds (i.e. risk identified for workers, no risk for consumer), the risk assessment has been targeted on the worker population only. Indeed no evidence is available from the registration dossiers that consumers may be exposed to NiO which is confirmed by the Nickel Institute. In the RAR, inhalation and dermal routes were the main exposure paths to all nickel compounds considered for workers.

## 3.3 Health hazard related to nickel oxide

### 3.3.1 Toxicokinetics

#### 3.3.1.1 Absorption

Nickel and its organic compounds can be absorbed in humans and in animals via the gastrointestinal tract as well as the respiratory routes. Percutaneous absorption is less important for the systemic effects than for the allergenic response (contact dermatis).

Solubility is an important factor to determine the amounts of Ni absorbed in all routes of absorption. Insoluble nickel compounds (including NiO) are relatively poorly absorbed (IPCS, 1991 and RAR, 2008).

Inhalation route

Absorption via the respiratory tract is the principal route of exposure to NiO, under occupational exposure conditions. Exposure to NiO by inhalation may be in the form of aerosols (dust) or attached to particles.

According to the available studies (Benson et al., 1995; Dunnick et al., 1995; NTP, 1996), NiO is poorly absorbed through the respiratory tract. Dose dependent increases in Ni concentration in the lung were reported following, 12-day, 13-week and 2-year inhalation studies in both mice and rats.

In a study of Benson et al. (1995), the fate and effects of inhaled green NiO in male rats and mice exposed 6h/day, 5d/week for up to 6 months, were examined. An accumulation of Ni in lung following repeated inhalation exposure of NiO is reported.

Depending on the particle size, insoluble and slightly soluble particles are expected to be retained in different region of the airways and to be removed to some extent by the mucociliary action and translocated into the GI tract.

Oral route

Absorption of Ni from GI tract occurs after ingestion of various Ni compounds in food, beverages or drinking water. In the occupational environment, an appreciable amount of Ni dust may be swallowed via the mucociliary clearance mechanisms. The rate of Ni absorption from the GI tract is dependent on the chemical form and thus, the solubility. The contribution of the poorly soluble compounds, including NiO, to the total Ni absorption may be more significant since they are more soluble in acid gastric fluids (IPCS, 1991).

Few data are available on the absorption of Ni from the GI tract. In the study of Ishimatsu et al. (1995), rats were orally administered with 10 mg NiO in 5% saline. The distribution of each compounds were investigated 24h after administration. The absorbed fraction was 0.01% for Ni oxide (green) and 0.04% for Ni Oxide (black).

Dermal route

No data are available on dermal absorption of NiO, but a low dermal absorption is expected for Ni.

#### 3.3.1.2 Distribution

Considering distribution and transport, available data generally indicated that in animals exposed for one month by inhalation, the Ni concentrations in the exposed rat lungs were much higher than those in controls in all animals evaluated.

Dunnick et al. (1988, 1989, 1995) and NTP (1996) reported dose-dependent increases in Ni concentrations in the lung following 12-day, 13-week and 2-year inhalation studies in both rats and mice. NiO had the greatest retention in the lung compare to the other tested compounds ($NiSO_4$ and Ni subsulphide).

#### 3.3.1.3 Elimination

No specific data available about NiO elimination.

For Ni, the elimination routes depend, in part, on the chemical form of the Ni compound and on the route of exposure. Following oral exposure, the elimination of Ni is primarily in faeces due to the relative low GI absorption. Urinary excretion is usually the major clearance route for absorbed Ni. Other routes of elimination, which are of minor importance, include hair, saliva, milk, sweat and tears (IPCS, 1991).

### 3.3.2 Acute toxicity

For oral route, the DL50 of NiO in rats is greater than 11 000 mg/kg bw for NiO green and 9 900 mg/kg bw for NiO black, according to Henderson et al. (2012). NiO is of low acute toxicity in rats after oral exposure. No classification is required.

NiO is of low acute inhalation toxicity, according to the available data (EPSL studies 2009 and 2010). In rats, CL50 is greater than 5.08 mg/L/4h for NiO green and greater than 5.15 mg/L/4h for NiO black. Rats were exposed nose only to aerosols. All animals survived the observation period, gained weight and appeared active and healthy. No classification is required.

For dermal route, no information is available. However, NiO is not classified for acute dermal toxicity according to the 1st ATP to the CLP regulation.

### 3.3.3 Irritation and corrosivity

According to the well conducted available studies (EPSL, 2008), no skin and eye irritation reaction has been observed in rabbit. NiO is not an irritant under the experimental conditions. No classification is required.

### 3.3.4 Sensitization

No sensitizing effect has been observed in a well conducted OCDE 406 guideline study realized with guinea pigs (FDRL, 1986). Animals were injected intradermaly with solution of 1% $NiSO_4$ (in distilled water). Topical application with a solution of 5% $NiSO_4$ has been realized on day 2 (48h after intradermal injection). After two weeks, the animals were challenged with topical applications of 1% different solutions, including NiO moistened with propylene glycol. Animals challenged with NiO produced no irritation compared to groups treated with $NiSO_4$ where very slight and well defined erythema was observed.

In a second study in guinea pigs (EPSL, 2009), the sensitization potential of NiO sinter (98% NiO + 1.5% cobalt oxide [classified R43]) has been evaluated using the Buehler method. Based on the results of this study, the test substance is not considered to be a skin sensitizer. However, the Buehler method (3 topical inductions) is not considered as sufficient for assessing the sensitization potential, therefore these results should be interpreted with caution.

In a recent study evaluating the bioaccessibility of a series of Ni compounds in synthetic sweat (KHMC, 2010), it has been indicated a low nickel ion release from Ni oxide compared to the other tested nickel salts. These results suggest a very low or no sensitization potency, considering that release of $Ni^{2+}$ is responsible of the sensitization potency of nickel compounds. However, NiO is currently classified as a dermal sensitizer (Skin Sens.1, H317) according to the 1st ATP to the CLP regulation based on human data on Ni.

### 3.3.5 Repeated dose toxicity

#### 3.3.5.1 Oral route

No specific chronic oral study on NiO is available.

A well conducted oral carcinogenicity study (OECD 451) in rats is available for Nickel sulfate hexahydrate ($NiSO_4$ $6H_2O$) (Hein et al., 2007). Decreased body weight gain ranging from 4% to 12% was recorded (males and females combined) following oral gavage of 2.2 to 11 mg Ni/kg bw/day. A dose-related reduced survival achieving statistical significance at the two highest dose levels was seen in females. The LOAEL of 6.7 mg Ni/kg bw/day based on significant reduced body weight and increased mortality and a NOAEL of 2.2 mg Ni/kg bw/day has been set.

$NiSO_4$ $6H_2O$ is a water soluble compound.

According to this study, evaluation of the carcinogenic potential of NiSO4 by oral route is a worst case for the insoluble compounds as NiO. Nickel sulfate have the highest bioaccessibility in gastric fluids and the highest systemic absorption compared to water insoluble compounds.

#### 3.3.5.2 Inhalation route

The United States national Toxicology Program (NTP) has carried out a series of inhalation studies in both rats and mice with three Ni compounds (NTP, 1996a, 1996b, 1996c reported in the RAR, 2008). The three compounds were: the soluble Nickel sulfate hexahydrate, the insoluble nickel subsulfide and the nickel oxide.

Males and females F344/N rats and B6C3F1 mice were exposed to NiO (high temperature, green NiO, mass mean diameter 2.2 ± 2.6µm, at least 99% pure) by inhalation for 16 days, 13 weeks and 2 years.

16-day rat study

In the 16-day rat study, a comparison of the results of the 3 compounds studied shows similar type of effects, including atrophy of olfactory epithelium, lung tissue inflammation and increased relative absolute lung weights, however to a varying degree of incidence and severity depending of the compound and dose. The following order of toxicity, based on mg Ni/m3, is indicated: $NiSO_4$ $6H_2O$ > Ni subsulphide > NiO. Similar type of toxic effects and similar order of toxicity to that of the rat study are observed in mice study.

13-week rat study

In the 13-week rat study, the comparison of the 3 compounds shows effects similar to those identified in the 16-day studies, including atrophy of olfactory epithelium, lung tissue inflammation, and increase absolute and relative lung weights.

Again, NiO appears less toxic than the other two compounds, based on mg Ni/m$^3$. In mice study, effects were similar to those identified in the 16-day study.

2-year rat study

In the 2-year rat study, animals were exposed to 0, 0.62, 1.25, or 2.5 mg NiO/m$^3$ (equivalent to 0, 0.5, 1.0, or 2.0 mg Ni/m$^3$) 6h/d and 5d/week.

Survival of exposed male and female rats was similar to that of the controls. Mean body weights of 1.25 mg/m$^3$ females and 2.5 mg/m$^3$ males and females were slightly lower than those of the controls during the second year of the study. No chemical-related clinical findings were observed in male or female rats during the 2-year study.

No chemical-related differences in haematology parameters were observed in male or female rats at the 15-month interim evaluation.

Absolute and relative lung weights of 1.25 and 2.5 mg/m$^3$ males and females were significantly greater than those of the controls at 7 and 15 months.

Chronic inflammation of the lung was observed in most exposed rats at 7 and 15 months and at 2 years; the incidences in exposed males and females at 2 years were significantly greater than those in the controls, and the severity of the inflammation increased in exposed groups. The incidences of pigmentation in the alveolus of exposed groups of males and females were significantly greater than those of the controls at 7 and 15 months and at 2 years.

Pigmentation in the bronchial lymph nodes similar to that in the lungs was observed in all exposure groups with the exception of 0.62 mg/m3 males and females at 7 months. Lymphoid hyperplasia was observed in the bronchial lymph nodes of 1.25 and 2.5 mg/m$^3$ males and females at 7 and 15 months, and the incidence at 2 years generally increased with exposure concentration.

Nickel concentrations in the lung of exposed rats were greater than those in the controls at 7 and 15 months (7 months, 173 to 713 µg nickel/g lung; 15 months, 262 to 1116 µg nickel/g lung), and nickel concentrations increased with increasing exposure concentration and with time.

Observed effects included lung tissue inflammation, and increased relative and absolute lung weights.

2-year mice study

In the 2-year mice study, animals were exposed to 0, 1.25, 2.5, or 5 mg NiO/m$^3$ (equivalent to 0, 1.0, 2.0 or 4.0 mg Ni/m$^3$) 6h/day, 5d/week.

Survival of exposed male and female mice was similar to that of the controls. Mean body weights of 5 mg/m$^3$ females were slightly lower than those of the controls during the second year of the study. No chemical-related clinical findings were observed in male or female mice during the 2-year study. No chemical-related differences in haematology parameters were observed in male or female mice at the 15-month interim evaluation.

Generally, incidences of chronic inflammation increased with exposure concentration in males and females at 7 and 15 months.

Bronchiolization of minimal severity in exposed animals and proteinosis were first observed at 15 months. At 2 years, the incidences of chronic inflammation, alveolar epithelial hyperplasia, and proteinosis in exposed groups of males and females were significantly greater than those of the controls. The severity of chronic inflammation increased with exposure concentration in females, and proteinosis was most severe in 5 mg/m3 males and females.

Pigment occurred in the lungs of nearly all exposed mice at 7 and 15 months and at 2 years, and the severity increased with exposure concentration.

Lymphoid hyperplasia occurred in two animals after 7 months; at 15 months, lymphoid hyperplasia occurred in males exposed to 2.5 and 5 mg/m$^3$ and in all exposed groups of females. At 2 years, lymphoid hyperplasia occurred in some control animals, but this lesion was still observed more often in exposed males and females and the incidence increased with exposure concentration. Pigmentation was observed in the bronchial lymph nodes of exposed males and females at 7 and 15 months and in nearly all exposed animals at 2 years.

Nickel concentrations in the lungs of exposed mice were greater than those in the controls at 7 and 15 months (7 months, 162 to 1034 µg nickel/g lung; 15 months, 331 to 2258 µg nickel/g lung), and nickel concentrations increased with increasing exposure concentration and with time.

Observed effects included lung tissue inflammation, and increase absolute and relative lung weights.

Conclusion

Inhalation of insoluble compound, including NiO, results in chronic lung inflammation and cellular lesions associated with inflammation and hyperplasia which are serious and potentially irreversible effects.

Classification as STOT RE 1; H372 has been established for NiO according to the CLP regulation.

No data is available on dermal route.

### 3.3.6 Mutagenicity

#### 3.3.6.1 In vitro data

According to the information presented in the RAR (2008), NiPERA (1996) in reviewing both soluble and less soluble compounds finds no evidence of qualitative differences between the different types of compounds. Positive results with test for gene mutations and chromosome aberrations have been seen with NiO and Ni sulfides, as well as other soluble Ni compounds.

A reported in the RAR, the NiPERA review concludes that "both soluble and insoluble Ni compounds are clastogenic in mammalian and human cells in culture".

In a well conducted study (BSL, 2008), according to OECD guideline 476, NiO sinter (98% NiO and 1.5% CoO) does not induce mutations at the tk locus in the mouse lymphoma cell line L5178Y, with and without metabolic activation.

However, some studies (Klein, 1994 and Biedermann, 1987), showed positive results for gene mutation in Chinese hamster lung fibroblast and human foreskin fibroblast, respectively.

Taken together, data indicate that NiO has "weak" genotoxic potential in a wide variety of cell types under the *in vitro* conditions studied. However, results were conflicting which is probably due to the different Ni oxide compounds evaluated (often not characterized by authors).

### 3.3.6.2 In vivo data

In the Kawanashi *et al*., (2002) study, DNA damages were evaluated in cultured cell (HeLa cells) and in lungs of rat after exposure to Ni compounds, including NiO. The findings are difficult to interpret because only a single, relatively high dose was administered to rats via intratracheal instillation (a non-environmentally relevant route of exposure).

They indicate that both black and green NiO increased DNA damage as measured by 8-hydroxydeoxyguanosine (8- OH-dG) lesions in lung tissues 48 hours after exposure. This group reported conflicting findings in HeLa cells as NiO (black or green) did not induced 8-OH-dG damage *in vitro*.

According to the author, disparities in DNA damage between cultured cells and animals could be accounted for by two different mechanisms for nickel-induced oxidative DNA damage in lungs of rat.

The first one is the direct oxidative DNA damage; NI(II) ion that enters into the cells reacts with endogenous $H_2O_2$ to give ROS and causes DNA damages.

The second mechanism is indirect oxidative DNA damage due to inflammation. ROS generated in inflamed tissues can cause injury to target cells and also damage DNA, which contributes to carcinogenic processes.

NiO is not classified for mutagenicity according to the 1st ATP to the CLP regulation.

## 3.3.7 Carcinogenicity

### 3.3.7.1 Oral route

In the Heim *et al*. (2007) study, no neoplastic effects related to treatment have been observed in rats exposed to $NiSO_4$ via oral gavage at 10, 30 and 50 mg $NiSO_4$/kg bw/d.

Reduction in weight gain relative to controls at study week 103 reached the level of biological significance (> 10% decrease) in the group 3 and 4 (30 and 50 mg $NiSO_4$/kg bw/d) males and the group 4 (50 mg $NiSO_4$/kg bw/d) females. This indicates that MTD was reached in the study.

In these experimental conditions, $NiSO_4$ did not cause any carcinogenic effects when administered orally. $NiSO_4$ represents a worst case scenario for systemic absorption of Ni compounds, it is readily solubilised and results in the highest systemic absorption of Ni(II) ions compared to less soluble nickel containing substances.

### 3.3.7.2 Inhalation route

In the NTP studies (1996), rats and mice were exposed to NiO (see details in section 3.3.5). Survival of exposed animals was similar to that of controls.

At 2 years, tumours were observed in the lungs and adrenal medulla of rats and/or mice (see Table 21).

Table 21. Observed tumours per animal species in the 2 years study

| Observed Tumours/animal specie | Tested concentrations (mg NiO/m$^3$) | | | |
|---|---|---|---|---|
| Rat | 0 | 0.62 | 1.25 | 2.5 |
| Lung: Alveolar/bronchiolar adenoma or carcinoma or squamous cell carcinoma (combined) | 1/54 (rat ♂) | 1/53 (rat ♂) | 6/53 (rat ♂) | 4/52 (rat ♂) |
| Lung: Alveolar/bronchiolar adenoma or carcinoma or (combined) | 1/53 (rat ♀) | 0/53 (rat ♀) | 6/53 (rat ♀) | 5/54 (rat ♀) |
| Adrenal medulla: benign or malignant pheochromocytoma (combined) | 27/54 (rat ♂)<br>4/51 (rat ♀) | 24/52 (rat ♂)<br>7/52 (rat ♀) | 27/53 (rat ♂)<br>6/53 (rat ♀) | 35/52 (rat ♂)<br>18/53 (rat ♀) |
| Mice | 0 | 1.25 | 2.5 | 5 |
| Lung: Alveolar/bronchiolar adenoma or carcinoma or (combined) | 6/64 (mice ♀) | 15/66 (mice ♀) | 12/63 (mice ♀) | 8/64 (mice ♀) |

There were some evidences of carcinogenic activity of NiO in rats based on the increased incidences of tumours in the lungs and of the adrenal medulla. There was equivocal evidence of carcinogenicity activity of NiO in female mice based on marginally increased incidences of lung tumours in the low- and mid- dose groups. There was no evidence of carcinogenic activity in male mice.

According to CLP regulation, NiO is classified Carc Cat 1A; H350 (1st ATP).

No information is available on dermal route.

There are some evidences from epidemiological studies suggested a lung cancer risk from human exposure to NiO. However, there are no available cohorts exclusively exposed to a single nickel exposure, therefore it is difficult to state with certainty which specific Ni compounds were associated with the suggested increases in respiratory cancer risk observed in workers with some exposure to NiO.

### 3.3.8 Reproductive toxicity

#### 3.3.8.1 Effects on fertility

No specific data on NiO is available.

In a two-generation rat study conducted with $NiSO_4$ $6H_2O$, animals were exposed to 0, 1.0, 2.5, 5 and 10 mg $NiSO_4$/kg bw/d by gavage. No indications of toxicity or adverse reproductive effects have been observed at dosage levels up to 10 mg $NiSO_4$/kg bw/d. A slight reduction in adult male liver weight was observed at the 10 mg $NiSO_4$/kg bw/d level in F0 males, and at the 5 and 10 mg $NiSO_4$/kg bw/d levels in F1 males. The NOAEL for fertility has been set at 10 mg $NiSO_4$/kg bw/d.

#### 3.3.8.2 Effects on development

In the study of Weischer *et al*., (1980) that evaluated developmental or reproductive effects after inhalation of NiO (the only study located and presented in the RAR), groups of wistar rats were continuously exposed to NiO at 0.8, 1.6, or 3.2 mg NiO/$m^3$ (0.6, 1.2 and 2.5 mg Ni/$m^3$) for 21 days, beginning on gestation day 1. The only foetal endpoints evaluated were foetal weight, leukocytes and serum urea. Maternal body weight gain was statistically significantly reduced in all exposed groups, and statistically significant decreases in foetal body weight were observed at the top two exposure levels. Other developmental effects, such as foetal survival, were apparently not evaluated.

