



Analysis of the most appropriate risk management option (RMOA)

Substance Name: diammonium peroxodisulfate (diammonium persulfate)

EC number: 231-786-5

CAS number: 7727-54-0

Substance name: dipotassium peroxodisulfate (dipotassium persulfate)

EC number: 231-781-8

CAS number: 7727-21-1

Substance name: disodium peroxodisulfate (disodium persulfate)

EC number: 231-892-1

CAS number: 7775-27-1

Authority: France

Date: 17 September 2018

Cover Note

Persulfates were initially prioritized by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) for further work after a screening on bibliography to identify causative chemical agents for occupational asthma. As presented during the "Ad hoc Expert Meeting on Risk Management" (i.e. "RiME" 2/2011) held in Paris on 24 October 2011, several hundreds of substances were identified as possible causative agents and among them, 26 substances with a harmonised classification as R42 (corresponding to H334 in the CLP Regulation), which were registered under REACH, which lead to (potential) risks not already managed, and which were not already included in the candidate list, where shortlisted. From this shortlist, the persulfate category (3 substances) was prioritized based on dispersive uses and high tonnage. During the course of the work, it was found that the overwhelming amount of evidences of adverse health effects in occupational settings were due to the use of persulfates in cosmetic products by professional end-users (hairdressers) which are almost entirely out of scope of REACH.

The first version of this RMOA was originally drafted on 20 January 2014. Anses published an opinion on 6 February 2014¹ focusing on risks related to cosmetic uses. The RMOA was then updated in September 2015 to include additional vigilance data received from the French Agency for medical products (ANSM) and was presented to Member States Competent Authorities (MSCAs), ECHA and EU Commission representatives on 16 October 2015 at RiME 3/2015. Comments and additional relevant information were provided by Slovakia, the Netherlands, Germany, the United Kingdom, Denmark, Portugal, ECHA and EU Commission, and were included in the report. A need to clarify the consumer uses and to update the risk assessment for consumers was identified, as the risks related to skin and respiratory sensitisation had not been addressed in the Chemical Safety Report (CSR) by the registrants which was considered as an incompliance to standard REACH requirements.

This incompliance was addressed in a compliance check (CCH) initiated by ECHA under Dossier Evaluation on 30 October 2015 for these 3 substances. This CCH also addressed data gaps in accordance with Annexes I, VI, VII, VIII, IX, X. In the final Decisions of 8 September 2016^{2,3,4}, the registrants were requested to provide data on intrinsic properties, hazards, exposure and risk-related endpoints (in particular, exposure assessment and risk characterisation for the environment and for workers and consumers taking into account the risks related to respiratory and skin sensitisation). Registrants were required to respond to the human exposure- and risk-related requests by 15 March 2017, and to the other requests by 15 September 2020.

On 15 March 2017 and 27 October 2017, the lead registrant updated its registration dossiers and deleted the consumers uses for PC 14 (water treatment chemicals) and PC 37 (metal surface treatment product) since no information

¹ Avis de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à l'analyse de la meilleure option de gestion de risques pour les usages cosmétiques des persulfates de potassium, d'ammonium et de sodium, 6 February 2014. Accessible at <https://www.anses.fr/fr/system/files/REACH2014re0002.pdf>.

² <https://echa.europa.eu/documents/10162/354ab374-b18f-bb8b-5ae9-57b6da7a1afa>.

³ <https://echa.europa.eu/documents/10162/734e2ae1-f446-e849-d7e0-3166853b82f8>.

⁴ <https://echa.europa.eu/documents/10162/8c9c55f8-4180-2d96-8737-d0c0948ebe17>.

about these uses could be collected from downstream users by registrants, and thus the uses were considered as non-existent in EU. All the other registrants of the SIEFs⁵ subsequently removed the PC 14 and PC 37 uses from their registration dossiers as well (last update taken into account: 27 February 2018). Consequently the only remaining consumer use is now the cosmetic use.

In addition, a thorough analysis of French vigilance data on persulfates was conducted between May and October 2016 at Anses in the context of an occupational medicine thesis, which was publicly defended on 7 December 2017 (Tomas-Bouil, 2017). The outcomes of this valuable work were taken into account in the RMOA.

Finally, the RMOA report was updated in May 2018 to its final version.

It is important to note that this RMOA focuses on skin and respiratory sensitisation. As it turned out that the major concern which requires urgent action targets specifically the **end-uses of persulfates as ingredients in cosmetics**, which are out of the scope of REACH, other options were investigated to trigger action from the Competent Authorities in charge of cosmetics and OSH (occupational safety and health) legislations.

The risks related to sensitizing effects of persulfates have been known since the 1930s and for hairdressers since the 1960s (if not even earlier), but obviously, no adequate prevention has been implemented yet. Products available on the market are still not safe, and no regulatory binding action has ever been taken. Between the last version of this RMOA (Anses opinion published in February 2014) and the current report, about 530 new cases of occupational diseases were reported in RNV3P for hairdressers⁶. This is not an acceptable situation in EU and therefore it is urgent to take actions.

Anses concludes that persulfates should be regulated in the framework of the Cosmetics Regulation (EC) 1223/2009 as a first step. Indeed, the necessary basis for adequate prevention in hair salons is to ensure that cosmetic products placed on the market are safe and that all necessary information regarding hazards and risk prevention are made available (Article 3 of the cosmetics regulation) to all users (professional users and consumers) by the person responsible for the placing on the market. Therefore, adequate regulation under the Cosmetics Regulation (EC) 1223/2009 is an essential prerequisite, especially as cosmetics in the finished state are exempted from classification and labelling (under CLP) and information to the supply chain via a safety data sheet (under REACH). Then a combination of better prevention at workplace, of training of professionals and of enforcement of occupational safety and health (OSH) legislation would be made possible as a further management option.

Anses is not in charge of cosmetics in France, and therefore may not be aware of all the available, practical and efficient options to manage risks related to cosmetics. Consequently, the choice of the most adequate risk management option(s) should not be limited to the ones presented in this RMOA, but could usefully be supplemented with any other options found relevant by the Competent Authorities in charge primarily of cosmetics (and then OSH), who are in the best position to identify the best risk management options for cosmetics.

⁵ Substance Information Exchange Forum.

⁶ The previous version included RNV3P data from 2001 to 2009 and the current version includes RNV3P data from 2001 to 2015. 617 cases of persulfates-related occupational diseases were identified for the period 2001-2009 (97.7% for hairdressers), and 1144 for the period 2001 to 2015 (97.9% hairdressers).

Therefore, Anses urges the Competent Authorities in charge of cosmetics to take actions and regulate end-uses of persulfates in cosmetics under the Cosmetics Regulation (EC) 1223/2009.

Complementary actions should be also be envisaged by OSH Competent Authorities regarding the uses of persulfates.

Anses also points out that, on a general basis, risk management at workplace for persulfates would benefit from improvement and enforcement of exposure scenarios in Chemical Safety Reports (CSR) and extended Safety Data Sheets (eSDS) and from establishing a harmonised OEL. Anses also recommends the National Enforcement Authorities to be vigilant for any consumer use other than cosmetics which are not supported by the REACH registrations.

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Table of contents

1	IDENTITY OF THE SUBSTANCES	8
1.1	<i>Identifiers of the substances</i>	8
1.1.1	Diammonium persulfate	8
1.1.2	Dipotassium persulfate	9
1.1.3	Disodium persulfate	10
1.2	<i>Similar substances/grouping possibilities</i>	11
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	12
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	17
3.1	<i>Classification</i>	17
3.1.1	Harmonised Classification in Annex VI of the CLP	17
3.1.2	Self classification	18
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	20
3.1.4	CLP Notification Status	20
3.2	<i>Additional hazard information</i>	21
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	26
4.1	<i>Tonnage and registration status</i>	26
4.2	<i>Overview of uses</i>	27
4.2.1	Uses declared in registration dossiers	27
4.2.2	Other available information on uses	29
4.2.3	Summary on uses	35
5	JUSTIFICATION FOR THE RISK MANAGEMENT OPTION	37
5.1	<i>Need for (further) risk management</i>	37
5.2	<i>Identification and assessment of risk management options</i>	40
5.2.1	Identification of risk management options	40
5.2.2	Assessment of risk management options	41
A.	Setting an occupational exposure limit (OEL) at Community level	41
B.	REACH restriction (Annex XVII)	42
C.	Substance evaluation	42
D.	REACH authorisation (Annex XIV) on the basis of the sensitising properties of persulfates	43
E.	Improvement of the hairdressers' training (including for apprentices) to raise awareness on risks related to exposure to persulfates, on organisational prevention measures and on collective and personal protective equipments	44
F.	Enforcement of OSH (occupational safety and health) legislation by the labour inspectorate	45
G.	Regulation of persulfates in the frame of Regulation (EC) 1223/2009 on cosmetic products	46
H.	Harmonised Classification and Labelling for disodium persulfate	48
I.	Improvement of exposure scenarios in Chemical Safety Reports (CSR) and extended Safety Data Sheets (eSDS)	48
J.	Enforcement of REACH regulation on exposure scenarios in extended Safety Data Sheets (eSDS)	49

5.3 Conclusions on the most appropriate (combination of) risk management options 50

References..... 53

Abbreviations 64

ANNEX I – CONFIDENTIAL INFORMATION **67**

1 IDENTITY OF THE SUBSTANCES

1.1 Identifiers of the substances

As many synonyms exist, "diammonium persulfate", "dipotassium persulfate", "disodium persulfate" or only "persulfates" are used in this RMOA to identify the three substances.