It has to be noted that the TC C&L has agreed to classify nickel sulfate, nickel chloride, nickel nitrate and the nickel carbonates as Repr cat 2, R61 based on the consistent evidence of developmental toxicity (stillbirth, post implantation, perinatal lethality) in rats at dose levels not causing maternal toxicity.

A subsequent study by Vaktskjold *et al*., (2006) investigated genital malformations in newborns of female nickel-refinery workers using a register-based cohort study design. No negative effect on genital malformations was seen, but, as it is also stated by the authors, this result should be interpreted with caution since there were few cases in the higher exposure groups.

## 3.4 Derivation of Reference Values

Inhalation and dermal routes are the main exposure paths to NiO considered for workers. Direct oral exposure is considered to be negligible and is ignored in this risk characterization.

### 3.4.1 Acute exposure

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

No classification for acute toxicity has been set for NiO.

Given the toxicological profile of the substance (lung burden after inhalation exposure leading to chronic inflammation and carcinogenic activity in animals), the DNEL long term for inhalation route is considered as sufficient for controlling risks, as stated in the REACh guidance document R.8[29].

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[29] Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterization of dose [concentration]-response for human health, version 2, December 2010.

### 3.4.2 Chronic exposure

#### 3.4.2.1 Dermal route

For dermal route, registrants only considered local effects as relevant, taking into account the sensitizing potential of the substance (read-across with Ni sulphate).

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.

#### 3.4.2.2 Inhalation route

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.

#### 3.4.2.3 The 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).

#### 3.4.2.4 The registrants’ approach (NiPERA[30])

The Registrants 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 Scientific Committee on Occupational Exposure (SCOEL) proposed inhalable OEL for nickel compounds of 0.01 mg Ni/m$^3$ (June 2011) with further

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[30] Nickel Producers Environmental Research Association (NiPERA)

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)[31]. MPPD[32] 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

### 3.4.2.5 Anses approach

The DNEL worker proposed by the registrant in the Nickel oxide 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 reasons/doubts should support the use of an additional assessment factor for interspecies extrapolation based on MPPD model.

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[31] 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

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

- 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 therefore 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 nickel sulphate (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 < 10 µm, 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 in this dossier.

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 presented by the registrants in the dossiers.

However, it has to be noted that this value covers the risk of cancer incidence 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).

## 3.5 Exposure data and risk characterization

### 3.5.1 Data description

Inhalation and dermal routes are the main exposure paths to nickel oxide considered for workers.

Exposure data presented below are from the Chemical Safety Report provided by registrants.

Two approaches have been considered in the risk characterization and the calculation of the Risk Characterization Ratio (RCR corresponding to Exposure/DNEL):

- Tier 1 represents the reasonable worst case scenario in which no Personal Protective Equipment (PPE) is taken into account;
- Tier 2 represents a more realistic scenario including PPE.

  A default protection factor of 20 has been taking into account for Respiratory Protective Equipment (RPE) for all the considered exposure phases as the information on the possibility to wear PPE during the different phases was not always available in the dossier and that the protection factor associated to the PPE reported by registrants was not specified.

### 3.5.2 Risk characterization per GES

A summary table of risk characterisation is presented in appendix 4.

For GES 1, 2 and 3, some information on the workers exposure and risk management measures that are implemented on sites are provided in the relevant SEA and are reported in appendix 3.

#### 3.5.2.1 GES 1: Production of nickel oxide contained in catalyst and catalyst precursors (catalyst manufacture and regeneration)

The production of NiO during NiO catalyst manufacture is the only NiO production process considered in this General Exposure Scenario (GES).

The two Contributing Exposure Scenarios (CES) are based on two different forms of the catalyst and of the raw materials, namely powdered and shaped (pellet or non-powder form) catalysts (Table 22). Each CES thus covers all production steps involved.

Measurements for inhalation in the catalyst production sector were obtained from registrants (see details in the CSR).

Inhalation route: Exposure estimates and calculated RCR

Table 22. CES developed for GES 1: exposure estimates and RCR

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
| **CES 1.1**<br>Production NiO-containing catalysts involving handling of powders containing Ni-compounds | 0.035 | 0.01 | **3.5** | 0.18 | 105 measurements<br>GSD = 7.8 |
| **CES 1.2**<br>Production NiO-containing catalysts from shaped precursors containing Ni-compounds and by regeneration | 0.028 | 0.01 | **2.8** | 0.14 | 178 measurements<br>GSD = 5.6 |

Tier 2*: considering a protection factor of 20 for Respiratory Protective Equipment (RPE)

** GSD: Geometric Standard Deviation

The long-term exposure estimate used in the risk characterization was obtained by calculating the 75th percentile value from the highest personal exposure measurements (inhalable and/or total dust) across all representative exposure classes, both for powder and for shaped catalyst production. This method was used to achieve an exposure estimate that would best reflect the scope and scale of the industry exposure data, while still representing a reasonable worst-case estimate.

A long-term exposure estimate of **0.035 mg Ni/m$^3$** (based on 75th percentile of maximum exposure distribution) was obtained for CES1.1 of the production of NiO catalysts where the representative exposure classes involved handling or processing powdered raw materials or product.

A long-term exposure estimate of **0.028 mg Ni/m$^3$** was obtained for the NiO shaped catalyst production where no powder was involved in the process.

For both scenarios, the risk characterization ratios (RCR) are below 1 taking into account that workers wear RPE during these scenarios. For the CES 1.1 and the CES 1.2, the RCR for long term inhalation exposure are equal to 0.18 and 0.14, respectively, leading to an acceptable risk.

According to the REACH guidance on occupational exposure estimation[33], the number of measurements presented for the CES 1.1 and the CES 1.2, 105 and 178 respectively, are

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

sufficient to determine confidently that the calculated RCR for long term inhalation exposure are truly below 1. With a high uncertainty (GSD > 3.5) and the RCR comprised between 0.1 and 0.5, a minimum of 50 measures is required to validate the RCR.

The registrants considered 8 representative tasks during catalyst production (drying, filling, cleaning…); exposure estimates are presented for each task.

However, exposure estimates are based on aggregate measurements for the different tasks considered (105 measurements for CES 1.1 and 108 measurements for CES 1.2). The results are difficult to interpret because some tasks for which exposure peaks were measured are completely smoothed out in the presented calculation (for example, exposure to 280 and 550 µg Ni/m$^3$ is recorded during "forming task"). Moreover, the calculated RCR are below 1 considering RPE but no clear information has been provided by registrants on the requirements of wearing RPE during these tasks.

Dermal route: Exposure estimates

There are no measurement data on dermal exposures.

Dermal exposure during catalyst production was modeled using the 90th percentile from MEASE modeling (PROC 8b, automated, contained transfer operations, gloves) for handling raw material and product. The daily estimated exposure (DEE) was estimated at 0.0005 mg Ni/cm$^2$/day$^{-1}$ based on an estimated skin surface area (ESA) of 480 cm$^2$.

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

#### 3.5.2.2 GES 2: Industrial use of powdered and shaped nickel oxide-containing catalyst and catalyst precursor (A)

Two CES were identified for the industrial use of NiO catalysts and these are presented in Table 23.

Inhalation route: Exposure estimates and calculated RCR

Table 23. CES developed for GES 2: exposure estimates and RCR

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
| **CES 2.1**<br>Industrial use of powdered NiO-containing catalysts | 0.01 | 0.01 | **1** | 0.05 | Measurements not specified<br>GSD = 2.7 |
| **CES 2.2**<br>Industrial use of shaped NiO-containing catalysts | 0.02 | 0.01 | **2** | 0.1 | Measurements not specified<br>GSD = 4.5 |

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

** GSD: Geometric Standard Deviation

The 75th percentile for filling operations in powdered catalyst production is **0.01 mg Ni/$^3$** (CES 2.1) and **0.02 mg Ni/m$^3$** for shaped catalyst production (CES 2.2).

RCR for long term inhalation exposure are below 1, 0.05 for the CES 2.1 and 0.1 for the CES 2.2, considering RPE.

For this GES, registrants provided information on the available PPE:

- a requirement for RPE (Particle filter with high efficiency for solid and liquid particles; e.g. EN 143 or 149, Type P3 or FFPE corresponding to an equipment with a protection factor of 20 according to the British standards reported in the TNsG on Human Exposure version 2[34]) has been identified during loading and unloading of reactor and for cleaning and maintenance operations and where exposure to NiO containing dust or powder is possible;
- an air-fed RPE is required if entry to the reactor is required.
- a protective suit conforming to EN13982-1 Type 5 and suitable chemical resistant safety gloves or other gloves meeting the required performance specifications is required during loading and unloading of reactor, during cleaning and maintenance and during any other operations where dermal contact is possible;
- other PPE is optional and chosen based on activities being undertaken, potential for exposure to airborne NiO and other relevant workplace hazards may include protective suit (with hood), safety shoes (e.g. according to EN 20346).

With RPE, the RCR are below 1 leading to an acceptable risk for the CES 2.1 and CES 2.2. However, the number of exposure measurements from which exposure estimates have been calculated is not available; it is therefore difficult to conclude on the RCR.

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. Only 9 maximal concentrations are reported in the dossier therefore, no conclusion can be made on the risk for these scenarios.

Dermal route: Exposure estimates

Dermal exposure during catalyst production was modelled using the 90th percentile from MEASE modelling (PROC 8b, automated, contained transfer operations, gloves) for handling raw material and product. The daily estimated exposure (DEE) was estimated at 0.0005 mg Ni/cm$^2$/day[1] based on an estimated skin surface area (ESA) of 480 cm$^2$.

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.3 GES 3: Industrial use of nickel oxide-containing catalyst precursors for the production of catalysts containing other nickel compounds (B)

Two CES were identified for the industrial use of NiO catalysts (see Table 24).

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[34] Technical Notes for Guidance on Human Exposure, Version 2, 2007

Inhalation route: Exposure estimates and calculated RCR

The maximum static and personal exposure concentrations measured for manufacturing processes relevant to the use of NiO in catalyst in involving powdered and shaped raw materials or products were presented in the dossier. These data were used to assess long-term exposure in NiO by CES 3.1 (powdered) and CES 3.2 (shaped). These measurements were assigned by registrant.

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

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD**** |
|---|---|---|---|---|---|
| **CES 3.1**<br>Industrial use of powdered catalysts | 0.045 | 0.01 | **4.5** | 0.22 | 33 measurements<br>GSD = 6.03 |
| **CES 3.2**<br>Industrial use of shaped catalysts (extrudates, pellets, tablets, spheres, encapsulated powders) | 0.026 | 0.01 | **2.6** | 0.13 | 109 measurements<br>GSD = 4.9 |

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

** GSD: Geometric Standard Deviation

A long-term exposure estimate of **0.045 mg Ni/m$^3$** was obtained for the CES 3.1 of the use of NiO catalysts where the representative exposure classes involved handling or processing powdered raw materials or product.

A long-term exposure estimate of **0.026 mg Ni/m$^3$** was obtained for the NiO shaped catalyst use where no powder was involved in the process (GES 3.2).

The RCR for long term inhalation exposure are below 1, 0.22 for the CES 3.1 and 0.13 for the CES 3.2, considering RPE.

For this GES, registrants provided information on the available PPE:

- a requirement for RPE (Particle filter with high efficiency for solid and liquid particles; e.g. EN 143 or 149, Type P3 or FFPE corresponding to an equipment with a protection factor of 20 according to the British standards reported in the TNsG on Human Exposure version 2) has been identified during loading and unloading of reactor and for cleaning and maintenance operations and where exposure to NiO containing dust or powder is possible;
- an air-fed RPE is required if entry to the reactor is required.
- a protective suit conforming to EN13982-1 Type 5 and suitable chemical resistant safety gloves or other gloves meeting the required performance specifications is required during loading and unloading of reactor, during cleaning and maintenance and during any other operations where dermal contact is possible;
- other PPE is optional and chosen based on activities being undertaken, potential for exposure to airborne NiO and other relevant workplace hazards may include protective suit (with hood), safety shoes (e.g. according to EN 20346).

With RPE, the RCR are below 1 leading to an acceptable risk for the CES 3.1 and CES 3.2.

The registrants considered 8 representative tasks during catalyst production (drying, filling, cleaning…); exposure estimates are presented for each task.

However, exposure estimates are based on aggregate measurements for the different tasks considered (33 measurements for the CES 3.1 and 109 measurements for the CES 3.2). The results are difficult to interpret because some tasks for which exposure peaks were measured are completely smoothed out in the presented calculation (for example, exposure to 306.1 µg Ni/$m^3$ is recorded during "cleaning task").

*Dermal route: Exposure estimates*

Dermal exposure during catalyst production was modelled using the 90th percentile from MEASE modelling (PROC 8b, automated, contained transfer operations, gloves) for handling raw material and product. The daily estimated exposure (DEE) was estimated at 0.0005 mg Ni/$cm^2$/day[1] based on an estimated skin surface area (ESA) of 480 $cm^2$.

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

#### 3.5.2.4 GES 4: Production of nickel based powders from nickel oxide

No process information was available to develop the CES, thus the CES have been derived from the monitoring details accompanying the static and personal exposure measurements (see Table 25).

Inhalation route: Exposure estimates and calculated RCR

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

| CES | Inhalation exposure (mg Ni/$m^3$) | DNEL (mg Ni/$m^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
| **CES 4.1 Raw materials handling**<br>The form of the NiO is unknown | 0.073 | 0.01 | **7.3** | 0.37 | 2 measurements<br>GSD not specified |
| **CES 4.2 Smelting**<br>The nickel metal is made by smelting the nickel oxide | 0.2 | 0.01 | **10** | **1** | 1 measurement<br>GSD not specified |
| **CES 4.3 Alloying and atomising**<br>The nickel produced is then alloyed with other ingredients by melting and the multi-metal melt is then atomised in order to produce a powder | 0.45 | 0.01 | **45** | **2.25** | 5 measurements<br>GSD not specified |
| **CES 4.4 Drying**<br>The powder is to be wetted in the atomisation process by cooling or | 0.013 | 0.01 | **1.3** | 0.07 | Modeled data |

| | | | | | |
|---|---|---|---|---|---|
| quenching | | | | | |
| **CES 4.5 Blending and sieving**<br>Dried powders are mixed to obtain the desired product (by density) and sieved into the final product (by size specification) | 0.22 | 0.01 | **22** | **1.1** | 3 measurements<br>GSD not specified |
| **CES 4.6 Packaging**<br>The powder is drummed on a semi or fully automated line | 0.193 | 0.01 | **19.3** | 0.97 | 3 measurements<br>GSD not specified |
| **CES 4.7 Cleaning and maintenance**<br>Working areas are kept clean on a daily basis by vacuuming and on a weekly or end-of-product-run basis by a full clean | 0.029 | 0.01 | **2.9** | 0.15 | 1 measurements<br>GSD not specified |

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

** GSD: Geometric Standard Deviation

The number of measurements in the above table is reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive. Data reported in section 9 of the CSR are different but not explained.

The highest personal exposure measurement value for each CES has been used to represent the long term summary exposure estimate, except for the CES 4.4 for which only modelled data are available.

Considering RPE, the RCR for long term inhalation exposure are below 1 for the CES 4.1, 4.4, 4.6 and 4.7; so an acceptable risk could be considered.

For the 3 other CES, an unacceptable risk is identified as the RCR is above 1 with RPE.

However, no information are available concerning the quality of the measured data (GSD not available), therefore it is difficult to conclude on the RCR. The number of measurements is also very low for each task, it is not sufficient to validate a RCR whatever the data quality.

In the consulting report provided in Appendix D4A of the CSR, no information on RPE has been reported for this GES, therefore a default protection factor of 20 has been considered here for the calculations of RCR. The registrant states in section 9 of its CSR that RPE with a protection factor of 20 is required at process steps that are not fully enclosed and are likely to give rise to Ni oxide or Ni metal fumes or dust (CES 4.1, 4.2 & 4.4); for CES 4.3, 4.5, 4.6 & 4.7, if particle size is below 10 µm, RPE with APF of 40 is required. This doesn't affect the risk assessment outcome.

Dermal route: Exposure estimates

Table 26. Dermal exposure estimates for GES 4

| CES Titles | Exposure (mg Ni/cm$^2$/d) |
|---|---|
| **CES 4.1 Raw materials handling** | 0.0005 |
| **CES 4.2 Smelting** | 0.0005 |
| **CES 4.3 Alloying and atomising** | 0.00005 |
| **CES 4.4 Drying** | 0.00005 |
| **CES 4.5 Blending and sieving** | 0.00005 |
| **CES 4.6 Packaging** | 0.011 |
| **CES 4.7 Cleaning and maintenance** | 0.00003 |

The dermal exposure estimate obtained from read across for this non-catalyst NiO DU is 0.011 mg Ni/cm$^2$/day[1] for the 90th percentile value for hands and arms. The 90$^{th}$ percentile is considered the most suitable value for the summary exposure estimate. The dermal exposure estimates for the other CES have been modelled as the 90$^{th}$ percentile value using MEASE.

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.5 GES 5: Production of Ni-containing electronics and thermally functioning (ceramics for solid oxide fuel cells and thermistor products)

One CES was developed in the GES 5 in order to consolidate all process steps, including raw materials handling, processing the ceramic, assembling the final product and cleaning and maintenance.

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

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

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
| **CES5.1 Raw materials handling**<br>Receiving raw materials into the process | No data available | | | | No data available |
| **CES5.2 Milling, mixing and calcining raw materials**<br>Mixing together of various metallic oxides including nickel oxide, grinding/milling them to give a powder and binding the mixture with an organic reagent (for calcining) | 0.02 | 0.01 | **2** | 0.5 | 3 measurements<br>GSD not specified |
| **CES5.3 Milling, mixing, extruding and sintering of** | 0.02 | 0.01 | **2** | 0.5 | 5 measurements |

| | | | | | |
|---|---|---|---|---|---|
| **calcined materials. Cutting of sintered ceramic slab**<br>Shaping the (calcined) mixture into a bead, rod, disc or slab and sintering (heating the powder mix to a temperature below the melting point of the major component & binding powder particles together). Cutting/trimming the sintered ceramic to give the thermistor | | | | | GSD not specified |
| **CES5.4 Assembly of thermistor into probes**<br>Assembly of thermistor into the probe by attaching connection leads and enclosing the thermistor in a sheath to make the probe. | Negligible | 0.01 | **-** | - | - |
| **CES5.5 Cleaning and maintenance**<br>Some machines quickly cleaned with alcohol | Negligible | 0.01 | **-** | **-** | - |

Tier 2*: considering a protection factor of 4 for RPE

** GSD: Geometric Standard Deviation

Note that the registrant provided in its CSR only one single and global reference of exposure and risk estimation covering the whole process where the inhalation exposure is reported at 0.02 mg/Ni m$^3$. Results in the above table for each detailed CES are reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive. By doing so, one may interpret that the registrant hides a lack of exposure measurements for CES 5.1 at least.

For this GES, registrants provided information on the available PPE:

- RPE FFP2 (3M, 9322), corresponding to an equipment with a protection factor of 10 according to the British standards reported in the TNsG on Human Exposure version 2 is used for weighing oxides and sieving the oxide mixture;
- RPE is worn {FFP1 (3M 9914)}, corresponding to an equipment with a protection factor of 4 according to the British standards reported in the TNsG on Human Exposure version 2 during extrusion by manual mixing, milling and machine-mixing, all with ventilation.