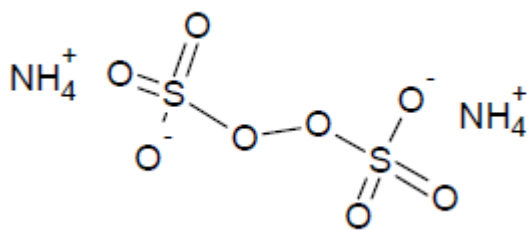
1.1.1 *Diammonium persulfate*

Table 1: Substance identifiers - Diammonium persulfate

EC name (public):	diammonium peroxodisulphate
IUPAC name (public):	diammonium peroxodisulphate
Index number in Annex VI of the CLP Regulation:	016-060-00-6
Molecular formula:	$H_3N \cdot \frac{1}{2}H_2O_8S_2$
Molecular weight or molecular weight range:	228.2 g/mol
Synonyms:	diammonium peroxodisulfate diammonium persulphate diammonium persulfate ammonium persulphate ammonium persulfate diammonium [(sulfonatoperoxy)sulfonyl]oxidanide (NH ₄) ₂ -peroxodisulfat diazanium sulfonatooxy sulfate peroxydisulfuric acid, diammonium salt

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



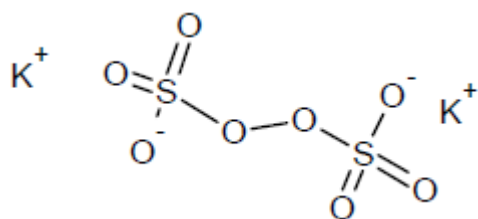
1.1.2 Dipotassium persulfate

Table 2: Substance identifiers - Dipotassium persulfate

EC name (public):	dipotassium peroxodisulphate
IUPAC name (public):	dipotassium peroxodisulphate
Index number in Annex VI of the CLP Regulation:	016-061-00-1
Molecular formula:	H ₂ O ₈ S ₂ .2K
Molecular weight or molecular weight range:	270.31 g/mol
Synonyms:	dipotassium peroxodisulfate potassium peroxydisulfate dipotassium persulphate dipotassium persulfate potassium persulphate potassium persulfate pottassium persulfat dipotassium sulfonatoxy dipotassium sulfonatoxy sulfate dipotassium O- [(sulfonatoperoxy)sulfonyl]oxidanidolate dipotassium [(sulfonatoperoxy)sulfonyl]oxidanide peroxydisulfuric acid (((HO)S(O)2)2O2), dipotassium salt peroxydisulfuric acid, dipotassium salt

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



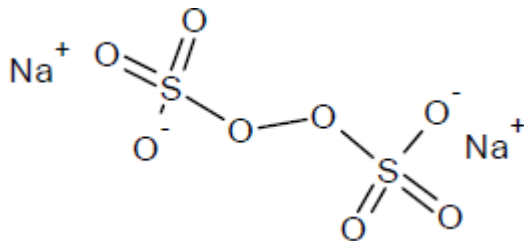
1.1.3 Disodium persulfate

Table 3: Substance identifiers - Disodium persulfate

EC name (public):	disodium peroxodisulphate
IUPAC name (public):	disodium peroxodisulphate
Index number in Annex VI of the CLP Regulation:	none
Molecular formula:	H ₂ O ₈ S ₂ .2Na
Molecular weight or molecular weight range:	238.1 g/mol
Synonyms:	disodium peroxodisulfate sodium peroxydisulfate disodium persulphate disodium persulfate sodium persulphate sodium persulfate disodium sulfonatoxy sulfate disodium [(sulfonatoperoxy)sulfonyl]oxidanide disodium [(sulfonatoperoxy)sulfonyl]oxidamide peroxydisulfuric acid disodium salt

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



Other relevant information about substance composition

-

1.2 Similar substances/grouping possibilities

According to REACH Annex XI: "substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances". This similarity may be based on a common functional group.

Then, and as reported in the registration dossiers and supported in OECD SIDS⁷ report (2005), disodium, dipotassium and diammonium persulfates belong to the same category because of their similar chemical structure sharing the same representative moiety (the persulfate anion $S_2O_8^{2-}$) and only differing by the cationic part of the salt. According to the registration dossiers, the cationic part is not expected to influence the hazardous properties of the molecule. Thus the three salts are expected to display the same environmental, ecotoxicological and toxicological behavior.

Therefore this risk management option analysis refers to the three persulfate salts described above.

⁷ Screening information datasets.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 4: Completed or ongoing processes

			Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
RMOA		Risk Management Option Analysis (RMOA) other than this RMOA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
REACH Processes	Evaluation	Compliance check, Final decision	<input checked="" type="checkbox"/> Decision of 8 September 2016 ⁸ : a follow-up according to Article 42 is available for the human exposure-related request (see confidential Annex I).	<input checked="" type="checkbox"/> Decision of 29 September 2014 ⁹ : a follow-up according to Article 42 is available (see confidential Annex I). Decision of 8 September 2016 ¹⁰ : a follow-up according to Article 42 is available for the human exposure-related request (see confidential Annex I).	<input checked="" type="checkbox"/> Decision of 8 September 2016 ¹¹ : a follow-up according to Article 42 is available for the human exposure-related request (see confidential Annex I).
		Testing proposal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		CoRAP and Substance Evaluation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

⁸ <https://echa.europa.eu/documents/10162/734e2ae1-f446-e849-d7e0-3166853b82f8>.

⁹ Not found on ECHA website.

¹⁰ <https://echa.europa.eu/documents/10162/8c9c55f8-4180-2d96-8737-d0c0948ebe17>.

¹¹ <https://echa.europa.eu/documents/10162/354ab374-b18f-bb8b-5ae9-57b6da7a1afa>.

ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION (RMOA)

			Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
	Authorisation	Candidate List	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Annex XIV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Restriction	Annex XVII	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Harmonised C&L		Annex VI (CLP) (see section 3.1)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Processes under other EU legislation		Plant Protection Products Regulation (EC) No 1107/2009	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Biocidal Product Regulation (EU) 528/2012 and amendments	<input type="checkbox"/>	<input checked="" type="checkbox"/> Listed in Annex I (<i>Active Substances identified as existing</i>) of the EU Regulation 1451/2007 ¹² (work programme for the review of biocidal active substances). However, as it was not listed in Annex II and in accordance with Article 4 of this Regulation, biocidal products containing dipotassium persulfate shall no longer be placed on the market.	<input checked="" type="checkbox"/> Listed in Annex I (active substances identified as existing) of the EU Regulation 1451/2007 ¹² (work programme for the review of biocidal active substances). Listed in Annex II (substance/product-type combinations ¹³) for PT04 (food and feed area disinfectants) in the EU Regulation 1062/2014 ¹⁴ (update of the work programme for the for the review of biocidal active substances). The

¹² Regulation (EC) 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market.

¹³ Annex II: Substance/product-type combinations included in the review programme on 4 August 2014, part 1 active substance/product-type combinations supported on 4 August 2014.

¹⁴ Regulation (EU) 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in EU Regulation 528/2012 concerning the making available on the market and use of biocidal products.

ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION (RMOA)

		Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
				Evaluating Competent Authority is Portugal. Note: under BPR, a substance classified as Resp Sens 1 is a candidate for substitution for biocidal uses.
Previous legislation	Dangerous substances Directive Directive 67/548/EEC (NONS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(UNEP) Stockholm convention (POPs Protocol)	Assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	In relevant Annex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other processes/ EU legislation	Other (seedetails below)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	EU Directive 98/24/EC on the protection of workers from the risks related to chemical agents, Art 2(b)(i).	Diammonium and dipotassium persulfates have harmonised classification as Acute Tox. 4 *, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2, Resp. Sens. 1 and STOT SE 3, and disodium meets the same criteria for classification. Hence they are considered as "hazardous chemical agents" and risks to the health and safety of workers at work shall be eliminated or reduced to the minimum by application of Article 5 of this Directive.		
	Occupational exposure limit values ¹⁵ (measured as [S ₂ O ₈])	Belgium, Ireland, Spain: the 8-hour TWA ¹⁶ is 0.1 mg/m ³	Belgium, Ireland, Poland, Spain: the 8-hour TWA is 0.1 mg/m ³ Denmark: the short-term value	Belgium, Ireland, Spain: the 8-hour TWA is 0.1 mg/m ³ Denmark: the short-term value is 4 mg/m ³ and the 8h- TWA is 2

¹⁵ As available on <http://limitvalue.ifa.dguv.de/> on 29 March 2018.

¹⁶ Time-weighted average.

ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION (RMOA)

		Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
			is 4 mg/m ³ and the 8h- TWA is 2 mg/m ³	mg/m ³
		<p>United Kingdom: the 8-hour TWA is 1 mg/m³ but “the UK Advisory Committee on Toxic Substances has expressed concern that (...) health may not be adequately protected because of doubts that the limit was not soundly-based. These OELs were included in the published UK 2002 list and its 2003 supplement, but are omitted from the published 2005 list.”</p> <p>Until now, no occupational limit value (OEL) at Community level has been adopted by the Scientific Committee on Occupational Exposure Limits (SCOEL).¹⁷</p> <p>OELs in non-EU countries:</p> <ul style="list-style-type: none"> - Australia: the short-term value (ceiling limit value) is 0.1 mg/m³ - USA¹⁸: TLV (Threshold Limit Values): (as persulfates) 0.1 mg/m³ as TWA (ACGIH¹⁹ 2001). 		
	EU Directive 94/33/EC on young people at work, as amended by Directive 2007/30/EC	Young persons under 18 are prohibited to use sensitizing substances according to Article 7 and Annex I of this Directive.		
	EU Regulation 1980/2000 on products not eligible for a positive Eco-Label	According to Article 6 of this Directive, the EU Ecolabel may not be awarded to goods containing substances referred to in Article 57 of REACH ie as the 3 persulfates meets the criteria of Article 57(f) of REACH(ELoC) the products containing persulfates are not eligible to Ecolabel.		
	EU Commission Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (INCI) as amended by decision 2006/257/EC Listed in CosIng ²⁰	<p>INCI name: AMMONIUM PERSULFATE</p> <p>Function: BLE (bleaching: lightens the shade of hair or skin) and OXI (oxidising: changes the chemical nature of another substance by adding oxygen or removing hydrogen).</p>	<p>INCI name: POTASSIUM PERSULFATE</p> <p>Function: OXI (oxidising: changes the chemical nature of another substance by adding oxygen or removing hydrogen). This means that dipotassium persulfate has been mentioned</p>	<p>INCI name: SODIUM PERSULFATE</p> <p>Function: OXI (oxidising: changes the chemical nature of another substance by adding oxygen or removing hydrogen). This means that disodium persulfate has been mentioned</p>

¹⁷ As available on <https://circabc.europa.eu/w/browse/3fea9535-be67-47b7-a7f7-ef9c41367d9c> on 29 March 2018.

¹⁸ <https://www.cdc.gov/niosh/ipcsneng/neng0632.html> accessed 4 April 2018.

¹⁹ American Conference of Governmental Industrial Hygienists.

ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION (RMOA)

		Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
		This means that diammonium persulfate has been mentioned within the composition of cosmetic products but does not mean that it has been evaluated by the Scientific Committee on Consumer Safety (SCCS).	within the composition of cosmetic products but does not mean that it has been evaluated by the Scientific Committee on Consumer Safety (SCCS).	within the composition of cosmetic products but does not mean that it has been evaluated by the Scientific Committee on Consumer Safety (SCCS).
	Regulation (EC) No 1223/2009 on cosmetic products	According to Article 10 of this Regulation, a cosmetic safety assessment must be performed prior to placing of the product on the market. According to Annex I the cosmetic safety report must include a particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation , and in the case of UV absorption photo-induced toxicity shall be made.		
	Regulation (EC) No 390/2007 imposing a provisional anti-dumping duty on imports of peroxosulphates (persulphates) originating in the United States of America, the People's Republic of China and Taiwan.			

²⁰ <http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple> accessed 29 March 2018.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

A harmonised classification according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP regulation) is available for diammonium persulfate and dipotassium persulfate.

Disodium persulfate has no harmonised classification; only a self-classification is available.

Table 5: Harmonised classification - Diammonium persulfate and dipotassium persulfate

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)		
016-060-00-6	diammonium peroxodisulphate ammonium persulphate	231-786-5	7727-54-0	Ox. Sol. 3 Acute Tox. 4 * Skin Irrit. 2 Skin Sens. 1	H272 H302 H315 H317	-	-
016-061-00-1	dipotassium peroxodisulphate potassium persulphate	231-781-8	7727-21-1	Eye Irrit. 2 Resp. Sens. 1 STOT SE 3	H319 H334 H335	-	-

H272: May intensify fire; oxidiser.

H302: Harmful if swallowed.

- * The current harmonised classification as Acute Tox 4*, H302 (harmful if swallowed) is a minimal classification established under the Directive 67/548/EEC, and due to a change in the classification thresholds in the CLP Regulation, the hazard class may not be adequate.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335: May cause respiratory irritation.

In addition, diammonium persulfate and dipotassium persulfate are Seveso substances category 3.

3.1.2 Self classification²¹

- In the registration:

Diammonium persulfate: identical to harmonised classification except Acute Tox. 4; H302, that does not mention * meaning that this classification arises from translation of classifications listed in Annex 1 of 67/548/EEC.

Dipotassium persulfate: identical to harmonised classification except Acute Tox. 4; H302, that does not mention * meaning that this classification arises from translation of classifications listed in Annex 1 of 67/548/EEC.

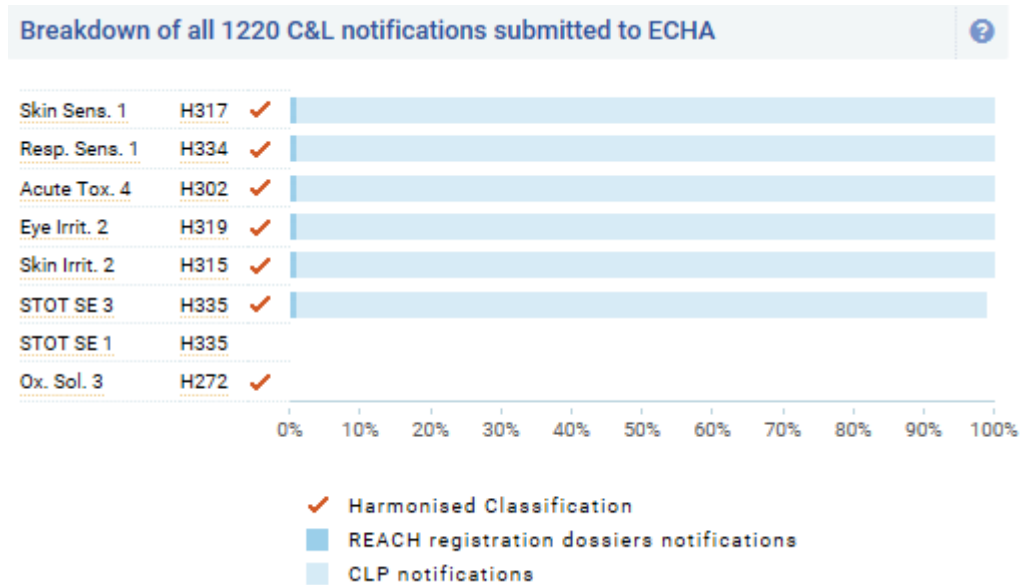
Disodium persulfate (no harmonised classification available): identical to the harmonised classifications of diammonium persulfate and dipotassium persulfate, except Acute Tox. 4; H302, that does not mention * meaning that this classification arises from translation of classifications listed in Annex 1 of 67/548/EEC.

- Ox. So. 3; H272: May intensify fire; oxidiser.
- Acute Tox. 4; H302: Harmful if swallowed.
- Skin Irrit. 2; H315: Causes skin irritation.
- Skin Sens. 1; H317: May cause an allergic skin reaction.
- Eye Irrit. 2; H319: Causes serious eye irritation.
- Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- STOT SE 3; H335: May cause respiratory irritation.

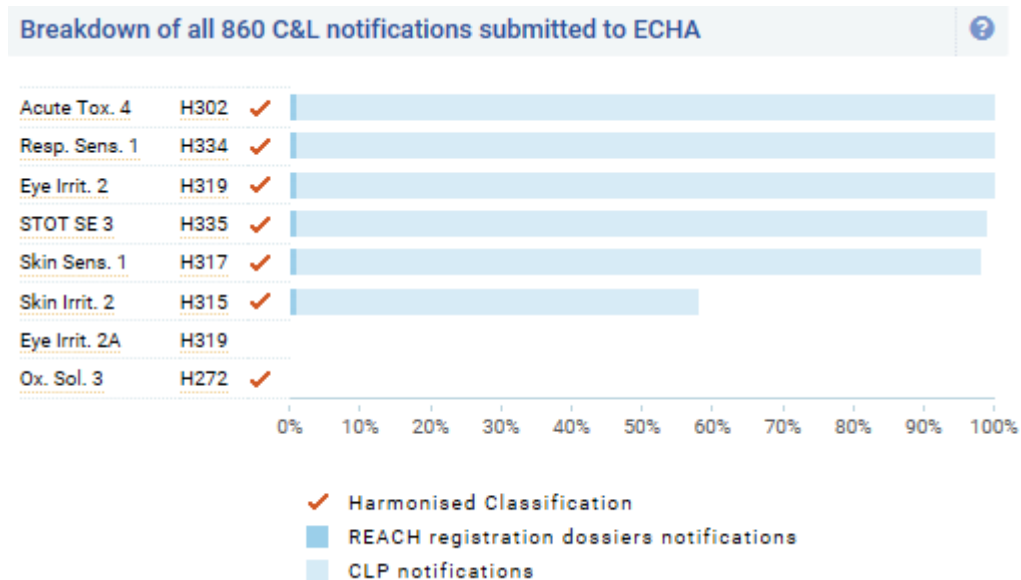
²¹ C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> as reported in Brief Profiles (accessed 29 March 2018).

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory, as available in the brief profiles of the substances:

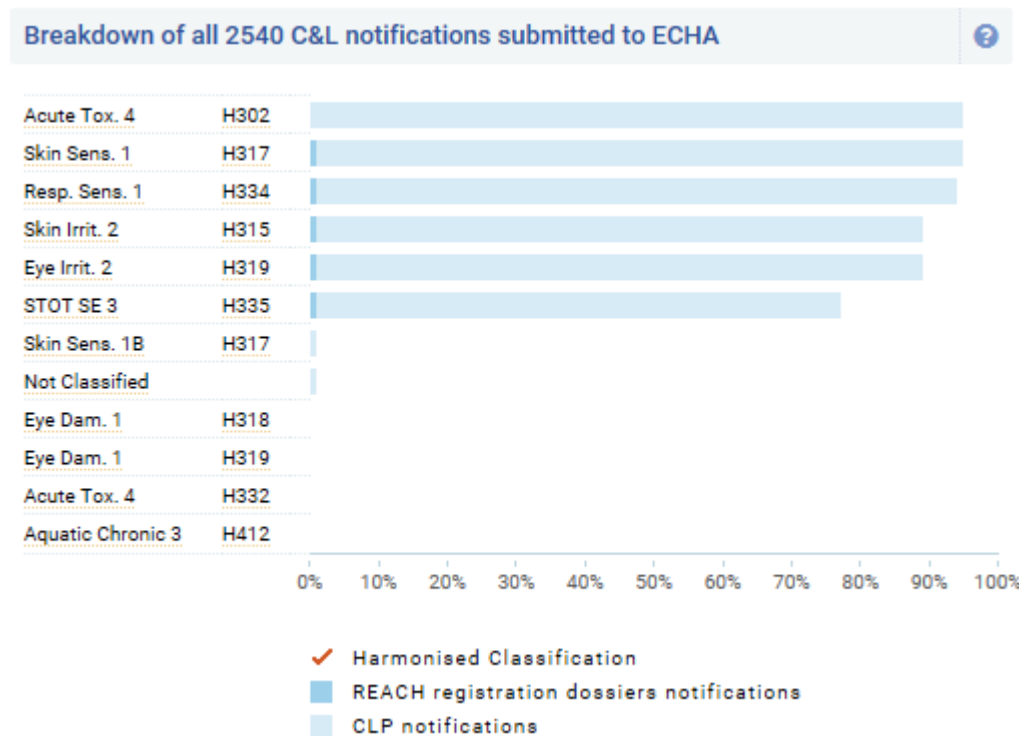
Diammonium persulfate:



Dipotassium persulfate:



Disodium persulfate:



3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

No new proposals for harmonised classification were made for diammonium persulfate and dipotassium persulfate.

In the context of the assessment of disodium persulfate as a biocidal active substance for PT04 (disinfectants for food and feed area²²) in the framework of the Biocidal Product Regulation, a proposal for harmonised classification will be made for disodium persulfate by the evaluating Competent Authority (Portugal).

3.1.4 CLP Notification Status

Table 6: CLP Notifications

	CLP Notifications		
	Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
Number of aggregated notifications	31	27	39
Total number of notifiers	1220	860	2540

²² Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

3.2 Additional hazard information

This RMOA focuses exclusively on skin and respiratory sensitisation. Other hazard endpoints (mutagenicity, reprotoxicity, ecotoxicity) are currently under review in the context of a Dossier Evaluation (CCH) and data are to be provided by 15 September 2020.

According to Sidi *et al.* (1966), warning toward eczema related to persulfates were reported as early as in the 1930s ("Seule l'interdiction, en 1933, des persulfates dans la farine a permis de faire disparaltre en France ce type d'eczema." i.e. "Only the ban of persulfates in 1933 in flour made it possible to eliminate in France this type of eczema"). Cases of skin and respiratory sensitization due to the use of persulfates in hair bleaching products have been reported since the 1960s and are still reported nowadays.

Indeed, when considering reported health adverse effects and mechanistic investigation of health effects due to persulfates related to skin/respiratory sensitization, at least 131 relevant publications were found on PubMed from 1955 to 2018 (see References). Additionally, these substances have been studied and assessed by various institutions (including NICNAS²³ in 2001, UK HSE²⁴ in 2001, OECD in 2005, Council of Europe in 2008, CIR²⁵ in 2001 and 2018, RIVM²⁶ in 2012 and 2014, ONAP²⁷ in 2003, 2006, 2016, Revidal-Gerda²⁸ in 2016 – some of which are detailed below) due to their sensitizing properties. Recently, a thorough analysis of French vigilance data on persulfates and updated bibliographical review was conducted between May and October 2016 at Anses in the context of an occupational medicine thesis, which was publicly defended on 7 December 2017 (Tomas-Bouil, 2017²⁹).