In some cases, registrants reported operating conditions as closed systems operating at room temperature giving rise to no volatile emissions therefore no exposure. No RMMs are reported.

For the CES 5.1, no exposure data is available.

For the CES 5.4 and 5.5, exposure is considered as negligible by registrants.

Considering RPE, the RCR for long term inhalation exposure are below 1 for the CES 5.2 and 5.3, leading to an acceptable risk for these scenarios.

However, no information is available concerning the quality of the measured data (GSD not available) and at least one CES is not covered by exposure measurements nor modelling; it is therefore difficult to conclude on the RCR. The number of measurements is also very low for each task, it is not sufficient to validate a RCR whatever the data quality. A minimum of 12 measurements would be necessary to validate the RCR, considering a low uncertainty (GSD < 2).

Dermal route: Exposure estimates

Dermal exposure during the production of ceramics was modelled as the 90th percentile value of 0.0005 mg Ni/cm$^2$/day[1] using the MEASE modelling tool (PROC 8b, 14, 22 automated with manual intervention, partly enclose processes with application of LEV and gloves). The daily estimated exposure (DEE) was estimated based on an estimated skin surface area (ESA) of 480 cm$^2$.

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.6 GES 6: Production of nickel-containing frits

Frits are used as constituents in alkali borosilicate enamels for iron and steel (pipes and bathroom fittings) and in ceramic glazes for pottery and porcelain (tiles). It appears that NiO is added to frits to provide adhesion to steel (in ground coats) and as a colorant in glazes. They are also reported as being used in paints, plastic, and construction materials such as concrete.

Table 28 below summaries the CES developed from the contextual data reported on the process by registrants. They describe two generic production processes, automated and manual, by 8 process steps. Automation is usually applied to continuous kilning operations.

Table 28. CES developed for GES 6

| CES Titles | Assumptions |
|---|---|
| **CES 6.1 Raw materials handling** | - NiO powder pumped into intermediate storage silo from delivery tanker; *or*<br>- NiO is stored in the bags unloaded from the delivery vehicle until added to kiln |
| **CES 6.2 Dosing, mixing and oven charging** | - NiO powder is (screw or open-belt) conveyed to the balance cone where it is weighed, mixed into a charge with the other ingredients and the mixed charge is (pneumatically and screw) conveyed to the kiln; or<br>- NiO is charged manually into the kiln from the bag |
| **CES 6.3 Kilning, quenching and drying** | Raw materials including NiO are melted together. The 'frit' melt may then pass between rollers to adjust the thickness. Then the melt is turned into small glass frits by quenching (rapidly cooled and shattered by pouring into water, spaying with water or passing through air cooled rollers). Frits not undergoing further processing are automatically recovered from the quenching bath, dried and sent to packaging. Frits undergoing milling are automatically recovered from the quenching bath and transferred (probably by vehicle) (intermediate packaging) or automatically (conveyor belt and via storage) |
| **CES 6.4 Milling and drying** | Frits and additives are ground to a powder product in ball mill, and if wet-milled, are then dried in a hot air |

| | |
|---|---|
| | drier. |
| **CES 6.5 Blending and/or packaging** | Powdered frits and intact frits are packed into bags or big (bulk container) bags. The bagging unit is manually operated (hanging the empty bag in the unit, securing the bag sock or spout to the feeder, initiating/terminating the automatic filling of the bag, manually decoupling and closing the full bag and driving it to the warehouse). |
| **CES 6.6 Cleaning and Maintenance** | Described by general company policy and not by a task or activity based approach |

Identical RMM were reported for each of the 8 process steps {dosing, mixing and oven charge; oven discharge; drying (if water quenching), milling (dry or wet), drying (if milled wet), mixing and/ or packaging, laboratory and cleaning and maintenance} described by registrants. These RMM are:

- RPE - dust masks FFP 1, 2 or 3 and face mask (thermal & mechanical protection (FFP 1 for raw materials handling), corresponding to an equipment with a protection factor of 4, 10 and 20, respectively according to the British standards reported in the TNsG on Human Exposure version 2;
- Gloves (thermal & mechanical protection);
- Other PPE - safety shoes, hearing protection, goggles* and special safety clothing* (*available at manufacturing sites and used for specific operations or tasks);
- local & general exhaust ventilation.

Other reported RMM are:

- RPE {full face mask in conforming to CE 0299 (SATA Vision 2000), corresponding to an equipment with a protection factor of 40 according to the British standards reported in the TNsG on Human Exposure version 2 and leather gloves in accordance with EN 420 (108 Super KM En 363)} for raw materials handling and charging the automatic weighing machine;
- dust mask FFP 2D conforming to EN 149:2001/CE 0121(Moldex 3305) and leather gloves conforming to EN 42 (108 Super KM En 363, EN 42) for feeding of the melting ovens.

Inhalation route: Exposure estimates and calculated RCR

Table 29. Exposure estimates and RCR for GES 6

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2 | Number of measurements/GSD*** |
|---|---|---|---|---|---|
| **CES 6.1 Raw materials handling** | 0.01 | 0.01 | **1** | 0.05 | 6 measurements<br>GSD not specified |
| **CES 6.2 Dosing, mixing and oven charging** | 0.01 | 0.01 | **1** | 0.05 | 6 measurements<br>GSD not specified |
| **CES 6.3 Kilning,** | 0.008 | 0.01 | 0.8 | NR | 9 measurements |

| | | | | | |
|---|---|---|---|---|---|
| **quenching and drying** | | | | | GSD not specified |
| **CES 6.4 Milling and drying** | 0.0006 | 0.01 | 0.12 | NR | 1 measurement<br>GSD not specified |
| **CES 6.5 Blending and/or packaging** | 0.021 | 0.01 | **2.1** | 0.1 | 13 measurements<br>GSD not specified |
| **CES 6.6 Cleaning and Maintenance** | 0.342 | 0.01 | **34.2** | **1.7***<br>/ 0.86** | 3 measurements<br>GSD not specified |

*: considering a protection factor of 20 for RPE

**: considering a protection factor of 40 for RPE

*** GSD: Geometric Standard Deviation

NR: Not Relevant

The number of measurements in the above table is reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive. Data reported in section 9 of the CSR are different but not explained. This however doesn't affect the conclusion.

For the CES 6.3 and 6.4, the RCR for long term inhalation exposure are below 1 without RPE (protection factor of 20).

Nine measurements were reported for the CES 6.3 leading to a validated RCR considering a low uncertainty; however, no information is available on the uncertainty value, and no conclusion can be made for this scenario. For the CES 6.4, only one measurement is reported, no conclusion can be drawn from these results.

For the CES 6.1, 6.2 and 6.5, RPE with protection factor of 20 is required to present a RCR below 1. Given the number of measurements reported for these scenarios (6 measurement for the CES 6.1 and 6.2 and 9 for the CES 6.5), the RCR could be validated with a low uncertainty (GSD < 2). However, no information is available on the quality of the data, and then no conclusion can be made.

For the CES 6.6, for this scenario a RCR above 1 is identified, considering a RPE with a protection factor of 20. In the dossier, the registrant reported other RMM as full face mask that could be associated with a higher protection factor, 40 instead of 20. Therefore, a RCR below 1 (0.86) is calculated considering this new protection factor. However, according to the registrant's information, this type of RPE is required for raw materials handling and charging the automatic weighing machine, but no data are available on the possibility to use this equipment for cleaning and maintenance. Furthermore, as the number of measurements presented is very low (3 measurements), it is difficult to conclude on this CES.

Dermal route: Exposure estimates

Dermal exposures were modelled as the 90th percentile value using MEASE apart from packaging where a read-across 90th percentile value from an analogous operation (packing 'carbonyl' nickel powder) was used.

Table 30. Dermal exposure estimates for GES6

| CES Titles | Exposure (mg Ni/cm$^2$/d) |
|---|---|
| **CES 6.1 Raw materials handling** | 0.0005 |

|  |  |
|---|---|
| **CES 6.2 Dosing, mixing and oven charging** | 0.0005 |
| **CES 6.3 Kilning, quenching and drying** | 0.0005 |
| **CES 6.4 Milling and drying** | 0.00005 |
| **CES 6.5 Blending and/or packaging** | 0.011 |
| **CES 6.6 Cleaning and Maintenance** | 0.00003 |

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.7 GES 7: Production of nickel-containing pigments

Exposure data (process description by process step and operating conditions, exposure measurements, exposure monitoring details and RMM) are supplied by registrants.

Table 31 summaries the CES developed from the exposure data reported on the process by registrants.

Table 31. CES developed for GES 7

| **CES Titles** | **Assumptions** |
|---|---|
| **CES 7.1 Raw materials handling** | - NiO powder is automatically charged into the reactor<br>- Bags of NiO powder are opened and the contents are tipped manually into the reactor with other ingredients such as water |
| **CES 7.2 Mixing** | The dry or wet mixing of raw materials is carried out in a reactor. Suspensions resulting from wet mixing are dried (atomized or jet drier) |
| **CES 7.3 Drying and calcining product** | - Continuous and automated drying of the wet mix and calcining in (tunnel or rotary) ovens<br>- In 'discontinuous' drying and calcining the mix is loaded into crucibles which are transported through the oven on wagons<br>The calcined product is conveyed to milling |
| **CES 7.4 Dry milling** | Milling of calcined product to a powder |
| **CES 7.5 Wet milling, washing and drying** | Calcined product containing salts are ground wet, washed to remove the excess soluble salts and dried |
| **CES 7.6 Packaging** | Bagging the calcined product (neat or as a blend) into bags or bulk containers |
| **CES 7.7 Cleaning and Maintenance** | - |

Identical RMM were reported for each of the 10 process steps {dosing and mixing (dry or wet); drying (if wet mixing), calcining (charge); calcining (discharge); milling (dry or wet), washing (optional), mixing and/or packaging; laboratory and cleaning and maintenance} described by the registrants. These RMM are:

- RPE - dust masks FFP 1, 2 or 3 and face mask (thermal & mechanical protection (FFP 1 for raw materials handling), corresponding to an equipment with a protection factor of 4, 10 and 20, respectively according to the British standards reported in the TNsG on Human Exposure version 2;

- Gloves (thermal & mechanical protection) ;
- Other PPE - safety shoes, hearing protection, goggles* and special safety clothing* (*used for specificoperations or tasks);
- local & general exhaust ventilation.

Inhalation route: Exposure estimates and calculated RCR

Table 32. Exposure estimates and RCR for GES 7

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
| **CES 7.1 Raw materials handling** | 0.006 | 0.01 | 0.6 | NR | 39 measurements<br>GSD = not specified |
| **CES 7.2 Mixing** | 0.006 | 0.01 | 0.6 | NR | 39 measurements<br>GSD = not specified |
| **CES 7.3 Drying and calcining product** | 0.02 | 0.01 | **2** | 0.1 | 43 measurements<br>GSD = not specified |
| **CES 7.4 Dry milling** | 0.04 | 0.01 | **4** | 0.2 | 12 measurements<br>GSD = not specified |
| **CES 7.5 Wet milling, washing and drying** | 0.004 | 0.01 | 0.4 | NR | 2 measurements<br>GSD = not specified |
| **CES 7.6 Packaging** | 0.03 | 0.01 | **3** | 0.15 | 38 measurements<br>GSD = not specified |
| **CES 7.7 Cleaning and Maintenance** | 0.342 | 0.01 | **34.2** | **1.7** | 3 measurements<br>GSD = not specified |

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

** GSD: Geometric Standard Deviation

NR: Not Relevant

The number of measurements in the above table is reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive. Data reported in section 9 of the CSR are different but not explained. This however doesn't affect the conclusion.

For the CES 7.1 and 7.2, the calculated RCR are below 1 without RPE.

For the CES 7.3 and 7.6, the RCR for long term inhalation exposure is below 1 with RPE during these tasks.

For these scenarios, the number of measurements reported (39 measurements for the CES 7.1 and 7.2, 43 for the CES 7.3 and 38 for the CES 7.6) is sufficient to validate the RCR values whatever the quality of the data. Therefore, an acceptable risk can be considered for these tasks.

For the CES 7.4, RCR is below 1 with RPE. However, the GSD is not specified, and then no information is available on the quality of the data. This RCR value could be validated taking into account a low uncertainty for the exposure measurements (*i.e* GSD <2). Without the information, no conclusion can be made for this scenario.

For the CES 7.5, RCR is below 1 without RPE. However, the number of measurements reported is very low (only 2) and the GSD is not specified. In these conditions, a minimum number of 20 measurements are required to validate the RCR according to the REACh guidance on occupational exposure estimation. No conclusion can be made for this scenario.

A RCR above 1 is identified for the CES 7.7 with RPE.

In the same way as for the CES 7.5, the number of measurements is very low (only 3) and no information on the data quality is available; therefore it is difficult to conclude on this scenario.

No information is available on the possibility to use RPE with higher protection factor, therefore, RCR has only been calculated with a protection factor of 20 corresponding to the RPE reported by registrants.

In the above table, the number of measurements is reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive; data reported by the registrant in section 9 of the CSR is different for CES 7.6 and 7.7 but not explained. This however doesn't affect the conclusion.

Dermal route: Exposure estimates

Table 33. Dermal exposure estimates for GES 7

| **CES Titles** | **Exposure (mg Ni/cm$^2$/d)** |
|---|---|
| **CES 7.1 Raw materials handling** | 0.0005 |
| **CES7.2 Mixing** | 0.0005 |
| **CES 7.3 Drying and calcining product** | 0.005 |
| **CES 7.4 Dry milling** | 0.0005 |
| **CES 7.5 Wet milling, washing and drying** | 0.00005 |
| **CES 7.6 Packaging** | 0.011 |
| **CES 7.7 Cleaning and Maintenance** | 0.00003 |

Dermal exposures were modelled as the 90th percentile value using MEASE apart from packaging which was a read-across 90th percentile value for an analogous operation (packing 'carbonyl' nickel powder).

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.8 GES 8: Production of nickel-containing glass

Table 34 summarises the CES developed largely from the process description reported to the registrants. Two generic production processes, automated and manual, are described by 6 or 7 process steps.

Table 34. CES developed for GES 8

| CES Titles | Assumptions |
|---|---|
| **CES 8.1 Raw materials handling** | - NiO powder is received in palletised bags/sacks/drums which are warehoused. The NiO is emptied into intermediate flow bins and driven to the mixing area (repacking).<br>- NiO powder pumped into intermediate storage silo from a delivery tanker. The NiO is conveyed to the mixing area using an automated (screw/vibratory conveyor) or manual/mechanised (repacking) system. |
| **CES 8.2 Formulation and mixing** | The NiO is manually tipped from bags (at the mixer), automatically conveyed or released from flow bins into the balance to weigh out the charge. The charge is (closed belt or pumped) conveyed to the mixer and the mixed batch (furnace charge) is conveyed to the furnace using an automated (closed belt conveyor) or manual/mechanised (repacking) system. |
| **CES 8.3 Melting** | The furnace charge is melted between 1425 and 1600 °C using refractory pots (specialized products), day tanks (coloured glass) and continuous tanks (flat and container glass). |
| **CES 8.4 Forming** | Shaping of molten glass incorporating NiO |
| **CES 8.5 Packaging** | Finished glass products are inspected and boxed for dispatch. |
| **CES 8.6 Cleaning and Maintenance** | Regular vacuum cleaning or wet brushing in batch house. |

For the CES 8.1 and the CES 8.6, RMM are reported:

- RPE {FFP3 mask approved to EN 149}), corresponding to an equipment with a protection factor of 20 according to the British standards reported in the TNsG on Human Exposure version 2;
- Safety glasses;
- Disposable overalls/ clothing (as single use safety dress).

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

Table 35. Exposure estimates and RCR for GES 8

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2 | Number of measurements/GSD*** |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **CES 8.1 Raw materials handling** | 0.028 | 0.01 | **2.8** | 0.14*/<br>0.07** | modelled data |
| **CES 8.2 Formulation and mixing** | 0.001 | 0.01 | 0.1 | NR | Measurement not specified<br>GSD not specified |
| **CES 8.3 Melting** | 0.0001 | 0.01 | 0.01 | NR | Measurement not specified<br>GSD not specified |
| **CES 8.4 Forming** | Negligible | - | **-** | - | - |
| **CES 8.5 Packaging** | Negligible | - | - | - | - |
| **CES 8.6 Cleaning and Maintenance** | 0.075 | 0.01 | **7.5** | 0.375*/<br>0.2** | modelled data |

*: considering a protection factor of 20 for RPE

**; considering a protection factor of 40 for RPE

*** GSD: Geometric Standard Deviation

NR: Not Relevant

In the above table, data on inhalation exposure are reported

- from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR for CES 8.2 to 8.5,
- from section 9 of the CSR for CES 8.1 and 8.6 where data are provided by the registrant but without explanation.

No data on inhalation exposure is available for the CES 8.1 and 8.6, only modelled data have been presented. For these scenarios, the RCR for long term inhalation exposure are below 1 with RPE (APF of 40 as reported by the registrant). An acceptable risk could be considered for these CES.

Exposure during forming and packaging, presented in the CES 8.4 and 8.5 respectively, has been considered negligible by registrants.

For the remaining two scenarios, CES 8.2 and CES 8.3, the RCR for long term inhalation exposure are below 1 without RPE, which gives rise to an acceptable risk for these tasks. However, the number of exposure measurements and the quality of the data are not specified; RCR values cannot be validated. Therefore, no conclusion can be drawn for these scenarios.

_Dermal route: Exposure estimates_

Table 36. dermal exposure estimates for GES 8

| **CES Titles** | **Exposure (mg Ni/cm$^2$/d)** |
|---|---|
| **CES 8.1 Raw materials handling** | 0.0005 |
| **CES 8.2 Formulation and mixing** | 0.00005 |
| **CES 8.3 Melting** | 0.00005 |

|  |  |
|---|---|
| **CES 8.4 Forming** | Negligible |
| **CES 8.5 Packaging** | Negligible |
| **CES 8.6 Cleaning and Maintenance** | 0.00003 |

The dermal exposure estimates for the CES 8.1 to 8.3 have been modelled as the 90th percentile value using MEASE. Cleaning and Maintenance has been modelled as well.

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.9 GES 9: Stainless, special steels and special alloys manufacturing

Six CES were developed by the registrants for GES 9.

Inhalation route: Exposure estimates and calculated RCR

Table 37. Exposure estimates and RCR for GES 9

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD***** |
|---|---|---|---|---|---|
| **CES 9.1 Raw materials handling** | 0.006 | 0.01 | 0.6 | NR | 5 measurements<br>GSD not specified |
| **CES 9.2 First processing** | 0.012 | 0.01 | **1.2** | 0.06 | 194 measurements<br>GSD not specified |
| **CES 9.3 Further processing** | 0.03<br>for hot rolling | 0.01 | **3** | 0.15 | 61 measurements<br>GSD not specified |
|  | 0.009<br>for cold rolling | 0.01 | 0.9 | NR | 14 measurements<br>GSD not specified |
| **CES 9.4 Finishing** | 0.038 | 0.01 | **3.8** | 0.38 | 41 measurements<br>GSD not specified |
| **CES 9.5 Cleaning and maintenance** | 0.115 | 0.01 | **11.5** | 0.6 | 13 measurements<br>GSD not specified |
| **CES 9.6 Packing, shipping and storage** | 0.03 | 0.01 | **3** | 0.15 | Modelled data |

*: considering a protection factor of 20 for RPE

**: considering a protection factor of 10 for RPE

*** GSD: Geometric Standard Deviation

NR: Not Relevant

The number of measurements in the above table and the PPE information are reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive. Data reported in section 9 of the CSR are different but not explained. This however doesn't affect the conclusion.