The adverse health effects in humans reported in all these studies include immediate and delayed contact hypersensitivity with irritant dermatitis, allergic eczematous dermatitis, localized contact urticaria, generalized urticaria, rhinitis, bronchitis, asthma, conjunctivitis, generalized allergic reactions. According to the classification of Kimber *et al.* (2003), Cruz *et al.* (2009) have established the sensitising potential of disodium, diammonium and dipotassium persulfate. Disodium persulfate is classified as a "strong" sensitiser whereas dipotassium and diammonium persulfate are classified as "moderate" sensitisers.

²³ Australian National Industrial Chemicals Notification and Assessment Scheme. Ammonium, Potassium and Sodium Persulfate – Priority Existing Chemical Assessment Report n°18. June 2001.

²⁴ Health and Safety Executive. Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma (2001).

²⁵ Cosmetic Ingredient Review (organization funded by US FDA and the American cosmetic industry). Safety assessment of ammonium, potassium and sodium persulfate (2001), Amended Safety Assessment of Persulfates as Used in Cosmetics (2018).

²⁶ National Institute for Public Health and the Environment of the Netherlands. De Wit-Bos *et al.* (2012), De Wit-Bos *et al.* (2014).

²⁷ Observatoire national des asthmes professionnels (national observatory for occupational asthma, France). Ameille *et al.* (2003), Ameille *et al.* (2006), Iwatsubo *et al.* (2016).

²⁸ REVIDAL (Réseau de Vigilance en Dermato-Allergologie – vigilance network on dermal allergology), GERDA (Groupe d'Etude et de Recherche en Dermato-Allergologie – group for study and research on dermal allergology), France. Gérard C and Gérard L (2016).

²⁹ Tomas-Bouil A (2017). Étude des cas d'expositions professionnelles et non professionnelles aux persulfates dans les dispositifs de vigilance. Thèse pour le diplôme d'État de Docteur en médecine. Université de Versailles Saint-Quentin en Yvelines [in French].

In France, by Decree no. 2003-110 of 11 February 2003 of the French social security Code, persulfates are recognised by the French National Health Insurance Fund for Employees as chemical agents responsible for occupational asthma and allergic eczema (Tables 65 and 66 of occupational diseases). In this context, workers can get compensation for these diseases. This is also the case in Germany, where occupational asthma is an acknowledged occupational disease and is listed as number 4301 when caused by a sensitiser.

In view of the existing information, it is not intended in the context of this RMOA to detail once more all the existing literature and data and to re-evaluate the hazards of the substances since it has already and recently been well done. **The hazards related to skin and respiratory sensitisation related to persulfates are very well known and acknowledged worldwide by the scientific and industrial communities**, as reflected in particular in the classification under the CLP Regulation (see above).

As they meet the criteria for classification as Resp. Sens. 1 H334 under CLP, which is reflected in the harmonised classification of diammonium and dipotassium persulfates and the self-classification of disodium persulfate, in principle persulfates would fulfil the criteria for Article 57(f) of REACH (equivalent level of concern).

In the context of this RMOA, additional vigilance data were collected from several vigilance systems in European Member States to get a better understanding of the severity of the health effects, as presented below.

- **French vigilance systems**

A thorough analysis of the French vigilance data on persulfates was performed in the context of an occupational medicine thesis publicly defended on 7 December 2017 (Tomas-Bouil, 2017).

The **RNV3P**³⁰ database records reports of medical consultations for occupational diseases via a network of 31 medical centers specialised in workers' pathologies. The analysis of RNV3P data revealed that **1144** cases of occupational diseases could be related to exposure to persulfates between 2001 and 2015 in France, with 93.8% of cases affecting women, **97.9%** affecting hairdressers, 26.5% affecting workers younger than 20 years old (average age: 28.9 years old) and **25.3%** affecting apprentices. The occupational diseases related to persulfates exposure are detailed in the table below.

Table 7: Occupational diseases related to persulfate exposure in RNV3P (2001-2015) – translated from Tomas-Bouil, 2017

Diseases	Women	Men	Total
Asthma	34.8% (N=373)	29.6% (N=21)	34.4% (N=394)
Allergic contact dermatitis	28.3% (N=304)	47.9% (N=34)	29.5% (N=338)
Rhinitis	21.4% (N=230)	12.7% (N=9)	20.9% (N=239)
Others*	15.5% (N=166)	9.9% (N=7)	15.9% (N=173)
Total	100% (N=1073)	100% (N=71)	100% (N=1144)

* "others" includes 64% of skin diseases including immediate hypersensitivity (urticaria, anaphylactic shock) and 14% of respiratory diseases.

³⁰ French Workers' Health Surveillance and Prevention Network.

The table below show the outcomes of the medical consultations when diseases were recognised as related to occupational exposure to persulfates. A large number of workers were declared unable to work (permanently and temporary) or able with reservation, meaning that the exposure to persulfates had a strong impact on their career.

Table 8: Ability to work following recognition of a disease related to occupational exposure to persulfates as recorded in RNV3P (2001-2015) – translated from Tomas-Bouil, 2017

Opinion on ability to work	Asthma	Rhinitis	Allergic contact dermatitis	Others	Total
Able to work	12.8% (N=33)	20.8% (N=33)	11.1% (N=28)	21.1% (N=37)	16.5% (N=131)
Able with reservation	35.4% (N=91)	39.6% (N=63)	34.5% (N=87)	38.6% (N=49)	36.5% (N=290)
Unable to work (temporary)	4.3% (N=11)	4.4% (N=7)	6.0% (N=15)	5.5% (N=7)	5.0% (N=40)
Unable to work (permanently)	45.9% (N=118)	30.8% (N=49)	41.3% (N=104)	22.8% (N=29)	37.7% (N=300)
Not applicable	1.6% (N=4)	4.4% (N=7)	7.1% (N=18°)	3.9% (N=5)	4.3% (N=34)
Total	100% (N=257)	100% (N=159)	100% (N=252)	100% (N=127)	100% (N=795*)

* no information available for the remaining 349 cases.

The analysis of the evolution of diseases overtime in women showed that, for asthma and rhinitis, the number of cases and the relative risks decreased between 2001 and 2015, and that for allergic contact dermatitis, no trend could be found. However it does not mean that the general prevalence of persulfate exposure decreased as other factors may be involved.

In the context of the thesis (Tomas-Bouil, 2017), in addition, data from French poison centers (SICAP³¹) were analysed for the period 2001-2015 and also revealed occupational (N=16) and non-occupational (N=115) cases of irritation and allergy related to the use of persulfates in hair bleaching products.

- **ONAP (French National observatory for occupational asthma)**

This French surveillance programme of occupational asthma (ONAP) was established in January 1996 to develop a monitoring system for occupational asthma in France and to promote primary prevention based on a better knowledge of the incidence of occupational asthma by sex, age, and occupation, and a better knowledge of its causal agents. It is based on voluntary reporting from physicians (mainly occupational and chest physicians). For the period 1996-1999 (Ameille *et al.*, 2003, 2006), 137 cases of occupational asthma related to persulfates were reported (5.8% of total reported cases, 5th most frequent causal agent, mainly in women who represented 14.8% of the total reported cases and 2nd most frequent causal agent – increasing over year). Hairdressers were the 4th most frequent occupation where asthma was reported (2nd for women) – also

³¹ Poison center information system, France.

increasing over year. Most cases for hairdressers were attributed to the inhalation of persulfates. In the context of the follow-up project ONAP II where data were collected for the period 2008-2014, persulfates were found the 2nd most frequent chemical agent related to occupational asthma (Iwatsubo *et al.*, 2016). *Note: the cases reported in ONAP were also included in the RNV3P database.*

- **ANSM (French Agency for medical products)**

According to the declarations made to ANSM between 2004 and 2014, 20 cases of contact allergy related to persulfates have been reported. The incriminated products are 8 hair bleaching products, 7 hair coloring products, 3 perm products (1 product is both a coloring and perm product), 1 hair straightener, 1 undefined hair product and 1 face cream. The effects reported are delayed eczema (14 cases), immediate cutaneous allergy (4), rhinitis (4), asthma (2) and one generalized allergic reaction with hypotension requiring an adrenaline injection (several effects may have been reported for the same product).

However, the composition of the products is not systematically reported in the database and it may be difficult to determine if the observed effects are actually attributed to persulfates in these products. Indeed, some of them may not contain persulfates even if a sensitisation to persulfates was revealed, and on the contrary, the effects observed after the use of a product containing persulfates may actually be related to another component. Despite these observations, 14 cases were very likely or likely attributed to the use of cosmetic products containing persulfates. The cases that are reported to ANSM are often the most serious ones; most of them (19) have lead to temporary unemployability or career change.

- **The Health and Occupation Research network (THOR) - COEH (Centre for Occupational and Environmental Health, University of Manchester, UK)**

Cases of occupational asthma and contact dermatitis attributed to the 3 persulfates reported to SWORD (Surveillance of Work-Related and Occupational Respiratory Disease, 2001-2014), EPIDERM (Occupational Skin Surveillance scheme, 2001-2014), OPRA (Occupational Physicians Reporting Activity, 2001-2009) and THOR-GP (The Health and Occupation Research network in General Practice, 2006-2014) were searched³². THOR is a research and information dissemination programme on the incidence and health burden of occupational disease and work-related ill-health³³.

Between 2001 and 2014, 3 cases of occupational asthma have been reported (one in a hairdresser, one in a photomechanical operator and one in a process worker), all related to disodium persulfate, and 534 estimated cases of contact dermatitis were reported, including 490 (92%) in hairdressers, all related to diammonium persulfate.

³² Request of 9 October 2015.

³³ <http://www.medicine.manchester.ac.uk/oeh/>.

- **RIVM (National Institute for Public Health and the Environment of the Netherlands)**

The RIVM established the CESES (Consumer Exposure Skin Effects and Surveillance), a monitoring system in which undesirable reactions caused by cosmetics can be registered.

In particular, the cosmetovigilance trend report 2011-2012 (De Wit-Bos *et al.*, 2012), and overview report of the period 2009-2014 (De Wit-Bos *et al.*, 2014) identify risks for professionals, e.g. hairdressers, related to the use of persulfates (especially diammonium persulfate).

Within the CESES project, diammonium persulfate was identified as the most important sensitising agent. The effects noted are allergic and irritant contact dermatitis, localised contact urticaria and generalised urticaria, asthma, rhinitis, and rare cases of anaphylactic reactions with unconsciousness.

- **IVDK (Information Network of Departments of Dermatology), Germany, Switzerland and Austria**

Uter *et al.* (2014) made a review of the contact allergy to ingredients of hair cosmetics, comparing female hairdressers and clients, based on IVDK³⁴ (Information Network of Departments of Dermatology) data from 2007 to 2012. The IVDK is a network dedicated to the clinical surveillance of contact allergy. Patch test data were collected along with clinical data and important items of the patient's history. Among 46 691 female patients, hairdressers diagnosed with occupational dermatitis (N=824), and clients whom hair cosmetics were regarded as a cause of dermatitis (N=2067) were identified. 18.7% [age-standardized prevalence] of hairdressers (3rd most frequent) and 2.1% of clients were tested positive to diammonium persulfate.