For the CES 9.4 and 9.5, registrants provided information on the available RPE:

- For CES 9.4: RPE P2, corresponding to an equipment with a protection factor of 20, is required.
- For CES 9.5: Air purifying full mask (for example with APF 10) is required

No information on RPE has been reported for the other CES, therefore a default protection factor of 20 has been considered here for the calculations of RCR.

The RCR for long term inhalation exposure are below 1 without RPE for the CES 9.2 and 9.3 (cold rolling). The RCR for long term inhalation exposure are below 1 with RPE (APF 10) for the CES 9.4 and with RPE (with APF of 20) for CES 9.5. The number of measurements is sufficient to validate the RCRs whatever the quality of the data. However, no information is available concerning the raw data including how they were collected and interpreted. Therefore, no firm conclusion can be drawn from these RCRs.

For the others CES, the RCR for long term inhalation exposure are below 1 considering RPE (with APF of 20).

However, no information is available concerning the quality of the measured data (GSD not available); it is therefore difficult to conclude on the RCR, except for CES 6 for which modelled data have been used. The number of measurements is also very low for CES 9.5, it is not sufficient to validate the RCR whatever the data quality. A minimum of 20 measurements would be necessary to validate the RCR, considering a low uncertainty (GSD < 2).

*Dermal route: Exposure estimates*

Dermal exposures were modelled using a Tier 1 model not specified by the registrant, except for CES 9.6, for which MEASE model has been used. For CES 9.1 and 9.5, dermal exposure measurements have been used (75th percentile value).

Table 38. Dermal exposure estimates for GES 9

| CES Titles | Exposure (mg Ni/cm$^2$/d) |
|---|---|
| **CES 9.1 Raw materials handling** | 0.0001 |
| **CES 9.2 First processing** | 0.00003 |
| **CES 9.3 Further processing** | 0.00003 |
| **CES 9.4 Finishing** | 0.00003 |
| **CES 9.5 Cleaning and maintenance** | 0.00035 |
| **CES 9.6 Packing, shipping and storage** | 0.0003 |

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.2.10 GES 10: Production of NiZn cores and solids from nickel oxide powder

3 CES have been reported by registrants to describe this exposure scenario.

Inhalation route: Exposure estimates and calculated RCR

Table 39. Exposure estimates and RCR for GES 10

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2** | **Number of measurements** |
|---|---|---|---|---|---|
| **CES 10.1 Raw materials handling** | 1.1 | 0.01 | **110** | **5.5***/<br>**2.75**** | Modelled data |
| **CES 10.2 Production of NiZn solids** | 0.66 | 0.01 | **66** | **3.3***/<br>**1.45**** | Modelled data |
| **CES 10.3 cleaning and maintenance** | 0.66 | 0.01 | **66** | **3.3***/<br>**1.45**** | Modelled data |

*: considering a protection factor of 20 for RPE

** considering a protection factor of 40 for RPE

The PPE information are reported from the consulting report (downstream users' consultation for data gathering) provided in Appendix D4A of the CSR which is much more detailed and comprehensive. Data reported in section 9 of the CSR are different but not explained. This however doesn't affect the conclusion.

Exposure data have been modelled with the Tier 1 model MEASE.

For the 3 CES presented, the RCR for long term inhalation exposure are above 1 considering RPE with a protection factor of 20 or 40, leading to unacceptable risks.

It has to be noted that RPE with a protection factor of 40 is reported in Appendix D4A of the CSR only for CES 10.1. In the CSR however, RPE (FFP3) with a protection factor of 20 or 40 is reported for CES 10.2 and 10.3.

Dermal route: Exposure estimates

Dermal exposures were modelled using the Tier 1 model MEASE.

Table 40. Dermal exposure estimates for GES 10

| **CES Titles** | **Exposure (mg Ni/cm$^2$/d)** |
|---|---|
| **CES 10.1 Raw materials handling** | 0.00005 |
| **CES 10.2 First processing** | 0.00003 |
| **CES 10.3 Further processing** | 0.00005 |

Given the classification as skin sensitizer for NiO, wearing PPE is required to avoid exposure during the use of the substance.

### 3.5.3 Overall conclusion on exposure assessment and risk characterization

Inhalation and dermal routes are the main exposure paths to nickel oxide considered for workers.

Measured exposure data and to a limited extent 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. 0.05 mg Ni/m$^3$) is considered not sufficiently protective, thus inappropriate.**

According to the exposure measurement data presented in the registrants' dossier, no definitive conclusion can be drawn regarding the risk assessment for workers using NiO.

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:

- the aggregation of exposure data provided for the GES 1 and 2 leads to an underestimation of worker exposure;
- a low number of exposure measurements is submitted for many scenarios;
- data on the quality of provided exposure measurements are missing (the Geometric Standard Deviation value is not specified in the majority of scenarios and is required to validate the RCR, raw data are unavailable);
- data on Risk Management Measures (RMMs) in place are insufficient for almost all scenarios.

Taken together, these uncertainties do not allow concluding on the risk for each GES, except GES 10 for which an unacceptable risk can already be identified based on modelled data exclusively (RCRs are above 1 for each CES, including a RPE with APF 40).

The quality and robustness of the 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 conclude on the current risk for all scenarios (all uses), except for GES 10 considered at risk, 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. Hence, Anses invites the registrants to use the DNEL of 0.01 mg Ni/m$^3$ and to voluntary update their registration dossiers.

A relevant and formal frame to achieve otherwise an equivalent exercise could be 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 minimum of a 3 years period[35] from the inclusion of the substance in the CoRAP could be expected in order to 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 in section 3.5.3 has to be overstepped for the purpose of the RMOA which aims at identifying and assessing potential risk management options as soon as a risk concern has been raised, as it is the case. To that respect, although the non-conclusive situation, a concern on the risk management of nickel oxide is still raised because, as already explained, an inappropriate DNEL (0.05 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 nickel oxide could 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 nickel oxide by inhalation below this exposure limit (the latter this would necessitate amongst others one or a combination of the following solutions: collective protection equipments, personal protection equipments, changes in the processes, closed systems and automation, substitution of the substance within the same/similar process, alternative process, stop of the use, etc.). The most stringent option would be the ban of some or all uses.

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).

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[35] 4 months to perform the SEV report and to prepare the Draft Decision (DD), then 4 months for the MSC to approve the DD, then 24 months waiting for an update and finally 6 months to reevaluate in the light of the update = 38 months

# 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 occupational health risk arising from the manufacture and uses of NiO. As already said, the target is the control of the exposure below the set DNEL. Therefore each risk management option (RMO) is assessed in this way. To a limited extent, pieces of European legislation that are framed on environment protection are also considered when it may indirectly impact the workers health concern.

It is noted that several pieces of European legislation already exist which aim at avoiding, controlling and/or reducing emissions on nickel compounds and exposure of workers. 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.

This section explores the potential of REACH and non-REACH risk management instruments to manage the hazards of NiO 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 / occupational exposure limit. 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 41 summarizes the RMOs identified and assessed as regards their consistency in addressing the risks related to NiO.

Table 41. The 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 | OELs |
| | 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)<br>AND<br>Directive 2004/37/EC on carcinogens at work |
| Other workplace EU legislations | Directive 2001/58/EC on "Safety Data Sheets"<br>Directive 89/656/EEC on the use of personal protective equipment.<br>Directive 92/85/EC (pregnant workers directive)<br>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 identification SVHC/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 requires companies to 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 provide 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 and Directive 98/24/EC (see infra) on the protection of workers from the risks related to exposure to carcinogens and chemicals at work.

Therefore the CLP regulation alone is considered as a useful tool but which is not fitted for the purpose of the control of inhalation exposure at the workplace for nickel oxide.

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 "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 subsumed into the REACH Regulation, specifically item 27 of Annex XVII on restrictions.

Focusing only on the dermal sensitisation effect of nickel oxide, this Directive now merged in REACH annex XVII is not fitted for the purpose of the control of inhalation exposure at the workplace for nickel oxide.

### 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[36] (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-economic 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 nickel oxide (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 nickel oxide 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 (biological limit values are always binding contrary to OELs). Setting binding value usually needs to take into account socio-economic and technical feasibility. Several limit values are set in Directive 98/24/EC and in the daughter Directives 2000/39/EC and 2006/15/EC.

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[36] This is carried out by the SCOEL when recommending OELs

*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 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.

<u>Content and scope of Directive 2004/37/EC (carcinogens at work)</u>

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 binding OELVs in Directive 98/24/EC.

The Directive also recommends 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.

### 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. Therefore a binding value for NiO is not yet expected easily achievable in the frame of 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"[37] 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 considering the difficulty to take into account socio-economic data in order to set a binding value. 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.

#### *Discussion on Directive 2004/37/EC (Carcinogens at work Directive)*

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.

Neither NiO 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)

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[37] proposal for a work plan for the 4th list of indicative occupational exposure limit values to be discussed in 2014-June

could be agreed soon[38] 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.

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 ten years will be 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.). A timeframe of 5 to 10 years could be envisaged to update again the Directive, taking into consideration that the scope broadening issue is still under discussions and that the merging of both Directives has also been launched for discussion.

*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. The choice of the best option is left to each company. It can be anticipated that companies won't phase out 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. Considering the costs for complying with the set OEL value, it is expected that Industry will preferably adapt the processes or work stations and/or improve collective protection equipments (for example local exhausted ventilation which may appear inappropriate or not tailor-made to the tasks) and personal protective equipments with adequate filtering (usually respirators with APF from 10 to 40, including air assistance if needed) before going to closed systems and automation, if it is technically possible.

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 (as said in SEA) by some registrants in specific applications (batteries for instance). 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 (for example 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.

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[38] probably in June 2014

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

NiO can be covered by Directive 98/24/EC based on its toxicological properties (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 NiO. 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 NiO 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 stricter 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 that is not the current expected objective considering the conclusions of the analysis of alternatives.

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 NiO 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 NiO.

## 4.2 Risk management measures under REACH

Under REACH, restriction(s) 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 NiO.

Taking a decision on measures under REACH for NiO 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 this would need to consider further the substitution ability between nickel salts process by process on a strict technical point of view which is considered not possible in the framework 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's 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 MS 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 NiO determined as to be "at risk" (see table 48) 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 NiO considered as "at risk" 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 most of the uses of NiO. 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 oxide

For the purpose of the RMOA and especially for the restriction option analysis, the non-conclusive situation stated in section 3 (except for GES 10) 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 42), **it is concluded for the inhalation exposure that the risk is estimated uncontrolled for 7 GES over 10.**

From the risk assessment provided in section 3, the risk has been concluded uncontrolled for GES 10 based on exposure data modeling (Mease modeling Tier 1) because of a high exposure for all CES, the provided RPE with APF 40 being insufficient to keep inhalation exposure of workers below the appropriate DNEL.

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 42. Results of the level of risk estimated for each GES of NiO

| GES / Uses | Is the risk from inhalation estimated controlled? | Explanation based on the available data on RPE:<br>APF needed / APF available | Is the risk from dermal exposure estimated controlled? |
|---|---|---|---|
| GES 1. Production of NiO-containing catalysts and catalyst precursors | NO | 20 / no proposed RPE | YES |
| GES 2. Industrial use of powdered and shaped nickel oxide containing catalysts and catalyst precursors (A) | YES | 20 / 20 | YES |
| GES 3. Industrial use of nickel oxide-containing catalysts precursors for the production of catalysts containing other nickel compounds (B) | YES | 20 / 20 | YES |
| GES 4. Production of nickel based powders from nickel oxide containing materials | NO | Higher than 40 / 20 | YES |
| GES 5. Production of nickel-containing electronic and thermally functioning ceramics | NO | no exposure data provided | YES |
| GES 6. Production of nickel-containing enamel frits | NO | 40 / 20 | YES |
| GES 7. Production of nickel-containing pigments | NO | 40 / 20 | YES |
| GES 8. Production of nickel-containing glass | YES | 40 / 40 | YES |
| GES 9. Stainless, special steels and special alloys manufacturing (SA4) | NO | 20 / no proposed RPE | YES |
| GES 10. Production of NiZn cores and solids from NiO powder | NO | higher than 40 / 40 | YES |

#### 4.2.1.3 Evaluation of the impact of the “non-use scenario” for each use covered by a SEA

The non-use scenario illustrate the most likely responses at each stage in the whole supply chain in the hypothetical case that NiO would no longer be available for use in the EU. It is reported from the provided SEA, has not been challenged and **reflects only the Industry view.**

NiO containing catalysts non-use scenario

The non-use scenario provided by Industry has been developed based on extensive consultation of business people in relevant industry sectors both inside and outside the

EU (individual catalyst manufacturers, catalyst service companies and catalyst recycling companies). The whole reasoning is available in the SEA document that is made available by the Nickel Institute. This non-use scenario is however based on the AoA conclusion that could be challenged and has thus to be considered as an interim position as it would differ if AoA conclusions were changed.

It has been slightly adapted in this document considering the proposed interpretation of the intermediate status under REACH. Indeed as an intermediate status is assumed a priori, the authorization route is not expected and a ban based on a potential restriction should be assessed too in this non-use scenario.

If the NiO use is considered as an intermediate use (which is the current interpretation) the authorisation route would not be an appropriate risk management measure to control the occupational risk linked to the manufacture of the NiO containing catalyst precursor and its use (when reduced to Ni or sulfided). Indeed intermediates are exempted from authorisation. A restriction would be an appropriate tool in theory and may cover either the manufacture, the use and the importation of the NiO catalyst precursors in a worst case scenario, or the manufacture only in a best case scenario (for Industry perspective). In the worst case, the most likely response from the catalyst manufacturers and the downstream users would be to find an alternative otherwise to abandon the use as it appears difficult to relocate the downstream users' plants outside from Europe. In the best case scenario, the most likely response from the catalyst manufacturers and downstream users would be relocation of catalyst production outside the EU but import of finished end-products (that is to say the NiO catalyst precursor) into the EU rather than switching to an alternative. The scope of the potential restriction would thus be the main driver.

If the NiO use in catalyst precursors manufacturing is not considered as an intermediate use (which might be not the case and not considered further in this document), the authorisation route would be an option and the whole use (including manufacturing and subsequent use when NiO is reduced to Ni or sulfided) would need to be authorized, would an application be submitted. Industry anticipates that, given the scale of economic and social benefits relative to the risks of continued use of a well-controlled substance, the benefits of authorisation would outweigh the risks to human health and the environment, and the authorisation would be granted. If it is not the case, the most likely response for the catalyst manufacturer and the downstream user would be to find an alternative otherwise to abandon the use as it appears technically and economically difficult to relocate the downstream users' plants outside from Europe. Indeed since NiO catalyst precursor is considered as a substance and not as an article, import would be possible but its use would need to be authorized. Only niche markets for which an alternative may be suitable would still exist in Europe: 10% of current hydrotreating capacity could be replaced by CoMo catalysts and 5% of hydrogenation capacity could be replaced by pgm. The restriction impact would be similar to the previous case.

NiO containing frits non-use scenario

In a non-use scenario, manufacturers of enamel frits would probably switch to the NiO free production by substituting NiO with a new combination of other metal oxides.

Stopping the production NiO containing glass frits in the EU is the considered option for glass colouring frits and ceramic glazes given that no suitable alternative has been identified so far. Frits manufactured with NiO for glass colouring and ceramic glazes are not produced in large quantities and are only of minor importance to the product portfolio of the companies, therefore the economic impact will be rather limited. Hence, the viability of many frits manufacturers is not depending on these specific frits. Capacity would be relocated to facilities outside from Europe who would be able to continue the use of NiO. Indeed almost all companies in the industry consultation, except for one, are globalised companies.

It is important to note that the non-use scenario and impact assessment has been based on contributions of medium users of NiO; one large manufacturer is lacking. This manufacturer was unable to respond due to the confidentiality of business information on alternatives.

### NiO containing pigments non-use scenario

In a non-use scenario, Industry considers that 71% of the current used tonnage of NiO (i.e. 249 t/y) could potentially be replaced by an alternative (switch to "copper chromite black spinel" alternative and to "chromium green black hematite" alternative), 29% (i.e. 100 t/y) would be relocated to developing countries (or even more if a suitable alternative for the customers is not found in time), and that a negligible part of manufacturers (0.2% of the production, i.e. 1 t/y) would stop production as the pigments produced with NiO only contribute to a minor extent to their product portfolio.

### Crystal glass manufacturing: the non-use scenario

In the course of an extensive industry consultation, it was indicated that a majority of crystal glass manufacturers would perform research to identify a potential alternative for their production process, test it and possibly adopt the alternative, even if it is at a substantially higher cost. Even if it is not entirely clear for each producer which alternative substances would be needed to replace the NiO's functionality and in which proportion, for sure, erbium oxide, cobalt oxide and neodymium oxide will predominantly be required. Thus Industry expects that 93% of the tonnage of used NiO for crystal glass production would be replaced by an alternative in time (2,790-4,650kg, average 3,720 kg). Cooperation between different manufacturers is excluded, as formulations today are already held closely proprietary, in case research cannot find a suitable alternative, these manufacturers would be forced to stop manufacturing in the EU and close the facilities considering that often more than 90% or 100% of their end products depend on the use of NiO. But this scenario is not really anticipated.

Considering that for some companies it is already clear which substances are needed to replace NiO and they would go for substitution by erbium and cobalt oxide, 1% of the tonnage of NiO (i.e. 30-50 kg, average 40 kg) used today could be immediately replaced by an alternative, namely erbium oxide and cobalt oxide.

Only minor part of production would relocate to a developing country. This is estimated to represent 6% of the tonnage of NiO used today in crystal glass production in the EU (180-300kg, average 240 kg). Choosing for relocation is preferable in case of automated production lines, when mainly low skilled labour is required. Considering that the unique skills for handmade glasses are present in the EU and that large investments would be needed in case of relocation, relocation is not the preferred approach for many SMEs. Other reasons are the lack of existing facilities, the significant investment costs needed and the expected loss of quality. Moreover, an important sales argument these days is the marketing label 'made in Europe' representing a high quality glass product which would no longer be used in case of relocation.

In the EU a number of regulations with respect to working conditions affect the input materials and the way they are stored, handled and used in production. For example the legislation regulating lead concentration and hazardous substances requires conversions in the production and stricter control of input materials. This means that the potential shift to developing countries could not entirely be attributed to the potential ban of NiO.

In case no alternative is found for colouring purposes, the specific NiO based activities could potentially be stopped because the manufacturer still has revenues from e.g. clear glass production and/or other coloured glass products. This would mean that the full range of coloured glass products can no longer be supplied on the market. This could lead to a situation whereby a distributor prefers to work with other manufacturers who are able to supply all colours and end products. This entails a potential threat for manufacturers who intend to stay on the European markets, but stop these specific colouring activities.