- **Danish Working Environment Authority (Danish Environmental Protection Agency)**

Between 2005 and 2013, the Danish Working Environment Authority reported 35 cases of occupational diseases for which persulfates were identified as cause, including 28 in hairdressers (14 dermatitis, 5 asthma, 7 rhinitis, 1 oedema, 1 non-specified allergy).

³⁴ www.ivdk.org

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

Confidential information is provided in Annex I.

4.1 Tonnage and registration status

Table 9: Tonnage and registration status of all 3 persulfates³⁵

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input checked="" type="checkbox"/> 1000 – 10,000 tpa (dipotassium persulfate)	<input checked="" type="checkbox"/> 10,000 – 100,000 tpa (diammonium persulfate, disodium persulfate)	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential

On 28 March 2018, as available in the disseminated website, there were (see also Annex I):

- 5 registration dossiers for diammonium persulfate (all updated between October 2017 and February 2018),
- 7 registration dossiers for dipotassium persulfate (5 updated between October 2017 and January 2018, one dated March 2016 and one dated November 2010),
- 8 registration dossiers for disodium persulfate (7 updated between October 2017 and February 2018 and one dated June 2014).

³⁵ Disseminated registration dossiers accessed 4 April 2018.

4.2 Overview of uses

4.2.1 Uses declared in registration dossiers

Table 10: Uses declared in registration dossiers³⁶

	Use(s)
Uses as intermediate	ERC 6a, PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 22, 23, substance supplied as such and in a mixture.
Formulation	ERC 2, PROC 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 13, 14, 15, substance supplied as such and in a mixture.
Uses at industrial sites	Manufacture: ERC 1, PROC 1, 2, 3, 4, 5, 8a, 8b, 9, 14. Formulation of preparations (see above). Use as intermediate (see above). Industrial use of reactive processing aids (ERC 6b), Industrial use of chemicals for polymer processing (ERC 6d), PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 22, 23, substance supplied as such and in a mixture.
Uses by professional workers	Wide dispersive indoor use of reactive substances, open systems (ERC 8b), Wide dispersive outdoor use of reactive substances, open systems (ERC 8e), PROC 8a, 8b, 9, 10, 11, 13, 14, 15, 19, 23, substance supplied as such and in a mixture. The professional use of cosmetics is referred to under PROC 19.
Consumer Uses	ERC 8a, PC 39: Cosmetics, personal care products, substance supplied as such and in a mixture. One registrant reports a use of disodium persulfate in PC 28 (perfumes, fragrances) but due to low tonnage an assessment for this use is not mandatory under REACH.
Article service life	None.

The registrants provided a CSR which covers the 3 persulfates as a category, and thus the uses reported above are applicable to all 3 persulfates.

Process categories (as reported in R12 guidance³⁷):

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations

³⁶ Disseminated registration dossiers accessed 4 April 2018.

³⁷ Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description, Version 3.0, December 2015.

- PROC 7: Industrial spraying
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 11: Non industrial spraying
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tableting, compression, extrusion, pelletisation, granulation
- PROC 15: Use as laboratory reagent
- PROC 19: Manual activities involving hand contact
- PROC 22: Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23: Open processing and transfer operations at substantially elevated temperature

Environmental release categories:

- ERC 1: Manufacture of the substance
- ERC 2: Formulation into mixture
- ERC 6a: Use of intermediate
- ERC 6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)
- ERC 6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)
- ERC 8a: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
- ERC 8b: Widespread use of reactive processing aid (no inclusion into or onto article, indoor)
- ERC 8e: Widespread use of reactive processing aid (no inclusion into or onto article, outdoor)

It should be noted that other consumer uses were initially registered in the previous versions of the registration dossiers: PC 14 (metal surface treatment products) and PC 37 (water treatment products). However, these uses were not appropriately assessed in the registration dossiers and in particular the assessment did not take into account the risks related to skin and respiratory sensitization. In the context of the recent CCH (Decisions of 8 September 2016) the registrants were asked to update their Chemical Safety Reports (CSR) to assess these risks and demonstrate safe use. The registrants conducted surveys to their downstream users. The result was that no such uses could be identified in EU and therefore these uses were dropped from the registration dossiers of the lead registrant and of all other registrants of persulfates in the updates that occurred between October 2017 and February 2018.

4.2.2 Other available information on uses

The OECD SIDS³⁸ Assessment report was prepared and reviewed in 2005 by the industrial group FMC Corporation (USA) and peer-reviewed by all of the persulfate manufacturers in the CEFIC³⁹ Persulfates Working Group, under sponsorship of the USA in the context of the OECD HPV⁴⁰ Chemicals Programme. According to the SIDS report, approximately 80% of all persulfates are used in two industrial applications: in polymer industry (>60% of total tonnage) as polymerisation initiators, depolymerisers, oxidant/bleaching agent, and in electrical/electronic engineering industry (20% of total tonnage) for printed circuit manufacture. They are also used as oxidants in cosmetics, including hair bleaching products (2-3% of total tonnage), non-biocidal shock treatment in swimming-pools and other recreational waters (1% of total tonnage), chemical synthesis, pulp and paperboard manufacture, textile processing, and in the photographic industry. They can have applications in other reactions requiring an oxidising agent. A use as food additive is authorised in the USA but not in EU.

The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) reports various uses in its report of 2001, but does not provide tonnage percentages for each use. Their main concern was the widespread use as ingredients in hair bleaches. In Australia most hair bleaching products are used by professionals in salons but some products are also available to consumers for home use. NICNAS also reports industrial uses as oxidizing agents in industrial processes, in metal etching, as oxidising agents for dyes and prints in the textile industry, uses in the industries of rubber, adhesives, paper and paperboard, uses to deodorize and bleach oils, uses as depolarisers in batteries, and uses in photography.

Uses as cosmetics are also reported in the CIR safety assessment of persulfates as used in cosmetics (February 2018) based on 2017 data of the FDA's Voluntary Cosmetic Registration Program in the USA. Most products are rinse-off products (a category that includes hair-coloring/bleaching products) but diammonium and dipotassium persulfates are also used in leave-on products. Overall, the use of persulfates in cosmetics include hair coloring/hair bleaching products, eye make-ups (diammonium persulfate), tonics, dressings, and other hair grooming aids (diammonium and dipotassium persulfate), toothpastes (disodium persulfate). The highest reported concentration of persulfate in cosmetic products is 72.5% (in a rinse-off product). The CIR additionally reports uses in denture cleansers which are medical devices. These uses are not declared in the REACH registration dossiers and even after the CCH they were not included. The CIR also reports the use as food additives in the USA which is not authorised in EU.

As indicated in manufacturers' and downstream users' brochures and websites⁴¹, persulfates are used in polymerization as initiators of polymerization of plastics and rubbers (acrylics, vinyl, polyvinyl chlorides, polystyrenes, neoprene, styrene

³⁸ Screening information datasets.

³⁹ European Chemical Industry Council.

⁴⁰ High production volume

⁴¹ http://www.peroxychem.com/media/90826/AOD_Brochure_Persulfate.pdf (2001), <http://www.peroxychem.com/chemistries/persulfates/>, <http://www.caruscorporation.com/resources/content/7/4/documents/persulfate-sr-fact-sheet.pdf> (2013), <http://dinox.com/en/produkte/textile-chemicals/aps/>, <http://dinox.com/en/produkte/textile-chemicals/wpo/>, <http://dinox.com/en/produkte/textile-chemicals/nps/>, <https://www.united-initiators.com/our-products/persulfates/>, https://www.united-initiators.com/wp-content/uploads/2017/06/UI_PSF_170511_M.pdf, <http://www.mgc.co.jp/eng/products/nop/09.html>, <https://www.redox-tech.com/persulfate/>.

butadiene, isoprene, other resins), latex polymers for paints, coatings, and carpet backing), initiators of polymerization of structural materials (concrete formulations), initiators of polymerization with inorganic chemicals and minerals (coating of graphite filaments), curing agent in chemical grout systems used to stabilize soil near dams, tunnels, and buildings, depolymeriser in modification of starch; as oxidants for surface preparation (microetching in the manufacture of printed circuit boards, plating and coating processes, cleaning of metal surfaces prior to plating or adhesive bonding), curing of low formaldehyde adhesives, removing of adhesive, cleaning and activating carbon and charcoal before and after their use as absorbents, production of binders and coating materials, cosmetics (booster in hair bleaching), organic synthesis, removal of non-filterable waste in swimming pools and other recreational water, soil remediation and wastewater/groundwater cleanup, waste gas treatment; and for other uses such as preparation of adhesives, gel breaker in enhanced oil recovery systems for gas and oil production, grafting of substrates to polymers, preparation of dispersants for inks, separation of nickel and cobalt in mining, photographic applications, pulp and paper applications (sizing of paper, preparation of binders and coatings, production of special papers, repulping of wet-strength paper), manufacture of peroxy monosulfate solutions, desizing and bleaching of textiles and development of dyestuffs. Manufacturers also report uses for pool and spa care and denture cleaners which actually involve potassium monopersulfate (peroxy monosulfate)⁴² (not in the scope of this RMOA) and not dipotassium persulfate, although they are sometimes included under the generic name "persulfates".

Persulfates are cosmetics ingredients listed in the European Cosmetic Ingredient database (CosIng⁴³): diammonium persulfate is listed with the "bleaching" and "oxidising" functions; disodium and dipotassium persulfates with the "oxidising" function.

To identify uses of persulfates and put the already collected data into perspective, searches were performed on the additional following databases (April 2018): Health Canada⁴⁴, BUMAC⁴⁵, HERA RA-database⁴⁶, IPCHEM⁴⁷, MEGA⁴⁸, KEMI Flow Analyses for chemical substances⁴⁹, KEMI Commodity Guide⁵⁰, CPCat⁵¹, SPIN⁵², USA Household Products Database⁵³, US-OSHA Chemical Exposure Health Data⁵⁴.

⁴² <https://www.united-initiators.com/products/carolat/>.

⁴³ <http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple> accessed 29 March 2018.

⁴⁴ http://recherche-search.gc.ca/rGs/s_r?st=s&langs=eng&st1rt=0&num=10&cdn=health.

⁴⁵ BUMAC database is a consumer product emission database created within the framework of the EPHECT Project. <http://bumac.uowm.gr/>.

⁴⁶ Human and environmental risk assessment on ingredients of household cleaning products. <http://www.heraproject.com/RiskAssessment.cfm>.

⁴⁷ Information Platform for Chemical Monitoring. <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>.

⁴⁸ Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. Measurements of hazardous substances along with workplace and exposure data are stored in IFA's exposure database MEGA (Messdaten zur Exposition gegenüber Gefahrstoffen am Arbeitsplatz"). <http://www.dguv.de/ifa/GESTIS/Expositionsdatenbank-MEGA/Expositionsdaten-aus-MEGA-in-Publikationen/Publikationen-nach-Stoffen/index.jsp>.