Ophtalmic glass manufacturing: the non-use scenario

The industry consultation allowed concluding that one of both European companies would stop the production line for sunglass blanks but would continue operating other production lines. Although both companies are globalised companies with facilities outside the EU, they only produce sunglasses in the EU and have special dedicated production lines. The production line will not be moved to the rest of the world because these facilities cannot accommodate the production of glass blanks. The company would suffer from a loss of income, however the social impact may be limited to the disappearance of a low number of skilled manufacturing jobs. The other company that produces glass blanks as its core activity considers that a hypothetical ban would cause its closure.

BLB glass manufacturing: the non-use scenario

The non-use scenario illustrates the most likely responses at each stage in the supply chain in the hypothetical case that NiO would no longer be available for use in the EU.

As no suitable alternative is currently identified, it is likely that the only one company identified so far will stop the BLB glass manufacturing. Relocation would not the preferred option due to high investment costs. It also expected that the lighting manufacturer (downstream user in the supply chain) will search for a glass supplier outside Europe that would develop the BLB glass manufacturing with NiO and import it in Europe.

#### 4.2.1.4 Analysis of the restriction option for each GES of nickel oxide

An analysis of the restriction option is proposed in Tables 43 for each GES estimated to be at risk from table 48 (GES 1, 4, 5, 6, 7, 9 and 10).

Tables 43. Analysis of restriction’s pros and cons per GES

GES 1. Production of NiO-containing catalysts and catalyst precursors

| **CES for which RCR >1** | **RMM proposed in the CSR** | **Possible forms of the restriction to limit the exposure** | **Conclusion / Caveat** | |
|---|---|---|---|---|
| No differentiation has been made by the registrant in the CSR between process steps, leading to 2 aggregated CES that are not sufficiently detailed and for which RCR are > 1<br>CES 1.1. Production of nickel oxide-containing catalysts and catalyst precursors<br>CES 1.2. Production of NiO-containing catalysts from shaped precursors containing Ni-compounds and by regeneration | RPE ( APF 20) required for cleaning and maintenance step only<br>It is not clear from the CSR if exposure is possible only for the cleaning step or for all process’ steps (at least during control operations for semi-automated lines). | Stricter/Binding OEL | •Overlapping with OELs Directive and SCOEL’s remit<br>• Given the provided information and the lack of detailed data on each specific CES (tasks) corresponding to this GES, it is difficult to propose targeted RMMs. A binding/stricter OEL should be applied to the whole GES<br>• Hindrances related to the proposal of a specific OEL for one single task/workstation (control operations + cleaning and maintenance?):<br>-Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms<br>-Might not be implementable by the company | Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk, given the lack of detailed data for each specific CES.<br>Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern especially because the CES are not detailed enough to identify the specific situations “at risk” |
| | | Additional/more appropriate PPE (RPE with APF 20 may be appropriate and implemented on each step with potential exposure) | • No expected overlapping with the PPEs Directive that is very superficial and generic<br>• Without additional information of the steps with potential exposure, would need to be required for the whole process by default | |
| | | Full 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<br>• Might not be suitable for that specific task as manual controls / interventions would still be necessary (as much as efficient? technically feasible?) |  |
|  |  | Switch to an alternative to produce catalysts and catalysts precursors | • Would imply to propose a ban of this use (the whole GES)<br>• Alternative drop-in chemicals or alternative processes meeting the same technical requirements do not seem to be available for this specific use except for niche markets |  |
|  |  | Improvement of the whole process in order to lower exposure (dust release etc.) | • Can be developed based on the current BAT (BREFs)<br>• Possible under a restriction procedure? |  |
|  |  | Limitation of NiO concentration in the process (i.e. substrates, etc.) | • Not relevant with the process aim as the highest possible NiO concentration/content is expected onto the catalytic substrate |  |

## GES 4. Production of nickel based powders from nickel oxide

| **CES for which RCR >1** | **RMM proposed in the CSR** | **Possible forms of the restriction to limit the exposure** | **Conclusion / Caveat** | |
|---|---|---|---|---|
| CES 4.2 Smelting<br>(partly enclosed)<br>CES 4.3 Alloying and atomizing<br>(partly enclosed - handlings)<br>CES 4.5 Blending and Sieving<br>(manually operated loading and unloading) | RPE (APF 20) required at process steps that are not fully enclosed and are likely to give rise to fumes or dust<br>+ LEV<br>RPE (APF 40) required if NiO containing particles < 10µm, but particle size is not known (available monitoring?) | Stricter/Binding OEL | •Overlapping with OELs Directive and SCOEL's remit<br>• Hindrances related to the proposal of a specific OEL for specific tasks/workstations:<br>-Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms<br>-Might not be implementable by the company<br>=> the proposed OEL should be applied for the whole GES | Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk given the current state of available data for such a specialized GES<br>Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern needed in the perspective of a task-targeted restriction |
| | | Additional/more appropriate PPE | • No expected overlapping with the PPEs Directive that is very superficial and generic<br>• Without additional information of the steps with potential exposure, would need to be required for the whole process by default<br>• no data on particle size; RPE might not be suitable for a task with 8 hours/day working duration<br>• APF 40 would be efficient for CES 4.2 but would remain insufficient for CES 4.3 (RCR>1 with APF 40): therefore appears not relevant for the whole GES | |
| | | Automation of the whole 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<br>• Might not be suitable for some specific tasks which require handlings (as much as efficient?) – unknown feasibility | |

| | | | | |
|---|---|---|---|---|
| | | Limitation of NiO concentration in the process | • Not relevant to reduce the amount of NiO in the raw material as the highest concentration of NiO is needed to produce the purest Ni powder | |
| | | Switch to alternative (safer?) substances or technologies | • No data on substitution has been provided (neither an analysis of alternatives nor an SEA); other means of Ni powders would exist from other nickel compounds (no risk reduction expected however) | |

GES 5. Production of nickel-containing electronics and thermally functioning ceramics

| CES for which RCR >1 | RMM proposed in the CSR | Possible forms of the restriction to limit the exposure | Conclusion / Caveat | |
|---|---|---|---|---|
| **No CES estimated at risk** (when RPE with APF 4 are used); the whole GES is nevertheless considered at risk (by default) because exposure data have not been provided for CES 5.1 (SEV issue); the negligible exposure reported for CES 5.4 and 5.5 is questioned without any additional information.<br>CES 5.1<br>Raw materials handling<br>(mainly handlings)<br>(no exposure data provided at all)<br>CES 5.4<br>Assembly of thermistor into probes<br>(mainly handlings)<br>(questionable exposure data: considered as negligible by the registrant without any additional information) | RPE (APF 10 and APF 4) | Stricter/Binding OEL | •Overlapping with OELs Directive and SCOEL's remit<br>• Hindrances related to the proposal of a specific OEL for specific tasks/workstations:<br>-Difficulty to define the specific targeted workstations and the corresponding tasks in generic terms<br>-Might not be implementable by the company<br>=> the proposed OEL should be applied for the whole GES. | Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk given the lack of data on exposure; the question raised is clearly a substance evaluation issue (data gathering needed to refine the RA)<br>Scope issue: significant difficulty expected to provide a precise and generic definition of the workstations/tasks of concern needed in the perspective of a task-targeted restriction (targeting made even worse due to the lack/uncertainties of exposure data) |
| | | Additional/more appropriate PPE | • No expected overlapping with the PPEs Directive that is very superficial and generic<br>• Risk would be under control with RPE (APF 4); relevancy to require a RPE with APF 4 because of the tasks duration (11.2 hours per day [1 shift], 7 days per week [2 shifts 4 days on/4 days off] = reported for the whole GES)? Any other preferable alternative (LEV)? | |
| | | Automation of the whole 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<br>• Might not be suitable for some specific tasks which require manual handlings (as much as efficient? technically feasible to clean without any handlings?) – unknown feasibility | |

| | | | | |
|---|---|---|---|---|
| CES 5.5<br>Cleaning and maintenance<br>Similar to CES 5.4 | | Limitation of NiO concentration in the process | • feasibility is not known without additional information on the process and the NiO functionality (no data provided) | |
| | | Switch to alternative (safer?) substances or technologies | • no data on substitution has been provided (neither an analysis of alternatives nor an SEA) | |

GES 6. Production of nickel-containing frits

| **CES for which RCR >1** | **RMM proposed in the CSR** | **Possible forms of the restriction to limit the exposure** | **Conclusion / Caveat** | |
|---|---|---|---|---|
| CES 6.6<br>Cleaning and maintenance<br><br>(mainly handlings) | RPE (APF 20) provided<br><br>APF 40 needed | Stricter/Binding OEL | •Overlapping with OELs Directive and SCOEL's remit<br><br>• Hindrances related to the proposal of a specific OEL for on single specific task/workstation:<br><br>-Difficulty to define the specific targeted workstation and the corresponding task in generic terms<br>-Might not be implementable by the company<br><br>=> the proposed OEL should be applied for the whole GES | Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. Proportionality is questioned as only one CES is at risk over 6.<br><br>Scope issue: significant difficulty expected to provide a precise and generic definition of the workstation/tasks of concern needed in the perspective of a task-targeted restriction |
| | | Additional/more appropriate PPE | • No expected overlapping with the PPEs Directive that is very superficial and generic<br><br>• Risk would be controlled with RPE (APF 40); the technical feasibility to implement such RPE is not known; the relevancy to require it is questioned because of the tasks duration (8 hours shifts)? | |
| | | Automation of the tasks related to cleaning and maintenance | • 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<br><br>• 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 NiO concentration in the materials / installations / devices cleaned and maintained | • Could be further discussed considering the low NiO concentration in the frits (would depend on the type of frits and the end-use; reported concentration from 0.7-2 to 10-15% of NiO) | |
| | | Switch to alternative (safer?) substances or technologies | • For enamel frits (adherence functionality), alternative combination of substances already available for some users or would be available soon<br>• No substitution for glass frits (colouring functionality) to obtain the same exact shade, but change in final colour would be possible (NiO-free frits)<br>• Would imply a total ban of the use although only one CES is at risk | |

GES 7. Production of nickel-containing pigments

| **CES for which RCR >1** | **RMM proposed in the CSR** | **Possible forms of the restriction to limit the exposure** | **Conclusion / Caveat** | |
|---|---|---|---|---|
| CES 7.7<br>Cleaning and maintenance<br>(mainly handlings) | RPE (APF 20) provided<br>APF 40 needed | Stricter/Binding OEL | •Overlapping with OELs Directive and SCOEL's remit<br>• Hindrances related to the proposal of a specific OEL for on single specific task/workstation:<br>-Difficulty to define the specific targeted workstation and the corresponding task in generic terms<br>-Might not be implementable by the company<br>=> the proposed OEL should be applied for the whole GES | Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk. Proportionality is questioned as only one CES is at risk over 7.<br>Scope issue: significant difficulty expected to provide a precise and generic definition of the workstation/tasks of concern needed in the perspective of a task-targeted restriction |
| | | Additional/more appropriate PPE | • No expected overlapping with the PPEs Directive that is very superficial and generic<br>• Risk would be controlled with RPE (APF 40); the technical feasibility to implement such RPE is not known; the relevancy to require it is questioned because of the tasks duration (8 hours shifts)? | |
| | | Automation of the tasks related to cleaning and maintenance | • 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<br>• 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 NiO concentration in the materials / installations / devices cleaned and maintained | • Could be further discussed considering the low NiO concentration in the pigments (would depend on the type of frits and the end-use; reported concentration from 1 to 10% of NiO, and up to 27% in rare cases) | |
| | | Switch to alternative (safer?) substances or technologies | • Alternative substance (pigment) does already exist for some applications but not all<br>• Otherwise no substitution to obtain the same exact shade, but the option to abandon the NiO based colour for another shade is possible<br>• Would imply a total ban of the use although only one CES is at risk | |

GES 9. Stainless steel, special steel and alloys manufacturing

| CES for which RCR >1 | **RMM proposed in the CSR** | **Possible forms of the restriction to limit the exposure** | **Conclusion / Caveat** | |
|---|---|---|---|---|
| CES 9.2 First processing<br>(handlings)<br>CES 9.3 Further processing<br>CES 9.6 Packing, shipping and storage<br>(handlings) | RPE not specified<br>APF 4 to 20 needed depending on the step | Stricter/Binding OEL | •Overlapping with OELs Directive and SCOEL's remit<br>• Hindrances related to the proposal of a specific OEL for on single specific task/workstation:<br>-Difficulty to define the specific targeted workstation and the corresponding task in generic terms<br>-Might not be implementable by the company<br>=> the proposed OEL should be applied for the whole GES | Risk issue: Significant uncertainties expected as regards the possibility of demonstrating an unacceptable risk.<br>Scope issue: significant difficulty expected to provide a precise and generic definition of the workstation/tasks of concern needed in the perspective of a task-targeted restriction |
| | | Additional/more appropriate PPE | • No expected overlapping with the PPEs Directive that is very superficial and generic<br>• Risk would be controlled with RPE (APF 4 to 20 depending of the process step); the technical feasibility to implement such RPE is not known; the task duration max is 4 hours (160 minutes mean). | |
| | | Automation of the tasks considered to be "at risk" | • 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<br>• 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 NiO concentration in the materials / installations / devices cleaned and | • Feasibility is not known without additional information on the process (and the concentration of NiO required) but expected no relevant as final Ni metal based alloy/steel is | |

| | | | | |
|---|---|---|---|---|
| | | maintained | produced from NiO (stoichiometry) | |
| | | Switch to alternative (safer?) substances or technologies | • no data on substitution has been provided (neither an analysis of alternatives nor an SEA) | |

GES 10. Production of NiZn cores and solids from NiO powder

| CES for which RCR >1 | **RMM proposed in the CSR** | **Possible forms of the restriction to limit the exposure** | **Conclusion / Caveat** | |
|---|---|---|---|---|
| CES 10.1. Raw material handling<br>(handlings + open transfer (powder) operations)<br>CES 10.2: Production of NiZn solids<br>(open transfer operations)<br>CES 10.3: Cleaning and maintenance<br>(handlings) | RPE 20 or 40 specified but insufficient regarding the high exposure levels (modeled) | Stricter/Binding OEL | • Overlapping with OELs Directive and SCOEL's remit<br>• Hindrances related to the proposal of a specific OEL for on single specific task/workstation:<br>-Difficulty to define the specific targeted workstation and the corresponding task in generic terms<br>-Might not be implementable by the company<br>=> the proposed OEL should be applied for the whole GES<br>• The OEL option would not be relevant (sufficient per se) as exposure is too high and risk cannot be controlled by the highest available RPE | <u>No expected risk issue</u>: significant and unacceptable risk could be demonstrated based on the provided modeled exposure data (at least for CES 10.1 based on a calculated RCR of 2,75 including RPE with APF 40)<br><u>Scope issue</u>: significant difficulty expected to provide a precise and generic definition of the workstation/tasks of concern needed in the perspective of a task-targeted restriction |
| | | Additional/more appropriate PPE | • No expected overlapping with the PPEs Directive that is very superficial and generic<br>• However risk cannot be controlled with the highest APF of 40; thus the PPE option is not relevant. | |
| | | Automation of the tasks considered to be "at risk" | • 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<br>• 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 NiO concentration in the | • Feasibility is not known without additional information on the process and the NiO | |

| | | | | |
|---|---|---|---|---|
| | | materials / installations / devices cleaned and maintained | functionality | |
| | | Switch to alternative (safer?) substances or technologies | • no data on substitution has been provided (neither an analysis of alternatives nor an SEA) | |

#### 4.2.1.5 Conclusion of the restriction option analysis

As regards the suitability of the REACH restriction in achieving the objectives of the risk reduction strategy:

- 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 NiO. 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 NiO, 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 48) 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 NiO 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 NiO could in principle be achieved by limiting the NiO 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.). Moreover, the efficiency expected (functionality) of the final product is often dependant on the Ni content which is also dependant of the NiO content of the used raw material; thus limiting the NiO content/concentration in the exposing material appears not consistent with the process.
- Finally, the proportionality of restricting one entire use of NiO when only one or few CES are estimated at risk is questionable.

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 could in principle be targeted and subject to a restriction proposal. However, except for GES 10 (see below), 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 NiO. 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 possible 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 NiO registration dossiers and have a better picture of the risk characterisation. 3 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 (this process is expected to last 3 years minimum).
- Refining the risk assessment by modeling the exposure with a Tier II approach based on the current information.
- 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 NiO 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.); this may however be anticipated time/resource consuming for the dossier submitter, without any certainty to be able to conclude on an unacceptable risk; moreover the availability of the expected data is not known and such data may not suit the current detail level of the registration dossiers (i.e. exposure assessment per sub-scenario), thus not

allowing a precise risk characterization; the data finally available may also not be substance specific but may cover several nickel compounds, which is not well fitted with the scope of a restriction except if a common approach of nickel compounds could be identified.

Nonetheless, reducing data uncertainties in order to conclude on the risk would not remove the difficulties related to the definition of the restriction's scope and its technical feasibility.

As regards to GES 10 (production of NiZn cores and solids from NiO powder), a restriction could already be envisaged at this step since it can be anticipated to demonstrate an unacceptable risk based on the provided modeled exposure data. However defining the scope would still remain an issue. This demonstration would also be surrounded by several uncertainties given that a Tier 1 model is used (Mease) and the calculated RCR over but close to 1 (i.e. RCR of 1.45, considering the use of RPE with APF of 40, for the CES 10.2 and 10.3) would need to be interpreted with caution. However the calculated RCR of 2.75 for CES 10.1 would be sufficient to consider an unacceptable risk at least for this step of the process

### 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 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 an SVHC (substance of very high concern). Due to its harmonized classification under Annex VI of the CLP as carcinogenic substance, nickel oxide could be de facto identified as SVHC under article 57(a) of the REACH regulation 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,f) 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, the prioritisation of NiO is questioned because on the total used but uncertain volumes (around 6,200 t/y reported by the Nickel Institute, and up to 69,840 t/y from the registration dossiers), only a minor part is considered as non-intermediate uses (640 t/y over 6,200 t/y; 12,560 t/y over 69,840 t/y) that is to say not exempted from the authorization requirements. For consistency reason, inclusion of NiO 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, **NiO meets the SVHC Roadmap 2020 criteria** (see Table 44). NiO is a substance that could be regarded as relevant under the SVHC roadmap.

Table 44. Fulfilment of SVHC Roadmap 2020 criteria for nickel oxide

| | 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 on 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 NiO adverse effects (carcinogenic property) 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 NiO considering the complexity and the number of uses reported. The SEA reports that have been provided by Industry during the elaboration of this RMO analysis show however to some extent that registrants already anticipate this issue.

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 challenge by the ECHA Committees, the other stakeholders (during the public consultation) and the 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. Indeed, 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
- 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[39]; therefore any occupational risk arising from manufacturing cannot be covered by the authorisation route; however the main NiO volume used is manufactured outside from EU except the NiO used in catalyst precursors that is considered as an intermediate use and therefore exempted from authorisation.
- The intermediate uses are exempted from authorisation requirements; therefore any occupational risk arising from intermediate uses cannot be covered by the authorisation route.

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[39] 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.

#### 4.2.2.3 Analysis of the authorisation option for each use of nickel oxide

The potential assets and drawbacks of subjecting the uses of NiO 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 (catalysts, frits, pigments, glass manufacturing), in order to assess the possibility that an application for authorisation could be granted in the case NiO would be included in Annex XIV. The SEA consists in an analytical approach describing and assessing all relevant impacts (i.e. both 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 NiO) 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 oxide production

Apart from the NiO production in catalysts precursors manufacturing, no other production exists within the EU and NiO is imported from extra-European countries.

In any case if the manufacturing of NiO containing catalyst precursors would not be considered as an intermediate use, the associated occupational risk would not be covered by the authorisation as authorisation doesn’t cover the manufacturing of the substance. Indeed NiO is only manufactured and then consumed/used within the same process of Ni containing catalyst manufacturing. Given that most of the NiO containing catalyst precursors as transported as such to the downstream users’ plants where they are reduced or sulphided, one can consider that GES 1 is the manufacturing step and GES 2-3 are the uses steps. Authorisation would thus cover GES 2-3 that are estimated as safe uses in our exercise but would not cover GES 1 for which the risk is estimated unacceptable. The reported volume of 5,400 t/y NiO apply to both GES 1 and GES 2-3 as they cover the same material.

Uses of NiO containing catalysts precursors

Eligibility under authorisation (volumes covered and intermediate status)

The use of NiO-containing catalysts precursors refers to GES 2 and 3 of the CSR (see above). Would the use of NiO containing catalysts precursors not seen as an intermediate. The eligible tonnage would be 5,400 t/y NiO . Nevertheless, as no risk has been estimated for GES 2 and 3, the proportionality of the authorisation for risk reduction in this case is raised.

Analysis of alternatives: substitutability

From the provided analysis of alternatives and as regards substitution, as mentioned above, the overview of alternatives carried out by industry is rather pessimistic: the substitution by other finished products or by alternative processes do not seem feasible at large-scale and the chemical drop-in substitution could be developed by (already underway) R&D activities but the solutions would anyway be of wide range and would need to be adapted on a use-by-use basis. It is considered that pgm metals (platinum group metals) like ruthenium, platinum or palladium could only substitute NiO in a limited number of niche applications with higher costs. Where pgm cannot be implemented, cobalt may be used in some other niche hydrotreating applications but also with a much higher cost considering that cobalt is less efficient than nickel in catalytic reactions. Without cost and yield consideration, suitable alternatives may be identified in a first approach for amination, sulphur trapping, hydrotreating (however with the sulphur issue) and some targeted applications on a case by case basis. The main activity sectors using Ni based catalysts do not benefit from suitable alternatives for the time being. No alternative processes/technologies has been identified so far. Regarding the steam reforming / methanation sector, there is the possibility to use an alternative technology than catalysts but not economically feasible yet because of high energy input and current energy cost.

Therefore, if authorization would be seen a possible option in case of a non-intermediate status (which is not considered the case so far), this option would be seen premature since substitution is not available for the most part of the used tonnage.

Socio-economic analysis

A SEA has been carried out by the Nickel Institute in the case where this use would be considered as a non-intermediate use.

As far as the socio-economic consequences of a refused authorisation would be concerned, one SEA report has been provided by Industry for the use of NiO in catalysts and catalysts precursors assessing the costs and benefits of a hypothetical refused authorisation (the so-called "non-use scenario").

On one side, the costs for the EU industry in this particular sector are evaluated showing the relocation (to existing sites outside the EU) as the most likely reaction of the market:

- The downstream users (DUs) in hydrotreating sector are expected to relocate between 90% and 100% and to adopt CoMo catalysts up to 10% (for niche markets), generating major costs. The yearly loss of added value in EU27 estimated by Industry ranges between €13 billion and more than €15 billion. The NPV[40] (20 years, 4%) of lost added value ranges between at least €185 billion and more than €200 billion. This figure is about half of the turnover EU-27's refinement sector has generated in 2009. Key countries contributing most added value in this business are Germany and France. Spain, the United Kingdom, Greece, Italy, Hungary and the Netherlands are other important countries regarding the refinement of petroleum. Investment costs related to application of CoMo catalysts, including R&D, are estimated in the range of €1 billion. Investment costs related to relocation range between €7.5 billion and €8.3 billion. This is more than half of the added value realised by EU-27's refinement sector in 2009. Sunk costs can be considered as significant, but could not be quantified.

- The DUs in hydrogenation sector for oleochemicals production are expected to relocate up to 95% outside the EU and to adopt pgm up to 5% (niche markets only). No major investment costs were reported for application of pgm catalysts, however purchasing costs are at least 5 to 10 times higher than for NiO and R&D

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[40] Net present value

costs associated are estimated at evaluated at € [confidential]. Investment costs for relocation could not be estimated. The European oleochemical industry generates an annual turnover of more than €4 billion and an annual added value of more than €1.5 billion. The NPV (20 years, 4%) of lost added value in EU27 of oleochemicals production is estimated by Industry at almost €20 billion.

- The economic impacts for DU sulphur trapping have not been assessed.

- The smallest DU would stop production because they don't have facilities outside the EU.

- If all NiO catalyst precursor manufacturers would relocate outside Europe, investments costs are estimated at about 2.4 billion €. Based on information from two companies, it seems that the lower end of the investment costs for relocation required per company is in the range of the yearly EU turnover figure of the NiO catalyst precursor business and the higher end is in the range of the yearly global turnover figures. Sunk costs related to relocation are estimated at 170 million €. Loss of yearly turnover in EU27 + Norway is estimated at least at 130 million €. This figure refers only to the NiO catalyst precursor related business. Furthermore, it is only based on information from 2 manufacturers; other manufacturers have confirmed that NiO catalytic systems provide a significant contribution towards their turnover, both in Europe and the ROW. Moreover, it was indicated by manufacturers that in case of relocation it is probable that not only the NiO catalyst precursor related business would relocate. This means that real loss of turnover would be a multiple of the indicated figure.

- From the alternative substances' markets which are expected to remain in the EU, additional operating income is expected however this could not be quantified by Industry. This is related to the lower efficiency of CoMo (2-10 times higher amount is needed) and the expected larger profit margin for pgm compared to Ni.

- For the catalyst service companies, a loss of operating income in the EU is expected due to reduced regeneration and presulfiding activities of NiO catalyst precursors, however it could not be quantified by Industry. This is (partly) compensated by additional operating income (outside the EU) due to new services for alternatives and more frequent change outs.

- For reclamation companies, a loss of operating income in the EU is estimated at several million of €. This is (partly) compensated by additional operating income (outside the EU) from an increased quantity of recycling alternatives. Recycling companies outside the EU will have additional income and will need additional employment to recycle the NiO catalyst precursors of DU who relocated.

- For suppliers of raw materials, there could be a net benefit in case the additional operating revenues are higher than the additional operating costs.

The social impacts of a refused authorisation are also assessed. As a whole, along the supply chain, thousands of jobs are expected to shift to ROW due to massive relocation: the expected scale of expected job losses related to the identified non-use scenarios is at least estimated at 150,000 jobs across the EU, but according to Industry, this can be much higher due to indirect employment effects. More than 85% can be attributed to jobs shifted from relocated refineries to ROW. No information was available regarding the amount of jobs at catalyst manufacturers shifted to ROW due to relocation. Net job losses are expected, however could not be quantified. Only a limited number of jobs could be offset by increased activity related to catalysts based on alternative substances (e.g. increased reclamation). The types of jobs likely to be lost include a mixture of low and often highly skilled manufacturing jobs, office, sales, marketing and site management related jobs (e.g. with health and safety and environment legislation). Relocation of companies (especially catalyst manufacturers and catalyst service companies) may also imply relocation of research institutes linked to these companies, as R&D investments are considered as less interesting if there is no home market. Apart from the decrease in the levels of innovation which this trend would imply, there is a loss of highly-skilled employees involved as well.

Overall, the analysis of economic and social impacts is based on the (main) following input data and assumptions: it is reported that around [confidential] per year of NiO-based catalysts are produced in the EU (based on 2012 data) of which around half is exported accounting for a turnover [confidential] per year; the market is organized around 20 major producers (as mentioned above) for 5 endmarkets (fine chemistry, bulk chemistry, fertilizers, oleochemistry and fuels) among which [confidential] hydrotreatment units and [confidential] steam reforming units operate; the refinery sector operating on that market counts for [confidential]companies and [confidential] employees all over Europe.

On the other side, the benefits of a hypothetical refused authorisation are evaluated for human health due to avoided exposure of workers (lung cancers only), as well as some benefit (qualified as "marginal" but not quantified) for environment due to the reduction of NiO production (estimated at -6.5%) but this latter has not been quantified. The health benefits from the non-use of NiO catalysts are estimated at less than 1 cancer avoided per year, valued at around €0.095 million per year. The report states however that this valuation might be somehow underestimated (based on 1,012 workers likely to be exposed but the exact number of workers is claimed to be not available) and somehow overestimated (the cancer risk computation being based on conservative assumptions), which makes in the end the conclusion rather unclear. The non cancer respiratory effects of NiO are considered as "potential" but are not further assessed. Dermal exposure is deemed not of concern by Industry and is not thus expected to bring any potential benefits in case of refused authorisation.

Regarding the impacts of the use of alternatives for health and environment, they are briefly analyzed in the provided report but not quantified. As regards the health impacts, additional adverse effects may occur due to reprotoxicity and respiratory effects of CoMo without any reduction in risk of lung cancers, and the use of pgm may cause skin and respiratory sensitization although there would be a potential to reduce cancer risk. As to the environmental impacts of alternatives, the use of CoMo is not expected to generate negative impacts. No other alternatives have been analyzed to that respect.

Finally, the relocation is likely to cause an increase in greenhouse gases emissions due to increased transportation from relocated companies.

Overall, the analysis of health impacts is basically carried out based on the computation of cancer risks (based on assumptions considered by Industry as conservative including the use of maximum exposure data and an exposure regime for production/use of 8 hours per day, 240 days per year, for 40 years) as well as the use of the value of statistical life. The analysis can be thus somehow considered as rather restrictive and underestimated since it could have also included other indirect costs such as the loss of life quality. Moreover, as already mentioned, no valuation of environmental impacts has been made. As a whole, the health and environment impact assessment of a refused authorisation performed for the use of NiO in catalysts can be deemed rather brief compared to the assessment of economic impacts.

Table 45 summarizes the results of a refused authorisation for the EU according to industry.

Table 45. Summary of the quantified impacts of a refused authorization according to Industry - Catalysts

| | Costs | Benefits |
|---|---|---|
| Economic impacts | Suppliers<br>DU (hydrotreatment)<br>• relocation 90%-100%: costs= €13-15 billion/y loss of added value+€7.5-8.3bn investment costs<br>• switch to CoMo (0-10%): costs= €1 billion + shutdown for the smallest<br>DU (hydrogenation)<br>• relocation 95%: lost added value= €1.5 billion/y<br>• switch to pgm (5%): purchasing costs 5-10 times higher + R&D costs= €[confidential] + shutdown for the smallest<br>DU (sulphur trapping): >0<br>Catalysts manufacturers<br>• relocation 100%: costs> €2.7 billion<br>Catalysts service companies, reclamation companies, suppliers and end-products: costs= several million Euros (partly compensated) | • additional operating incomes from the supply of alternatives<br>/<br>/<br>/<br>• lower operating costs in ROW + additional operating incomes from alternatives<br>/ |
| Social impacts | Shift of jobs outside the EU > 150,000 jobs | / |
| Health impacts | Reduction use of NiO<br>/<br>CoMo: reprotoxicity and respiratory effects<br>Pgm: skin and respiratory sensitization<br>ZnO: / | Benefit: >1,012 workers no longer exposed / less than 1 lung cancer avoided/y<br>=€0.095 million/y<br>+ non cancer respiratory effects<br>/<br>Reduction in cancers<br>/ |
| Environmental impacts | increase in greenhouse gases emissions | None to Marginal |

Again, these figures could not be challenged and are surrounded with many uncertainties. They thus have to be read with some 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. This situation may be considered to some extent as a worst case scenario. Moreover, the benefits might be underestimated since they are not totally quantified and valued.

To this analysis provided by Industry, it can be added that the markets of alternatives would benefit the most from a refused authorization, and that net jobs creation could be expected, additionally to higher profits.

Use of NiO or the production on nickel containing frits

*Eligibility under authorisation (volumes covered and intermediate status)*

The use of NiO for the production of frits is considered by Anses as a non-intermediate use under REACH that is therefore covered by the authorization requirements. The eligible tonnage would be 450 t/y NiO (cf. section 2.2.5.3) (~7% of the total used tonnage of NiO).

Analysis of alternatives: substitutability

From the provided analysis of alternatives (see section 2.2.5.8), it is considered that the development of an drop-in alternative is on the way and it is expected that the majority of manufacturers will continue the on-going R&D activities in order to identify a potential alternative combination for their ground coat enamel frits process. Today, it is not clear however which alternative combination is the most suitable and in which proportion for a specific type of frit it has to be processed.

Socio-economic analysis

From the non-use scenario, it is considered that manufacturers of enamel frits will probably switch to the NiO free production by substituting NiO with a new combination of other metal oxides (combination of cobalt oxide, manganese oxide, copper oxide and perhaps antimony oxide). Production of NiO containing frits for glass production for which no alternative is yet available would be relocated to facilities outside the Europe given that frits for glass only contribute to a small extent to manufacturers profits.

As far as the socio-economic consequences of a refused authorisation are concerned, one SEA report has been provided by Industry for the use of NiO in frits on the costs and benefits of a hypothetical refused authorisation (the so-called "non-use scenario").

As a result of a refused authorization, it is considered that 340 tons[41] of NiO in frits could be replaced by a new combination of metals while approximately 60 tons of NiO may be relocated outside the EU since no alternative is available for ceramic glazes and glass colouring frits. Consequently, on the costs side:

- In the first situation (340 tons of NiO replaced): the manufacturers of frits who would switch to alternatives would bear additional operating costs between €1.1 million per year and per €1.3 million per year (depending on the combination chosen: either a 1 by 1 replacement with an hypothetical share of 80% of Co oxide, either a [confidential] more adhesion agents combination with 80% Co oxide) and associated one-time R&D expenditures of €2.6million. According to Industry, these financial efforts can be a threat for the small SMEs, as the cost is in the range about 7-15% of their annual turnover. However, there is only one small sized company identified by Industry. Other companies are all globally-oriented large sized companies, for which the costs represent a share of only 0.01% to 0.02% of their yearly turnover.

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[41] Over a total volumes of 400 t/y estimated by the consultant, whereas a maximum volume of 450 t/y has also been reported in the SEA and taken into account in this RMOA.

- Other costs such as the loss of operating income due to increased competition from lower price products in ROW are also taken into account in the SEA but not quantified.
- As regards the suppliers of raw materials upstream the supply chain, no cost impact is expected in the case of a 1 by 1 replacement but additional profits are however likely in the case of adhesion agents, due to their potential need to be increased by 3 to 4.3%. The enamellers (end-users) would bear an increase in frits price between 23% and 31% (amount not valued). No resulting potential economic impacts on the consumers have been assessed.

- In the second situation (60 tons relocated due to the absence of alternatives), the manufacturers of frits would face a loss of production value estimated at €0.7 million per year. The EU suppliers of NiO would lose EU NiO revenues up to €0.8 million per year, probably compensated though with gain in revenues by ROW suppliers who would take over the supply (shift in production value). Overall, the glass and ceramic activities are expected to be able to continue to produce only with the use of imported frits. They might however be only impacted in a limited way since these activities represent a minor share of the total turnover of the sector. This impact has not yet been quantified in the report due to a lack of information.

- At the end of the supply chain, a price increase for enamelled products is to be expected. Additional costs borne by the manufacturers, i.e. the higher costs for raw materials, would need to be passed on to the customer to a maximum. According to Industry, it is possible that frits prices are increased with around 3 to 4 euro per kg depending on the scenario (1 on 1 replacement or increase in adhesion agents). Only a small part of the glass industry may be affected, more specifically only those DUs producing soda-lime glasses in a brown-grey tint. These glass manufacturers will only be able to produce brown-grey glasses when using imported frits, since no suitable alternative is available. Some globally oriented downstream users have reported that they would prefer to relocate their business to ROW, by integrating in existing facilities. However, too little information was available to elaborate this impact.

As far as the social impacts of a refused authorization are concerned, no major impact is expected. Figures for employment are estimated, as there are no official statistics available reflecting the total number of employees in the European frits industry. It is estimated that around 1.5 employees are needed per tonne of NiO that is consumed. Total employment depending on the use of NiO is estimated to be around 600 people of around 4,000 people being employed in the EU frits industry. It is expected that the production based on an alternative requires the same job numbers and skills and switching to an alternative substance will not give rise to major social impacts. Probably an additional researcher may need to be recruited or external expertise may need to be hired (on a temporary basis). Manufacturers producing ceramic glazes and glass colouring frit are considering moving production outside of the EU, to their facilities abroad. This situation is expected to shift employment in a range of maximum 90 jobs from the EU to developing countries. The types of jobs likely to be lost include a mixture of skilled manufacturing jobs, office, sales, marketing and site management related jobs (e.g. health and safety and environment).

Overall, the analysis of economic and social impacts is based on the (main) following input data and assumptions: it is estimated that around 25,000 tons of frits are produced using NiO as a raw material in the EU annually; it is assumed that the use of NiO for frits production is between 400 and 450 tonnes per year; total frits production value in EU27 amounted to [confidential] in 2011 and, around [confidential] of the total value can be attributed to the manufacture of frits using NiO; total employment depending on the use of NiO in frits sector is estimated to be around 600 people and it is estimated that turnover share depending on NiO is between [confidential] per company (with an average of [confidential]); finally, more than [confidential] of production is exported. Regarding the alternatives in general no precise data on prices are provided.

On the benefits side, the human health impact assessment associated to a refused authorization is qualitative and the conclusion is to some extent unclear. As regards the non-use of NiO, benefit is deemed probable since risk of lung cancer and non-cancer respiratory effects is claimed to be potential while it is also considered that adverse effects are not expected to be experienced by workers exposed to NiO. No impacts are identified on workers in relation to adverse effects (sensitization) related to dermal exposure. Concerning the human health effects of alternatives, the conclusion is that based on the available information, it is not possible to assess whether new health impacts associated with skin and respiratory sensitisation and an increase in excess cancer risk might arise from a switch to the alternative mix of metal oxides: there may not be any potential for a reduction in cancer risk or skin sensitization effects based on the classifications of antimony oxide and cobalt oxide, respectively; there may be potential for additional respiratory sensitization and neurological effects among workers exposed to cobalt oxide and manganese dioxide, respectively, based on the hazard profile for these substances; and finally, there is not expected to be an increased risk of non-cancer respiratory effects following long-term exposure to cobalt oxide, manganese dioxide and copper oxide if a switch were made to the alternative mix of metal oxide (based on a crude assessment).

In conclusion, it has not been possible for Industry to identify a change in human health risks accompanied by the various non-use scenarios nor to draw any conclusion, because of a lack of exposure data and needs for additional information are claimed. The potential benefits associated to a refused authorization are thus unclear.

Likewise, regarding the environmental impacts in the baseline scenario it is concluded that due to a lack of data, it has not been possible to assess the change in risk accompanied by the alternatives. As to the non-use of NiO, the majority of the frits producers have no risk identified under REACH. It is concluded that regarding the impact when NiO is abandoned, only for a few companies with high exposure data a decrease in impact is noticed. Overall, a full stop in use of NiO in the production of frits would not or only slightly decrease the impacts for the environment.