⁴⁹ <http://webapps.kemi.se/flodesanalyser/FlodesanalyserSok.aspx>.

⁵⁰ <http://webapps.kemi.se/varuquiden/Default.aspx>.

⁵¹ <https://actor.epa.gov/cpcat/faces/home.xhtml>.

⁵² Substances and preparations in Nordic countries. <http://spin2000.net/>.

⁵³ <https://hpd.nlm.nih.gov/cgi-bin/household/list?tbl=TblChemicals&alpha=A>.

⁵⁴ <https://www.osha.gov/opengov/healthsamples.html>.

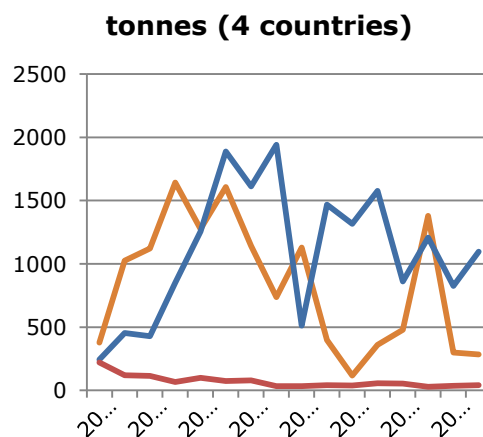
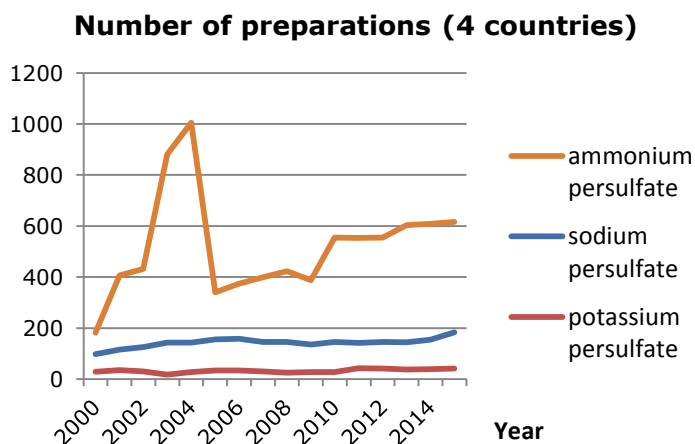
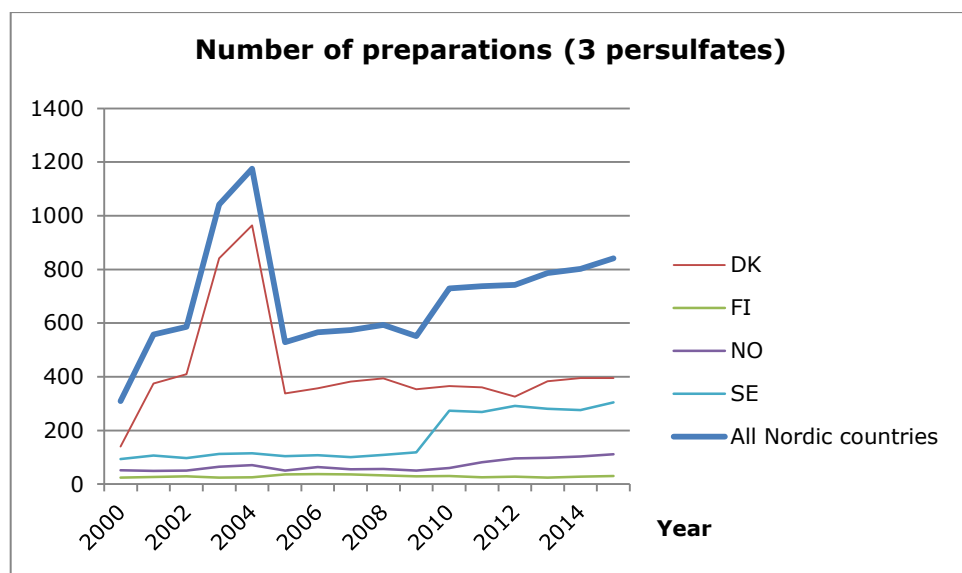
Data were found on SPIN, CPCat (which include SPIN data) and USA Household Products Database.

- **SPIN (Substances and preparations in Nordic countries)**

As explained in the use guide, the Nordic substance register database (SPIN) contains non confidential use information on chemical substances extracted from national product Registers in the Nordic countries. Manufacturers and importers are required to declare chemical substances and products according to their national legislations, **except for cosmetics**, foodstuffs, medicinal products and quantities less than 100 kg/year per company. However it is estimated that around 70-75 % of all information is not publicly available.

Data on total use, use categories and industrial use were found for all three persulfates in Denmark (DK), Finland (FI), Norway (NO) and Sweden (SE) from 2000 to 2015.

Figure 1: Total use as available in SPIN database



The peak in the years 2003 and 2004 is due to a much higher number of preparations declared in Denmark for diammonium persulfate, which is unexplained in comparison to the other years.

Table 11: Use information gathered in SPIN database (with non-null number of preparations)

Substance	Industrial uses (NACE codes)	Use categories (UC62 ⁵⁵)
Diammonium persulfate	<p>Highest⁵⁶ tonnages: extraction of crude petroleum and natural gas (70t); manufacture of chemicals and chemical products (up to 1052t).</p> <p>Highest number of preparations (but very low tonnages): manufacture of fabricated metal products except machinery and equipment (up to 731; 1t); manufacture of furniture (up to 748; < 100kg); manufacture of wood, of products of wood and cork, and of articles of straw and plaiting materials (up to 735; 1t); undifferentiated goods- and services-producing activities of private households for own use (up to 96; <100kg).</p> <p>Other recorded uses: construction; electricity, gas, steam and air conditioning supply; manufacture of basic metals, of other transport equipment, of pulp, paper and paper products, of textiles; publishing, printing and reproduction of recorded media; repair and installation of machinery and equipment; repair of computers and personal and household goods; repair of motor vehicles and motorcycles; retail, wholesale trade and commission trade; private households with employed persons; other business activities.</p>	<p>Highest tonnages: process regulators (up to 434t), surface treatment, others (up to 341t).</p> <p>Highest number of preparations: paints, laquers and varnishes (up to 812; 4.7t),</p> <p>Other recorded uses: adhesives and binding agents, colouring agents, surface treatment, oxidizing agents, cleaning/washing agents, fillers, impregnation materials, non-agricultural pesticides and preservatives, reprographic agents, others.</p>
Dipotassium persulfate	<p>Highest tonnages: manufacture of chemicals and chemical products (up to 16t).</p> <p>Highest number of preparations: manufacture of chemicals and chemical products (up to 7).</p> <p>Other recorded uses: manufacture of pulp, paper and paper products, civil engineering, construction.</p>	<p>Highest tonnages: bleaching agents (54t) and oxidizing agents (up to 209t).</p> <p>Highest number of preparations: oxidizing agents (6); with very low tonnages: non-agricultural pesticides and preservatives (up to 6; <100kg), paints, laquers and varnishes (5; <100kg).</p> <p>Other recorded uses: laboratory chemicals, others.</p>
Disodium persulfate	<p>Highest tonnages: manufacture of chemicals and chemical products (up to 608t), of fabricated metal products except machinery and equipment (up to 163t).</p> <p>Highest number of preparations: manufacture of chemicals and chemical products (up to 16); with very low tonnages: construction (up to 17; <100kg), fishing and aquaculture (12; <100kg), manufacture of manufacture of pulp, paper paper products (up to 25; 5t), retail trade except of motor vehicles and motorcycles, repair of personal</p>	<p>Highest tonnages: process regulators (up to 413t), surface treatment (up to 602t), others (up to 1189t).</p> <p>Highest number of preparations: surface treatment (up to 13), others (up to 11), flux agents for casting (10; up to 71t); with very low tonnages: paints, laquers and varnishes (up to 39; up to 1t), cleaning/washing agents (10; 200 kg), non-</p>

⁵⁵ 62 harmonised use categories which describe the technical function of chemical substances and preparations.

⁵⁶ 10% top with at least 2 values.

	and household goods (up to 39; up to 2t). Other recorded uses: manufacture of computer, electronic and optical products, civil engineering, and of radio, television and communication equipment; mining support service activities; health and social work; hotels and restaurants; manufacture of electrical equipment, of food products, of textiles; private households with employed persons; publishing, printing and reproduction of recorded media; undifferentiated goods- and services-producing activities of private households for own use.	agricultural pesticides and preservatives (up to 15; up to 300kg). Other recorded uses: adhesives, binding agents, construction materials, corrosion inhibitors, electroplating agents, fillers, oxidizing agents, surface-active agents.
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Unfortunately, although consumer uses are recorded by Norway and Sweden, it is not possible to know which uses/functions correspond to consumer uses.

- **CPCat (Chemical and Product Categories)**

CPCat is a database containing information mapping >43,000 chemicals to a set of terms categorizing their usage or function. Data were collected for all 3 persulfates by CAS numbers. CPCat gathers information from many other sources including CDR⁵⁷ (Chemical Data Reporting Rule under TSCA), IUR 2006 (Inventory Update Reporting)⁵⁸, ACToR (Aggregated Computational Toxicology Resource), retailers data, SPIN database, US EPA data, FDA data etc.

Excluding data from SPIN database (which are addressed above and which represent European data on the contrary to the other CPCat data collected on persulfates which represent American data), the following uses were identified:

Table 12: Use information gathered in CPCat database

Substance	Use information	Sources
Diammonium persulfate	Expressed as "uses": adhesives and sealants; industrial chemicals; fabrics, textiles and apparel; food additives; fracking; paper products; personal care products; pesticides (inert ingredients); rubber and plastic products. Expressed as "sectors": manufacture of basic inorganic chemicals; manufacture of asphalt paving, roofing, and coating materials; manufacture of plastics material and resin; manufacture of soap, cleaning compound, and toilet preparation; oil and gas drilling, extraction. Expressed as "products": beauty products (face, hair color, moisturizers, styling products); home improvement paints and primers. Expressed as "function": bleaching agents; ion exchange agents; oxidizing/reducing agents, plating agents and surface treating agents; processing aids, specific to petroleum production.	CDR 2012 Product retailers data (USA) IUR 2006 ACToR
Dipotassium persulfate	Expressed as "uses": adhesives and sealants; industrial chemicals; food additives; fracking; paints and coatings; paper products; personal care products; pesticides (including	CDR 2012 Product retailers data

⁵⁷ <https://www.epa.gov/chemical-data-reporting>.

⁵⁸ https://www.epa.gov/sites/production/files/documents/iurdbbackground_0.pdf.