Table 46 below summarizes the results of a refused authorisation for the EU according to industry. Industry concludes that it has not been possible to weigh the economic and social benefits of continued use against the environmental and human health risks and thus, it was not possible to draw conclusions for the impact assessment.

Table 46. Summary of the quantified impacts of a refused authorization according to Industry - Frits

| | Costs | Benefits |
|---|---|---|
| Economic | <u>340 tons of NiO replaced:</u> | |

| | | |
|---|---|---|
| impacts | Manufacturers of frits:<br>•Substitution Costs= €1.1-1.3 million/y + €2.6 million R&D<br>•loss of operating income due to competition<br>•7-15% loss of turnover by SMEs<br>EU suppliers of raw materials:<br>/<br>Enamellers:<br>•Price increase= 23%-31%<br>60 tons of NiO relocated:<br>Manufacturers of frits:<br>• Costs= €0.7 million/y<br>EU suppliers of raw materials:<br>• Costs= €0.8 million/y<br>Glass and ceramic industry:<br>• limited cost (import) | /<br>• additional profits in case of adhesion agents mix increased by 3-4.3%<br>/<br>/<br>/<br>/ |
| Social impacts | Shift of jobs outside the EU (Glass and ceramic industry) =90 jobs | / |
| Health impacts | No conclusion | |
| Environmental impacts | No conclusion | |

Again, these figures could not be challenged and are surrounded with many uncertainties. They thus have to be read with some precaution. Moreover, without a robust human health and environmental impacts assessment, the socio-economic impacts cannot be relevantly weighted.

To this analysis provided by Industry, it can be added that only some EU countries might be mostly affected by a refused authorisation, an Spain in particular which concentrates 80% of frits production. Spain might thus be more impacted by additional costs than other countries.

Finally, as regards the costs associated to a potential application for authorisation, they might be high. However, almost all frits manufacturers are already global-oriented companies and should face these costs without major difficulty, likely to stand for only a tiny share of their benefits. Nevertheless, one SME is operating on this market for which these costs might be significant, except if it joins a consortium.

### Use of NiO for the production of nickel containing pigments

Eligibility under authorisation (volumes covered and intermediate status)

The use of NiO for the production of pigments is considered by Anses as an intermediate use under REACH when NiO is a main constituent but as a non-intermediate use when NiO is a modifier. The exact tonnage of each sub-use is not known and has been set arbitrary by Anses as half the tonnage, that is to say 175 t/y each. The eligible tonnage would thus be 175 t/y (2,8% of the total used tonnage of NiO)

Analysis of alternatives: substitutability

From the provided analysis of alternatives, it is considered that for some low firing applications (e.g. roof tiles) NiO pigments can be replaced by "copper chromite black spinel" or "chromium green black hematite"; for other applications it is likely that research will be done in order to find and introduce an alternative contra type if a different colour in the end product would be accepted by the customers (reason for which Industry considers available alternatives not suitable).

Socio-economic analysis

From the non-use scenario, Industry considers that 71% of the current used tonnage of NiO (i.e. 249 tonnes per year) could potentially be replaced by an alternative, 29% (i.e. 100 tons per year) would be relocated to developing countries, and that a negligible part of manufacturers (0.2% of the production, i.e. 1 tonne per year) would stop production as the pigments produced with NiO only contribute to a minor extent to their product portfolio.

The SEA has been carried out on the hypothesis that the whole pigments manufacturing use would be a non-intermediate use; it doesn't distinguish between both sub-uses identified by Anses according its interpretation of the intermediate status.

As far as the socio-economic consequences of a refused authorisation are concerned, one SEA report has been provided by Industry for the use of NiO in pigments assessing the costs and benefits of a hypothetical refused authorisation (the so-called "non-use scenario").

As a result of a refused authorization, it is considered that [confidential] tons of NiO ([confidential] %) in pigments (over a total of 349 tons of NiO used in frits annually) could be replaced by an alternative while [confidential] tons of NiO ([confidential]%) may be relocated outside the EU since no alternative is available. [confidential] ton (negligible part of [confidential] %) would disappear from the EU market due to a production stop for ceramic glazes and glass colouring frits. Consequently, on the costs side, the following impacts are expected:

- In the first situation ([confidential] tons of NiO replaced): knowing that 11 facilities are manufacturing pigments with NiO, extrapolating this figure would mean that nearly 8 facilities will be impacted (assuming use of NiO evenly distributed among facilities). They will need to perform research to identify a new contra type for each pigment in their product portfolio. In either case the alternative that is to be developed will not exactly be the same as the original pigment, it will have a different colour tonality. Thus, downstream users and end-consumers will need to accept these new more uniform colour tonalities, e.g. different look for black roof tiles. It is not known whether these colour tonalities will be accepted; anyway if downstream users and end-consumers have the possibility to buy imported pigments/frits/end-products, they can keep exactly the same aesthetics. According to Industry, capital investments (adaptations to the batch equipment) for the sector are estimated in the range of €180,000. R&D costs are expected to be €155,000. Regarding the operating costs, it is not clear whether the production method needs to be adapted, what implications a change to batch equipment might have or if it is mostly limited to changing the raw materials composition. Definitely the use of copper chromite black spinel or chromium green black hematite will require the use of other raw materials. It appears that cost price per unit of these pigments is in the same order of magnitude as the nickel pigments, which could imply that no major impact is to be expected. Total costs are nearly €335,000, without taking the operating costs into account. An attempt was made to bring these one-time impacts in perspective and develop the relation between these costs and turnover generated. The one-time additional costs consist of about 0.003% of annual turnover for the two European oriented companies. The other companies are globally oriented companies, for which the one-time additional costs represent 0.004% of yearly turnover. The economic impacts on DU are uncertain and not quantified: some might face a price increase (depending on the contra type suitable to replace NiO) and some might relocate in response to some pigments manufacturers own relocation. Finally, prices for consumer goods might increase (not quantified).

- In the second situation ([confidential] tons relocated due to the unavailability of alternatives and [confidential] ton phased out), the manufacturers of frits would bear a loss of production value estimated by Industry at €15 million per year.
- The EU suppliers of NiO might lose EU NiO revenues up to €2.3 million per year due to relocation or production stop in the EU. This loss would probably be compensated however with gain in revenues by ROW suppliers who would take over the supply (shift in production value).

As far as the social impacts of a refused authorization are concerned, no impact is expected for the majority of NiO that will be substituted (after a research period) since the production based on alternatives is expected to require the same job numbers and skills. According to Industry, potentially, there would be an extra recruitment of additional researchers (on a temporary basis) to identify the optimal batch combination and production process. Some (but negligible) loss of jobs is expected (estimated at 16) due to the part of activities that would relocate to ROW (shift of employment from EU to developing countries).

Overall, the analysis of economic and social impacts is based on the (main) following input data and assumptions: it is estimated that 349 tons of NiO is used annually to produce pigments in the EU, the sale price of NiO is [confidential]; the production value of the whole sector amounts to €50 million per year and stands for [confidential] jobs. Regarding the alternatives in general no precise data on prices are provided.

On the human health impact assessment side, the impacts associated to a refused authorization are qualitative and the conclusion is to some extent unclear. As regards the non-use of NiO, benefit is probable since risk of cancer and non-cancer respiratory effects is claimed to be potential while it is also considered that adverse effects are not expected to be experienced by workers exposed to NiO. The industry concludes that due to limited set of data and in particular lack on data on worker numbers, it is not possible to produce meaningful results on expected cancer cases among workers for the EU sector. No impacts are identified on workers in relation to adverse effects (sensitization) related to dermal exposure. Concerning the human health effects of alternatives, Industry states that pigment manufacturers would research and adopt alternatives, and that for some applications "copper chromite black spinel" or "chromium green black hematite" can be used and thus exposure of those workers to NiO would cease. A reduction in cancer risk would be expected since neither alternative is classified for carcinogenicity. Subsequently, long-term reduction in additional cancer risk would be expected, eventually to zero, although it is unknown how this would impact actual expected numbers of additional cancer cases.

As a result, it has not been possible for Industry to identify a change in human health risks accompanied by the various non-use scenarios nor to draw any conclusion, because of a lack of data and needs for additional information are claimed. The potential benefits associated to a refused authorization are thus unclear.

Likewise, the environmental impact assessment is brief and to some extent incomplete due to important lack of data. Regarding the baseline scenario, Industry concludes that the majority of the pigment producers have no risk identified under REACH. Regarding the alternatives "copper chromite black spinel" or "chromium green black hematite" provide a better hazard profile as apparent from the qualitative comparison of the hazard profiles. However, Industry concludes that insufficient data (lack of PNEC, fate and exposure parameters) are available for these alternatives in order to perform a meaningful quantitative comparative risk assessment age. Finally, there might be a potential increase in CO2, NOx and SO2 emissions related to increased transportation due to relocation and new imports in the EU (also potentially impacting human health).

Table 47 below summarizes the results of a refused authorisation for the EU according to industry. Industry concludes that it has not been possible to weigh the economic and social benefits of continued use against the environmental and human health risks and thus, it was not possible to draw conclusions for the impact assessment.

Table 47. Summary of the quantified impacts of a refused authorization according to Industry - Pigments

| | Costs | Benefits |
|---|---|---|
| Economic impacts | 249 tons of NiO replaced:<br>Manufacturers of pigments:<br>•costs> €0.335 million<br>EU suppliers of raw materials:<br>•R&D costs<br>DU:<br>•costs>0 (price increase or relocation)<br>Consumers:<br>•costs>0 (probable price increase)<br>100 tons of NiO relocated and 1 phased out:<br>Manufacturers of pigments:<br>• Costs= €15 million/y<br>EU suppliers of raw materials:<br>• Costs= €2.3 million/y | /<br>• additional income in case of increased (alternative) raw materials |
| Social impacts | Marginal shift of jobs outside the EU=16 jobs | / |
| Health impacts | No conclusion | |
| Environmental impacts | No conclusion | |

Again, these figures could not be challenged and are surrounded with many uncertainties. They thus have to be read with some precaution. Moreover, without a robust human health and environmental impacts assessment, the socio-economic impacts cannot be relevantly weighted.

To this analysis provided by Industry, it can be added that Spain might be more impacted by additional costs than other countries since it concentrates 90% of EU pigments production. Moreover, as regards the costs associated to a potential application for authorisation, they might be high. However, almost all pigments manufacturers

(8/10) are already global-oriented companies and should face these costs without major difficulty, likely to stand for only a tiny share of their benefits. Nevertheless, 2 SMEs are operating on this market for which these costs might be significant, except if they join a consortium.

Use of NiO for the production on nickel containing glass

Eligibility under authorisation (volumes covered and intermediate status)

The use of NiO for the production of glass is considered by Anses as a non-intermediate use under REACH which is therefore covered by authorization requirements. The eligible tonnage would be [confidential] t/y NiO. But for the time being no risk has been estimated for this use.

Analysis of alternatives: substitutability

From the provided analysis of alternatives (see section 2.2.7), it is considered that several drop-in substances are available as substitute for crystal glass manufacturing with higher cost. No suitable alternative is considered available for the production of tinted ophthalmic glass except if a sight change in color is accepted by the customer. No alternative is identified for the production of BLB glass.

Socio-economic analysis

In case of non-use scenario, some part of the production would stop in the EU for crystal, and the whole production of ophthalmic and BLB glass is expected to shutdown without relocation outside EU, with socioeconomic consequences.

As far as the socio-economic consequences of a refused authorisation are concerned, one SEA report has been provided by Industry for the use of NiO in glass assessing the costs and benefits of a hypothetical refused authorisation (the so-called "non-use scenario"). The consequences are very different for the 3 applications of glass (crystal glass, ophthalmic glass and BLB glass).

Regarding **the production of crystal glass**, as a result of a refused authorization, it is considered that [confidential] (more precisely [confidential]) corresponding to [confidential] of the amount of NiO used today could be directly replaced by erbium and cobalt oxide, around [confidential] corresponding to [confidential] of NiO used today could be replaced y an alternative and [confidential] ([confidential] of the total) would be relocated outside the EU.

- In the first situation ([confidential] of NiO replaced by Er and Co oxide): the manufacturers of crystal glass who would switch to would bear extra operating costs estimated at €0.005 million (likely to concern only 2 companies according to Industry). As regards the suppliers of raw materials upstream the supply chain, no extra cost would occur but additional incomes are expected due to higher amounts of (alternative) raw materials required. These additional incomes are estimated at €0.005 million per year. The economic impacts on the end-users are uncertain and not quantified: according to Industry, additional costs of manufacturers would need to be passed on to the customer to a maximum. Depending on the willingness to pay for the 'Made in Europe' label, the consumer could either accept the higher price or change to lower price products made in ROW.

- In the second situation ([confidential] of NiO replaced by an alternative), the manufacturers of crystal glass are expected to bear operating costs between €0.5 million per year (e.g. in case of Er and Co oxide) and €17.5 million per year (e.g. in case of neodymium oxide), additionally to capital investments (€22.2 million) and R&D expenditures (€8.5 million), likely to be borne by around 22 companies, according to Industry. Sunk costs and loss of operating income due to higher competition from ROW are also expected but have not been quantified. Similarly to the first situation, additional costs of manufacturers would need to be passed on to the customer to a maximum. Depending on the willingness to pay for the 'Made in Europe' label, the consumer could either accept the higher price or change to lower price products made in ROW. The suppliers of raw materials upstream the supply chain are expected to benefit from additional incomes due to higher amounts of (alternative) raw materials needed, amounted between €0.5 million per year (in case of Er and Co oxide) and €17.5 million per year (in case of neodymium oxide).

- An attempt was made by Industry to bring these figures in perspective and make the relation between these costs and the turnover generated. Turnover share depending on NiO is very company specific and depends on whether NiO is used for colouring/decolouring and the share of coloured/clear glass in the companies' output. The turnover range of the companies concerned is large because of the presence of small SMEs (generating turnover of €0.5 million) to large companies (generating turnover of €750 million) and medium sized companies (generating on average €20 million). For each company that has provided figures, it can be stated that turnover per kg NiO is similar at an average of €260,000 per kg NiO used. The one-time impacts (investment costs and R&D) are similar for an SME and a large company, and independent from company size. Each company would need to make one-time financial efforts of around €482,500. According to Industry, this financial effort can be a serious threat for many small SMEs, as the cost is in the range of their annual turnover. For medium-sized and large companies this cost only represents 0.06% to 2% of yearly turnover. Regarding the operating costs, additional costs per kg NiO do not pose a financial threat to companies when considering erbium and cobalt. However, the use of neodymium as the only substitute would very heavily increase the raw material cost. Moreover, one needs to take into account the limited availability and political risks that are related to the supply of rare earths, which can heavily influence the price.

- In the third situation ([confidential] of NiO relocated), a minor part of European manufacturers would relocate to their existing facilities in the ROW. In this situation, no additional investments would be needed in case there is sufficient production capacity at the foreign furnaces. In a worst-case scenario, new furnaces need to be installed at a unit investment cost of between €5 million to €12 million. Operating costs for raw materials remain the same, as NiO could still be used. Moreover, operating costs can be lower due to lower manpower cost. This scenario can potentially cause an annual loss of production value of around €12 million. The EU suppliers of NiO might lose EU NiO revenues up to €0.003 million per year due to relocation of this part of the crystal glass production.

As far as the social impacts of a refused authorization are concerned in the crystal glass sector, Industry estimates that maximum 25 companies, employing 11,000 people, would be affected either by having to finance research to find a suitable alternative for their production process or by relocating their business. The major part of manufacturers is confident to find and adopt an alternative. It is assumed that the production based on an alternative requires the same job numbers and skills, this is thus not likely to give rise to a significant social impact. It is probable that an additional researcher will need to be recruited or that external expertise will need to be hired. A minor part of manufacturers considers moving production outside of the EU. This would give rise to an expected shift of employment in the range of 660 jobs from the EU to developing countries. The types of jobs likely to be lost include a mixture of skilled manufacturing jobs (unique skills are required to manufacture handmade crystal glass), office, sales, marketing and site management related jobs (e.g. health and safety and environment).

Overall, the analysis of economic and social impacts is based on the (main) following input data and assumptions: it is estimated as a mean that 4 tons of NiO is used annually to produce crystal glass in the EU, 30,000 tons of crystal glass using NiO is produced today annually in the EU by 25 manufacturers accounting for 11,000 jobs; Finally, NiO contributes to 1% of the raw materials ([confidential] per pot of glass). Regarding the alternatives in general no precise data on prices are provided.

Regarding **the production of ophthalmic glass**, as a result of a refused authorization, it is considered that the EU production would stop due to the lack of suitable and available alternatives. Consequently, the manufacturers of ophthalmic glass are likely to bear a loss of production value estimated at €60 million per year. The impacts affecting the segment of the supply chain related to lens processing and frames production is assessed, in a worst-case perspective, up to [confidential] (probably overestimated assuming no import of finished glass blanks into EU and no further processing in the EU) additionally to a loss of income less than €0.1 million per year for suppliers. It was not possible for Industry to assess the impacts on other actors in the supply chain, as too little information is available.

As far as the social impacts of a refused authorization are concerned in the ophthalmic glass sector, both the producers sharing the duopolistic market are expected to lose jobs, all jobs for one of them (the manufacturing of ophthalmic glass is its core activity) and uncertain order of magnitude for the other one (whose activities are diversified). As a whole, due to manufacturing stop, there might be a potential loss of jobs of at least 350. For the lens processing and frames production, the loss of jobs is uncertain among the 7,459 people employed in this sector (one company).

Overall, the analysis of economic and social impacts is based on the (main) following input data and assumptions: it is estimated that [confidential] of NiO (as a maximum) are used annually in the EU to produce ophthalmic glass (tinted sunglasses more precisely); 2 companies evenly share the manufacturing market with more than 350 jobs.

Regarding **the production of BLB glass**, as a result of a refused authorization, it is considered that the EU production (only one company) would also stop due to the lack of suitable and available alternatives. Consequently, although only a minor part of the company’s turnover (less than 10%) is depending on these activities, Industry considers an important product in the product range supplied to the downstream user. Moreover, worldwide this company is the only provider of lead-free Black Light Blue glass. In case production is stopped in the EU, an annual loss of production value is to be expected between €100,000 and €250,000 per year. The European manufacturer will also bear sunk costs due to past investments in infrastructure and equipment. In the last 10 years, the company has invested more than €100,000 to develop lead-free BLB glass in order to comply with the RoHS Directive (2002/95/EC). Loss of income in the EU for raw material suppliers is estimated at less than €100,000 per year. Assembling of the inside components and the glass is carried out by the lighting industry. Based on consultation of the BLB glass producer, the lighting industry will most likely import the finished glass back into the EU and continue assembling in the EU. It is possible that a higher price will need to be paid for the finished glass due to increased transportation costs, however this effect may be compensated by lower operational costs in BLB manufacturing in China. Currently Industry states that there is too little information to quantify these impacts.

As far as the social impacts of a refused authorization are concerned in the BLB glass sector, the sole EU manufacturing company has also other activities which may continue, hence not all jobs might be potentially lost. According to Industry, the exact number of jobs that are potentially threatened is confidential but it is less than 50 jobs. No other social impact is expected.