	<p>biocides); plastic and rubber products; plastics: drinking water contact substances.</p> <p>Expressed as "sectors": manufacture of basic inorganic and organic chemicals; manufacture of asphalt paving, roofing, and coating materials; manufacture of plastics material and resins; manufacture of soap, cleaning compound, and toilet preparations; oil and gas drilling, extraction.</p> <p>Expressed as "products": beauty products (hair color, styling products); toys pool supplies.</p> <p>Expressed as "function": bleaching agents; ion exchange agents; oxidizing/reducing agents; plating agents and surface treating agents.</p>	(USA) IUR 2006 ACToR
Disodium persulfate	<p>Expressed as "uses": adhesives and sealants; industrial chemicals; electrical and electronic products; food additives; fracking; oxidants-stabilizers; paints and coatings; paper products; pesticides (including biocides and inert ingredients); rubber and plastic products; water treatment products.</p> <p>Expressed as "sectors": agriculture, forestry, fishing and hunting; manufacture of basic inorganic chemicals; manufacture of other chemical products and preparations; manufacture of plastics material and resin; oil and gas drilling, extraction.</p> <p>Expressed as "products": beauty (hair color).</p> <p>Expressed as "function": ion exchange agents; oxidizing/reducing agents; plating agents and surface treating agents; processing aids.</p>	CDR 2012 Product retailers data (USA) IUR 2006 ACToR DfE (design for the environment program of US EPA)

Table 13: Product information gathered in CPCat database

Substance	Number of products	Concentrations
Diammonium persulfate	64	Data available for 41 products. Concentration: - 38 products > 90%
Dipotassium persulfate	41	Data available for 20 products. Concentration: - 12 products > 80% - 6 products at 20-63% - 2 products at 1-5%
Disodium persulfate	32	Data available for 21 products. Concentration: - 12 products > 95% - 1 product at 50% - 8 products (including 7 for photography products) at 1-10%.

The names of the products do not usually enable to identify their uses.

- **USA Household Products Database**

The USA Household Products Database is maintained by the National Library of Medicine and contains information on consumers products collected from Safety Data Sheets and products labels.

The following products are recorded:

- 10 hair color products from 2 manufacturers. Clairol's 6 products are liquids or powders and contain >1% persulfates (5 contain all 3 persulfates, and 1 diammonium and dipotassium persulfates); Garnier's 4

products are kits which contain <61% dipotassium persulfate and for 3 products also disodium persulfate.

- 3 liquid paints which contain 0.1-1% of diammonium persulfate.
- 1 swimming pool shock treatment product, granular form, which contains 1-5% dipotassium persulfate but also 30-60% of potassium peroxymonosulfate and 10-30% potassium hydrogensulfate.

4.2.3 Summary on uses

- **Manufacture, formulation, industrial and professional uses (other than cosmetics)**

In the registration dossiers, the manufacture of persulfates, the formulation of products, the use of persulfates as intermediates to manufacture other substances, the use of persulfates and products in industrial settings and the use of persulfates and products by professional workers are described by the registrants. Unfortunately for industrial and professional uses, no information is available regarding the sectors, types of products etc. For example, professional uses are referred to as "wide dispersive indoor/outdoor use of reactive substances" which is rather unspecific. Therefore the exposure scenarios are quite generic. Other information were collected to attempt to describe these uses better, as detailed above, and overall persulfates are used in a wide and diverse range of industrial and professional activities.

- **Cosmetic uses**

Professionals and consumers both use cosmetic products containing persulfates. In the context of REACH, cosmetic use by consumers is declared in the registration dossiers as PC 39. In addition, the professional use of cosmetics could correspond to PROC 19 (manual activities involving hand contact). But as such the cosmetic uses are not assessed in the REACH registration dossiers, since, according to Article 14(5)(b), "The chemical safety report need not include consideration of the risks to human health from the following end use[s]: in cosmetic products within the scope of Directive 76/768/EEC."

Persulfates are used to color, lighten or bleach hair. According to NICNAS (2001), they are used together with hydrogen peroxide to boost the oxidation process initiated by hydrogen peroxide to liberate activated oxygen, and are supplied as powders to be mixed with aqueous hydrogen peroxide just prior the use, to create a liquid, gel or slurry which is applied on the hair with a tinting brush. Cream and liquid formulations also exist. NICNAS identified only uses for hair bleaching, but CIR (2018) identified uses in leave-on products such as other hair grooming aids, eye make-ups, tonics, dressings and toothpastes. The highest reported concentration of persulfates in cosmetic products (in rinse-off product) is 72.5% (CIR, 2018). Hairdressing products generally contain a combination of two or, in some cases, all three persulfates.

It should be noted that the maximum concentration of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide is restricted in ready for use preparation to 12 % H₂O₂ (40 volumes), present or released, according to Annex III of the Cosmetic Regulation (EC) 1223/2009, but the concentration of persulfates is not restricted.

- **Other consumer uses**

As indicated above, in addition to cosmetic uses, two other consumer uses were initially registered under REACH: PC 14 (metal surface treatment products) and PC 37 (water treatment products) for swimming pool shock treatment. In the context of this RMOA, it was considered that they could lead to consumers exposure but not much information was available in the dossiers to conclude whether there were risks that could necessitate risk management. The MSCA France observed that the risks related to skin and respiratory sensitization was not assessed for these uses in the REACH registration dossiers, and hence considered that the registration dossiers were not compliant with Annex I, 5 and 6 of REACH. ECHA conducted a CCH and registrants were required to update their CSR. In reply, the registrants dropped these uses from the registration dossiers since they could not identify such uses in EU.

Regarding metal surface treatment product (PC 14), no information could be found from other sources either regarding any existing such use by consumers.

Regarding PC 37 (water treatment products) i.e. swimming pool shock treatment as initially reported in the registration dossiers, the situation was more confusing. Indeed several indications let think that persulfates could be used for swimming pool shock treatment. In OECD SIDS (2005), 1% of the total tonnage was considered as attributed to shock treatment in swimming-pools and other recreational waters. Wojtowicz (2001) cites dipotassium persulfate as a possible but minor substance for that purpose. In several manufacturers and downstream users' brochures and websites, (non-biocidal) swimming-pool treatment was presented. For example in FMC/Peroxychem brochure on persulfate⁵⁹, one product was mentioned for this purpose ("Swimming pools - Clear Advantage® shock treatment is used to oxidize non-filterable waste in swimming pools and other recreational water. Clear Advantage® shock clarifies water and prevents the formation of combined chlorine") but this reference is from 2001 and the product could not be found anywhere. One product was also recorded in the USA household product database which contains 1-5% dipotassium persulfate but also 30-60% of potassium peroxymonosulfate and 10-30% potassium hydrogenosulfate. Based on data extracted from SICAP and from the literature, it was found that swimming pools products actually contain peroxymonosulfate (monopersulfate), and not the persulfates targeted in this RMOA, and that "persulfates" was sometimes used as a general term for monopersulfates and persulfates, and/or persulfates were confused with peroxymonosulfate (Yankura *et al.*, 2008). Formulations containing potassium peroxymonosulfate⁶⁰ are out of the scope of this RMOA. The question whether the use of oxidants for swimming pool shock treatment falls under the Regulation (UE) 528/2012 (Biocidal Product Regulation) was also raised, since persulfates are not currently evaluated nor approved for use as PT02 (disinfectants and algaecides not intended for direct application to humans or animals) under the Biocidal Product Regulation, which means that this use is not authorised in EU. Considering that all registrants of persulfates removed the consumers exposure scenario for PC 37 from their registration dossiers, and that they are not authorised for biocidal use either, it is considered that persulfates must not be used for biocidal or non-biocidal swimming pool treatment by consumers in EU.

⁵⁹ FMC/Peroxychem, 2001: http://www.peroxychem.com/media/90826/AOD_Brochure_Persulfate.pdf.

⁶⁰ Several substances are listed under the name of "potassium peroxymonosulfate": CAS n° 37222-66-5 (pre-registered), CAS n° 10058-23-8 (pre-registered), CAS n° 70693-62-8 (registered and assessed as biocidal active substance).

The CIR report mentions a use in denture cleaners, which in EU would fall under the medical devices legislation, but would need to be registered under REACH nevertheless. Here also, the question is raised about possible confusion between peroxymonosulfate and persulfates since peroxymonosulfate are known to be used for denture cleansing⁶¹ and data found in SICAP referred mainly (if not totally) to peroxymonosulfate for this use. Overall, as this use is not registered under REACH, it is considered persulfates must not be used for dental appliance cleaning in EU.

5 JUSTIFICATION FOR THE RISK MANAGEMENT OPTION

5.1 Need for (further) risk management

In view of the available information, Anses considers that there is a need for further risk management. The reasons are the following:

- *Adverse health effects are well established, and affect especially the end-uses of persulfates as cosmetics ingredient and the hairdressing sector:*

Diammonium persulfate, dipotassium persulfate and disodium persulfate are classified under CLP as Skin Sens. 1, H317 (may cause an allergic skin reaction) and Resp. Sens. 1, H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled). This classification is not questioned as it is widely supported by data and acknowledged by the scientific and industrial communities. Due to their classification as Resp. Sens. 1, H334, persulfates meet the criteria of Article 57(f).

During the course of the RMOA, it was found that the overwhelming amount of evidences of adverse health effects in occupational settings were due to the use of persulfates in cosmetic products by professional end-users (hairdressers).

Indeed, on the one hand, only a few cases were identified over the years in the literature, in occupational settings where persulfates were manufactured (Pichat and Duc, 1955; White *et al.*, 1982; Wrbitzky *et al.*, 1995; Merget *et al.*, 1996; Polychronakis *et al.*, 2013); where persulfates were used to produce other substances (Barsotti *et al.*, 1951, cited in NICNAS 2001); where persulfates were handled (Baur *et al.*, 1979); where persulfates were used to formulate cosmetics (Munoz *et al.* 2003 and 2008), and where persulfates were used as flour additive, a use that is not authorised anymore in EU (Baccaredda and Palminteri, 1955; Sabatini *et al.*, 1955; Palminteri, 1961). However cases of dermatitis in pizza makers were identified recently (Lembo *et al.*, 2014) which raise the question of enforcement of this ban.