Overall, the analysis of economic and social impacts is based on the (main) following input data and assumptions: it is estimated that [confidential] of NiO are used annually in the EU to produce BLB glass (also referred to as UV light); only one company holds the EU manufacturing market.

Regarding the impact on human health and the environment, the SEA report on glass does not strictly provide an assessment and the analysis is brief. Industry comes to the same conclusion for the 3 glass applications. The HHIA concludes that workers engaged in the production of glass from NiO are not expected to be at an increased risk of developing cancer or non-cancer effects on the respiratory system or skin sensitisation effects as a result of long-term exposure to NiO. Worth considering is that shifting manufacturing to the ROW would shift also NiO exposure from workers in the EU to workers in ROW but to what extent the exposure may increase, decrease, or remain the same is uncertain (depending on changes in manufacturing processes, worker activities, size and age of facilities, use of PPE, etc. and differences in workplace regulations in ROW). Overall, it has not been possible for Industry to identify a change in human health risks accompanied by the various non-use scenarios nor to draw any conclusion, because of a lack of exposure data. Additional information would be needed, especially as regards the impact assessment of alternatives.

Table 48 below summarizes the results of a refused authorisation for the EU according to industry.  Industry concludes that it has not been possible to weigh the economic and social benefits of continued use against the environmental and human health risks and thus, it was not possible to draw conclusions for the impact assessment.

Table 48. Summary of the quantified impacts of a refused authorization according to Industry - Glass

| | Costs | Benefits |
|---|---|---|
| Crystal glass | | |
| Economic impacts | [confidential] of NiO replaced by Er and Co oxide: | |

| | | |
|---|---|---|
| | 2 Manufacturers of crystal glass:<br>•costs= €0.005 million | / |
| | Suppliers of raw materials:<br>/ | • additional income= €0.005 million/y |
| | End-users/Consumers:<br>•costs>0 (price increase) | / |
| | [confidential]of NiO replaced by alternatives: | |
| | 22 Manufacturers of crystal glass:<br>• Costs> €0.5-17.5 million/y+€30.7 million | / |
| | Suppliers of raw materials:<br>/ | • additional income= €0.5-17.5 million/y |
| | End-users/Consumers:<br>•costs>0 (price increase) | / |
| | [confidential] of NiO relocated: | |
| | Manufacturers of crystal glass:<br>• Costs=€12 million/y | / |
| | Suppliers of raw materials:<br>• Costs= € 0.003 million/y | / |
| Social impacts | Loss of jobs= 660 | / |
| Ophthalmic glass | | |
| Economic impacts | Manufacturers of opthalmic glass:<br>•costs= €60 million/y | / |
| | Lens processing and frame production:<br>•costs= €[confidential] (worst-case) | / |
| | Suppliers<br>Loss of income<€0.1million/y | / |
| | End-users:<br>•costs>0 (price increase) | / |
| Social impacts | Loss of jobs> 350 | / |
| BLB glass | | |
| Economic impacts | Manufacturers of BLB glass:<br>•costs= €0.1-0.25million/y+€0.1-1 million | / |
| | Suppliers of raw materials:<br>•costs< €0.1million/y | / |
| Social impacts | Loss of jobs<50 | / |
| For the 3 glass applications | | |
| Health impacts | No conclusion | |
| Environmental impacts | No conclusion | |

Again, these figures could not be challenged and are surrounded with many uncertainties. They thus have to be read with some precaution. Moreover, without a robust human health and environmental impacts assessment, the socio-economic impacts cannot be relevantly weighted.

To this analysis provided by Industry, it can be added that, regarding the costs associated to a potential application for authorisation in the crystal glass sector, they might be high for SMEs (quite many), except if they join a consortium. For the ophthalmic and BLB glass sectors however, which are very concentrated (2 and 1 company respectively), the costs should be borne without major difficulty. Nevertheless it has been shown that according Industry, these two productions would stop and no application for authorisation is expected.

Conclusion

Feasibility

The inclusion of a substance in Annex XIV is not strictly a risk-based process 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 nickel oxide can be identified as a SVHC based on its classification. Despite a high potential total tonnage that however remains unclear, its prioritisation for Annex XIV listing may obviously suffer from the fact that an important part of the volume could be used as intermediate. It should be kept in mind that no data on volume and processes has been provided for 4 remaining uses including the manufacturing of stainless steel and special alloys which may represent a high used tonnage and for which the intermediate status cannot be assessed.

Ability to achieve the objective set by the risk reduction strategy

By phasing out uses and promoting substitution of nickel oxide, 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 which is the expected first target.

Proportionality

Authorisation applies to all uses without distinction. From table 48, 5 uses over 8 (GES 4, 6, 7, 9 and 10) of nickel oxide are currently estimated at risk and GES 5 is seen potentially at risk in a worst case scenario because no exposure data has been provided for one CES; in a way, this may limit the proportionality of an authorisation. GES 6 and 7 are seen to be at risk based on one deficient CES (the cleaning and maintenance step that requires handlings); in that the proportionality of the authorisation can be discussed 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 exceeding the objectives stated in risk reduction strategy, authorisation may 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 NiO 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 the catalytic sector which is the most important end-use (in terms of volumes, markets, economic stakes, and duty) of NiO. For this use, authorisation may possibly fail its objective of promoting substitution. No information is available for the 4 uses not covered so far.

Cost benefits analysis

From the provided SEA, no reliable conclusion can be stated on the balance of the costs and 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.

For the uses considered without possible substitution even at long term (catalytic sector in particular), authorisation may bring the European Industry in a weakness position especially in activity sectors with high socio-economic benefits for many downstream applications. But again, the use of NiO in catalyst precursors manufacturing is not expected to fall under the authorisation requirements; the impact of the authorisation on this sector appears out of topic while the intermediate status is not challenged.

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 is 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 and at least for the catalytic uses.

# 5 CONCLUSIONS ON THE MOST APPROPRIATE (COMBINATION OF) RISK MANAGEMENT OPTION(S)

Nickel oxide is used in seven main applications: manufacturing of NiO containing catalyst precursors, of nickel based powders, of nickel containing electronics and thermally functioning ceramics, of frits for glass and enamel production, of pigments for enamel and ceramics production, of stainless steel and special alloys and of NiZn cores and solids from NiO powders. NiO as such is not manufactured within the EU but imported, except NiO produced as an intermediate from other nickel compounds and used for the manufacturing of NiO containing catalysts precursors and Ni based catalysts.

From an in depth Industry consultation by Anses in which the Nickel Institute was the main contact point, several technical documents and four socioeconomic analysis (SEA) 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 has been carried out by Denmark on five nickel compounds and published in 2008 but doesn't cover NiO. For the purpose of the RMOA, a risk assessment has been carried out by Anses based on the data provided in the registration dossiers and targeted on the occupational risk only (dermal and inhalation exposure). No definitive conclusion can be drawn on the occupational risk because of the high level of uncertainty associated with the exposure estimates (either modelled either measured) making difficult the interpretation of the risk assessment results.

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 Anses (0,01 mg NiO/m$^3$) which differs from the registrants' DNEL (0,05 mg NiO/m$^3$), risk is estimated unacceptable for 7 GES over 10. Hence, the minimum objective of a risk reduction strategy (RRS) would be to formally set a binding inhalable occupational exposure limit of 0,01 mg NiO/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 NiO 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 NiO.

Some evidence exists that feasible alternatives are already available or expected in a short timeframe for the frits and pigments manufacturing (see the summary table below for the sectors for which data have been provided), but for some of them with changes in the end product properties (change in colour/shade) that may generate an imbalance with articles/products still manufactured from NiO and imported within the EU. For the main activity sector (catalytic sector), which is of economic importance, no suitable alternative even at a long timeframe is seen so far by industry. Stainless steel and special alloys manufacturing is another main use (in terms of NiO tonnage used) that is not yet assessed as no information has been provided so far by industry.

Table 49. Substitution possibilities per activity sector for which data have been provided by Industry

| Activity sector | Substitution possibility |
|---|---|
| Catalyst | Very low possibility / Impossibility |
| Frits | Possibility |
| Pigments | Possibility |
| Glass | Possibility<br>Except BLB glass: impossibility |

From the currently identified legislation covering directly or indirectly the risk from the manufacturing and uses of NiO, 3 risk management options have been considered relevant for further processing: a binding OEL under Directive 2004/37/EC that is out the scope of REACH 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 50. 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 (RRS)(1)** | Well fitted | Outsized | 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** | Moderate | Possibly High | Possibly moderate (depending on the conditions and scope) |
| **Technical feasibility for the operators** | Expected feasible | Substitution: possible for a limited number of applications<br>Application for an authorisation: feasible but costly | 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 on a short term** | (Significant) | (Significant for 3 uses ; unknown for 4 uses; not relevant for the main use/volume) | (Limited) |

(1): the RRS (Risk Reduction Strategy) is herein defined as the minimum proposal, i.e. binding OEL and exposure below the OEL at the workplace

Table 51. Comparative assessment of the selected risk management options per use of NiO

| Uses (with 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 and use of NiO** | | | | | | | |
| Production and use of NiO catalyst precursors (GES 1, 2 & 3) | 5,400 | Yes (if considered as such) | almost not possible | high | yes | No (if considered as intermediate) | possible |
| **Downstream uses of NiO** | | | | | | | |
| 1. Use of NiO for the production of nickel based powders (GES 4) | unknown | unknown | expected possible | unknown | yes | unknown | possible |
| 2. Use of NiO for the production of NiZn cores and solids from NiO powder (GES 10) | unknown | unknown | unknown | unknown | | unknown | possible |
| 3. Use of NiO for the production of nickel-containing electronics and thermally functioning ceramics (GES 5) | unknown | unknown | unknown | unknown | | unknown | possible |
| 4. Use of NiO for the production of nickel-containing enamel frits (GES 6) | 450 | no | possible | Low-moderate | | yes | possible |
| 5. Use of NiO for the production of nickel-containing pigments (GES 7) | 350 | no (1/2)<br>Yes (1/2) | possible | Low-moderate | | yes (on half volume) | possible |
| 6. Use of NiO for the production of nickel-containing glass (GES 8) | [confidential] | no | Crystal: possible<br>Ophthalmic: possible<br>BLB: impossible | Crystal: moderate-high<br>Ophthalmic: high<br>BLB: moderate | | yes | possible |
| 7. Use of NiO for the production of stainless steel, special steels and special alloy (GES 9) | unknown (expected high) | unknown | unknown | unknown | | 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.

***

**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* | [confidential] |

| | | | |
|---|---|---|---|
| | | *sulphamate)* | |
| 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: Summary of the NiO risk assessment**

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD**** |
|---|---|---|---|---|---|
| **GES 1 : Production to NiO contained in catalyst (catalyst manufacture and regeneration)** | | | | | |
| **CES 1.1**<br>**Production NiO-containing catalysts involving handling of powders containing Ni-compounds** | 0.035 | 0.01 | **3.5** | 0.18 | 105 measurements<br>GSD = 7.8 |
| **CES 1.2**<br>**Production NiO-containing catalysts from shaped precursors containing Ni-compounds and by regeneration** | 0.028 | 0.01 | **2.8** | 0.14 | 178 measurements<br>GSD = 5.6 |
| **GES 2: Industrial use of powdered and shaped nickel oxide-containing catalyst (A)** | | | | | |
| **CES 2.1**<br>**Industrial use of powdered NiO-containing catalysts** | 0.01 | 0.01 | **1** | 0.05 | Measurements not specified<br>GSD = 2.7 |
| **CES 2.2**<br>**Industrial use of shaped NiO-containing catalysts** | 0.02 | 0.01 | **2** | 0.1 | Measurements not specified<br>GSD = 4.5 |

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD**** |
|---|---|---|---|---|---|
| **GES 3: Industrial use of nickel oxide-containing catalysts for the production of catalysts containing other nickel compounds (B)** | | | | | |
| **CES 3.1**<br>**Industrial use of powdered catalysts** | 0.045 | 0.01 | **4.5** | 0.22 | 33 measurements<br>GSD = 6.03 |
| **CES 3.2**<br>**Industrial use of shaped catalysts (extrudates, pellets, tablets, spheres, encapsulated powders)** | 0.026 | 0.01 | **2.6** | 0.13 | 109 measurements<br>GSD = 4.9 |
| **GES 4: Production of nickel based powders from nickel oxide** | | | | | |
| **CES 4.1 Raw materials handling** | 0.073 | 0.01 | **7.3** | 0.37 | 2 measurements<br>GSD not specified |
| **CES 4.2 Smelting** | 0.2 | 0.01 | **10** | **1** | 1 measurement<br>GSD not specified |
| **CES 4.3 Alloying and atomising** | 0.45 | 0.01 | **45** | **2.25** | 5 measurements<br>GSD not specified |
| **CES 4.4 Drying** | 0.013 | 0.01 | **1.3** | 0.07 | Modeled data |
| **CES 4.5 Blending and sieving** | 0.22 | 0.01 | **22** | **1.1** | 3 measurements<br>GSD not specified |
| **CES 4.6 Packaging** | 0.193 | 0.01 | **19.3** | 0.97 | 3 measurements |

| CES | Inhalation exposure (mg $Ni/m^3$) | DNEL (mg $Ni/m^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
|  |  |  |  |  | GSD not specified |
| **CES 4.7 Cleaning and maintenance** | 0.029 | 0.01 | **2.9** | 0.15 | 1 measurements<br>GSD not specified |
| **GES 5: Production of Ni-containing electronics and thermally functioning (ceramics for solid oxide fuel cells and thermistor products)** |  |  |  |  |  |
| **CES5.1 Raw materials handling** | No data available |  |  |  | No data available |
| **CES5.2 Milling, mixing and calcining raw materials** | 0.02 | 0.01 | **2** | 0.5 | 3 measurements<br>GSD not specified |
| **CES5.3 Milling, mixing, extruding and sintering of calcined materials. Cutting of sintered ceramic slab** | 0.02 | 0.01 | **2** | 0.5 | 5 measurements<br>GSD not specified |
| **CES5.4 Assembly of thermistor into probes** | Negligible | 0.01 | **-** | - | - |
| **CES5.5 Cleaning and maintenance** | Negligible | 0.01 | **-** | **-** | - |
| **GES 6: Production of nickel-containing frits** |  |  |  |  |  |
| **CES6.1 Raw materials handling** | 0.01 | 0.01 | **1** | 0.05 | 6 measurements<br>GSD not specified |
| **CES6.2 Dosing, mixing and oven charging** | 0.01 | 0.01 | **1** | 0.05 | 6 measurements<br>GSD not specified |

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD**** |
|---|---|---|---|---|---|
| **CES6.3 Kilning, quenching and drying** | 0.008 | 0.01 | 0.8 | NR | 9 measurements<br>GSD not specified |
| **CES6.4 Milling and drying** | 0.0006 | 0.01 | 0.12 | NR | 1 measurement<br>GSD not specified |
| **CES6.5 Blending and/or packaging** | 0.021 | 0.01 | **2.1** | 0.1 | 13 measurements<br>GSD not specified |
| **CES6.6 Cleaning and Maintenance** | 0.342 | 0.01 | **34.2** | **1.7 (AFP 20)**<br>**/** 0.86 (AFP 40) | 3 measurements<br>GSD not specified |
| **GES 7: Production of nickel-containing pigments** | | | | | |
| **CES7.1 Raw materials handling** | 0.006 | 0.01 | 0.6 | NR | 39 measurements<br>GSD = not specified |
| **CES7.2 Mixing** | 0.006 | 0.01 | 0.6 | NR | 39 measurements<br>GSD = not specified |
| **CES7.3 Drying and calcining product** | 0.02 | 0.01 | **2** | 0.1 | 43 measurements<br>GSD = not specified |
| **CES7.4 Dry milling** | 0.04 | 0.01 | **4** | 0.2 | 12 measurements<br>GSD = not specified |

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD**** |
|---|---|---|---|---|---|
| **CES7.5 Wet milling, washing and drying** | 0.004 | 0.01 | 0.4 | NR | 2 measurements<br>GSD = not specified |
| **CES7.6 Packaging** | 0.03 | 0.01 | **3** | 0.15 | 38 measurements<br>GSD = not specified |
| **CES7.7 Cleaning and Maintenance** | 0.342 | 0.01 | **34.2** | **1.7** | 3 measurements<br>GSD = not specified |
| **GES 8: Production of nickel-containing glass** | | | | | |
| **CES8.1 Raw materials handling** | 0.028 | 0.01 | **2.8** | 0.14 (APF 20)/<br>0.07(APF 40) | modelled data |
| **CES8.2 Formulation and mixing** | 0.001 | 0.01 | 0.1 | NR | Measurement not specified<br>GSD not specified |
| **CES8.3 Melting** | 0.0001 | 0.01 | 0.01 | NR | Measurement not specified<br>GSD not specified |
| **CES8.4 Forming** | Negligible | - | **-** | - | - |
| **CES8.5 Packaging** | Negligible | - | - | - | - |
| **CES8.6 Cleaning and Maintenance** | 0.075 | 0.01 | **7.5** | 0.375 | modelled data |

| **CES** | **Inhalation exposure (mg Ni/m$^3$)** | **DNEL (mg Ni/m$^3$)** | **RCR Tier 1** | **RCR Tier 2*** | **Number of measurements/GSD**** |
|---|---|---|---|---|---|
| | | | | (APF 20)/<br>0.2 (APF 40) | |
| **GES 9: Stainless, special steels and special alloys manufacturing** | | | | | |
| **CES9.1 Raw materials handling** | 0.006 | 0.01 | 0.6 | NR | 5 measurements<br>GSD not specified |
| **CES9.2 First processing** | 0.012 | 0.01 | **1.2** | 0.06 | 194 measurements<br>GSD not specified |
| **CES9.3 Further processing** | 0.03<br>for hot rolling | 0.01 | **3** | 0.15 | 61 measurements<br>GSD not specified |
| | 0.009<br>for cold rolling | 0.01 | 0.9 | NR | 14 measurements<br>GSD not specified |
| **CES9.4 Finishing** | 0.038 | 0.01 | **3.8** | 0.19 | 41 measurements<br>GSD not specified |
| **CES9.5 Cleaning and maintenance** | 0.115 | 0.01 | **11.5** | 0.6 | 13 measurements<br>GSD not specified |
| **CES9.6 Packing, shipping and storage** | 0.03 | 0.01 | **3** | 0.15 | Modelled data |

| CES | Inhalation exposure (mg Ni/m$^3$) | DNEL (mg Ni/m$^3$) | RCR Tier 1 | RCR Tier 2* | Number of measurements/GSD** |
|---|---|---|---|---|---|
| **GES 10: Production of NiZn cores and solids from NiO powder** | | | | | |
| **CES10.1 Raw materials handling** | 1.1 | 0.01 | **110** | **5.5 (APF 20)/**<br>**2.75 (APF 40)** | Modelled data |
| **CES10.2 Production of NiZn solids** | 0.66 | 0.01 | **66** | **3.3 (APF 20)/**<br>**1.45 (APF 40)** | Modelled data |
| **CES10.3 cleaning and maintenance** | 0.66 | 0.01 | **66** | **3.3 (APF 20)/**<br>**1.45 (APF 40)** | Modelled data |

* when not specified, a default protection factor of 20 has been considered