On the other hand, **there are numerous evidences demonstrating that the use of persulfates in cosmetics and especially by hairdressers leads to unacceptable risks.** To summarise, at least **82 publications** from 1963 to 2018 report adverse health effects due to skin and/or respiratory sensitization related to cosmetics use in hairdressers. Furthermore, when looking at vigilance data (see 3.2), RNV3P (French Workers' Health Surveillance and Prevention Network) data showed that among the **1144** cases of occupational diseases related to

⁶¹ <https://www.united-initiators.com/products/caroot/>.

exposure to persulfates from 2001 to 2015 in France, **97.9%** affected hairdressers and especially young people and apprentices; **more than 1/3** were declared as **permanently unable to work** as hairdressers. ONAP (National observatory for occupational asthma, France) showed that persulfates were the **2nd most frequent causal agent** for occupational asthma in women, and hairdressers the 2nd most frequent occupation where asthma was reported for women, and most cases for hairdressers were attributed to the inhalation of persulfates. ANSM (French Agency for medical products) cosmetovigilance data also showed that **95%** of the cases reported between 2004 and 2014 in France for cosmetics lead to temporary unemployability or career change. In the UK, data collected between 2001 and 2014 showed that **92%** of cases of persulfates-related contact dermatitis affected hairdressers. In the Netherlands, the RIVM identified risks for professionals, e.g. hairdressers, related to the use of persulfates in cosmetics, and diammonium persulfate was identified as **the most important sensitising agent**, based on data from 2009 to 2014. In Germany, Switzerland and Austria, IVDK (Information Network of Departments of Dermatology) data showed that for the period 2007 to 2012, 18.7% of hairdressers (**3rd most frequent**) and 2.1% of clients were tested positive to diammonium persulfate. In Denmark **80%** of cases of persulfates-related occupational diseases between 2005 and 2013 affected hairdressers. Health adverse effects and especially asthma and hand eczema were identified as **the main reason for leaving the profession** for hairdressers in a Finnish study (Leino *et al.*, 1999b).

- *For cosmetic use, the only assessment currently available and the risk management measures currently in place fail to ensure safe use:*

The CIR concluded in 2018 that "Ammonium, Potassium, and Sodium Persulfate are safe as used as oxidizing agents in hair colorants and hair lighteners designed for brief discontinuous use followed by thorough rinsing from the hair and skin. The Panel also concluded that the available data are insufficient for determining the safety of these persulfates in leave-on products and dentifrices." However the vigilance data show clearly that persulfates cannot be considered as safe for cosmetic uses and therefore it is disturbing that the only currently published assessment of persulfates for cosmetic uses are in contradiction with the literature and vigilance data.

Consumer exposure can occur when using products at home or as clients in salons; occupational exposure of workers to cosmetics can occur during the transport, storage, preparation, application and rinsing of hair bleaching products. Inhalation and dermal exposure to dust released to the atmosphere and deposited on surfaces is observed even for "dust-free" formulations. According to NICNAS (2001), visible clouds of dust could be observed when opening and closing containers, or during dispensing of the product with the provided scoop, even for products labeled as dust-free. According to CIR (2018), particles smaller than 10 µm (i.e. inhalable fraction) can be emitted when powdered bleaching products are used, even with "dust-free" powders. Measurements were performed and showed that the "measured level of persulfate sampled in the breathing zone of the hairdressers was 26 µg/m³ (average value) when the regular powder was used, and was 11 µg/m³ (average value) when the dust-free powder was used". Uter *et al.* (2014) noted that "improved product formulation to prevent airborne exposure and subsequent type I sensitization evidently did not have any impact on contact sensitization through skin exposure"; Nielsen *et al.* (2016) found that even if dust-free powder emits less persulfates than regular powders, effects are still elicited in symptomatic hairdressers.

OELs do exist in several countries, but may not be protective enough to avoid sensitization. Some measured values are available in hairdressing salons and are below the OELs: CIR (2018) measured average concentrations of 26 $\mu\text{g}/\text{m}^3$ for regular powder and 11 $\mu\text{g}/\text{m}^3$ for dust-free powders in the breathing zone of the hairdressers; Leino *et al.* (1999a) measured average air concentrations ranging from 0.9 $\mu\text{g}/\text{m}^3$ in large salons to 2.9 $\mu\text{g}/\text{m}^3$ in small salons, with peaks up to 30 $\mu\text{g}/\text{m}^3$ in the breathing zone during mixing of bleaching powder, in 20 randomly-selected Finnish hairdressing salons. It is worth noting that these values are lower than the available OELs which range between 0.1-2 mg/m^3 (8-hours TWA) and 0.1-4 mg/m^3 (short-term values) (see section 2).

In view of the widespread use as cosmetic ingredient and the prevalence of skin disease and asthma related to this use, NICNAS declared persulfates as "Priority Existing Chemicals". This assessment (2001) identified the following health and safety issues: all the products available for consumer and salon use are harmful if swallowed, irritant to the skin and eyes and able to cause allergic responses such as dermatitis and asthma; the majority of formulations are not optimal for minimising exposure due to dust formation; most of the material safety data sheets (MSDS) and labels of salons products are deficient; most hair salons would benefit from a workplace risk assessment and health surveillance program; and the training of salon workers for the safe use of chemicals used in hairdressing appears inadequate.

- *Further risk management options were identified previously, but do not seem to have been voluntarily implemented yet:*

NICNAS (2001) recommended to develop safer product formulation (sufficiently dust-free), improved packaging to avoid the dispersal of dust particles, better hazard communication to improve MSDS, workplace controls for formulators/importers and re-packagers of persulfate bleaches and for hairdressing salons, health surveillance of workers, training and education for workers, use of the ACGIH TLV of 0.1 mg/m^3 TWA for the hairdressing salons, and investigation of the long-term and reproductive toxicity of persulfates.

Based on Gérard and Gérard (2016) and Tomas-Bouil (2017), the only treatment of occupational allergic rhinitis and asthma is to totally remove the allergen from the working environment. Surveillance is therefore key to identify early signs and especially rhinitis as an early sign for asthma. Only compact powders, granules and creams should be made available to users. Powders should be restricted from placing on the market under the Cosmetic Regulation. Closed packaging should be preferred which allow mixing without opening the packaging. Conditions of use must be available on the products labels. Collective protective equipment must be put in place: good general ventilation, hoods, separate room to prepare the products. Personal protective equipment (PPE) i.e. gloves must be worn during preparation, application, rinsing of hair and material cleaning to prevent dermatitis. Organisational measures such as wet cleaning of surfaces, rotation of workers from the most exposed tasks, training of apprentices and employees are necessary.

The option to restrict the type of formulation was proposed in several reports as presented above, but although it may lower exposure (see above), this measure alone may not be sufficient.

- *Note regarding other consumer uses:*

In the course of the RMOA, a concern was raised also for the other consumers uses which were initially registered since not much information was available and

adequate risk management was not demonstrated in the registration dossiers. Also, some consumer uses are recorded in the SPIN database but no details are available. Following a CCH, these consumers uses were removed, which means that it is now a matter of enforcement to ensure that persulfates are not used by consumers as reported in the registration dossiers.

Table 14: Summary of concerns identified

Use	Target population	Conclusion	Follow-up
Manufacture of persulfates Formulation of products Industrial and professional (non-cosmetic) use of persulfates and products containing persulfates	Workers (industrials and professionals)	A few cases of occupational diseases reported Exposure scenarios are available in REACH registration dossiers, but some flaws were identified	Improvement of CSR General enforcement of REACH implementation
End-use of persulfates in cosmetic products	Workers (professionals) and consumers	Risk identified No exposure scenarios available in REACH registration dossiers (out of scope of REACH)	Risk management necessary
Other potential consumer uses	Consumers	Uses removed from REACH registration dossiers	General enforcement

No need for a specific EU wide action was identified at the moment for the manufacture of persulfates, formulation of products, industrial and professional (non-cosmetic) use of persulfates and products containing persulfates, mainly because no full assessment has been done for these uses in the context of this RMOA, considering that all available data directly support the urgent need for risk management for one use (cosmetics) and the concerned population, and therefore the RMOA targets this risk. However, this RMOA is a good opportunity to point out possible improvements which could help improve workers safety and to inform the National Enforcement Authorities to be vigilant for any consumer use other than cosmetics which are not supported by the REACH registrations.

5.2 Identification and assessment of risk management options

5.2.1 Identification of risk management options

For professionals:

- A- Setting an occupational exposure limit (OEL) at Community level.
- B- REACH restriction (Annex XVII).

C- Substance evaluation.

D- REACH authorisation (Annex XIV) on the basis of the sensitising properties (Art. 57f) of persulfates.

E- Improvement of the hairdressers' training (including for apprentices) to raise awareness on risks related to exposure to persulfates, on organisational prevention measures and on collective and personal protective equipments.

F- Enforcement of OSH (occupational safety and health) legislation by the labour inspectorate.

G- Regulation of persulfates in the frame of Regulation (EC) 1223/2009 on cosmetic products.

H- Harmonised Classification and Labelling for disodium persulfate.

For consumers:

B- REACH restriction (Annex XVII).

C- Substance evaluation.

D- REACH authorisation (Annex XIV) on the basis of the sensitising properties (Art. 57f) of persulfates.

G- Regulation of persulfates in the frame of Regulation (EC) 1223/2009 on cosmetic products.

H- Harmonised Classification and Labelling for disodium persulfate.

General considerations for all uses of persulfates (except cosmetics):

I- Improvement of exposure scenarios in Chemical Safety Reports (CSR) and extended Safety Data Sheets (eSDS)

J- Enforcement of REACH regulation on exposure scenarios in extended Safety Data Sheets (eSDS)

5.2.2 Assessment of risk management options

A. Setting an occupational exposure limit (OEL) at Community level

This option is applicable is the framework of the chemical agents Directive 98/24/EC. So far, OELs are established in several but not all EU countries⁶² (all values are expressed as measured as [S₂O₈]):

- Belgium, Ireland, Spain: 8-hour TWA⁶³ of 0.1 mg/m³ (diammonium, dipotassium and disodium persulfates);
- Poland: 8-hour TWA of 0.1 mg/m³ (dipotassium persulfate only);
- Denmark: short-term value of 4 mg/m³ and 8-hour TWA of 2 mg/m³ (dipotassium and disodium persulfates only);

⁶² As available on <http://limitvalue.ifa.dguv.de/> on 29 March 2018.

⁶³ Time-weighted average.

- United Kingdom: 8-hour TWA of 1 mg/m³ but “the UK Advisory Committee on Toxic Substances has expressed concern that (...) health may not be adequately protected because of doubts that the limit was not soundly-based. These OELs were included in the published UK 2002 list and its 2003 supplement, but are omitted from the published 2005 list.”

In non-EU countries the following OELs are established:

- Australia: short-term value (ceiling limit value) of 0.1 mg/m³;
- USA⁶⁴: threshold limit value (TWA) as persulfates of 0.1 mg/m³ (ACGIH 2001).

A common value at EU level could be established by the SCOEL and/or RAC⁶⁵ in order to harmonise the OELs between Member States and provide an OEL to Member States which have not yet established any. However establishing an OEL to avoid sensitization is tricky. Sensitization is usually considered as a non-threshold hazard and therefore an evaluation would need to be performed to determine whether a threshold can be established nevertheless, at least for the sensitization phase, and whether the OEL should be lower than the currently existing ones. Individuals who are already sensitized would not be protected however, but this measure could help prevent new cases.

Generally speaking, an harmonised OEL would improve the overall prevention of risks related to persulfates in occupational settings, for example during manufacture of persulfates, formulation of products, industrial and professional (non-cosmetic) use of persulfates and products containing persulfates. However, the practicality of implementation and enforcement of OELs in hairdressing salons is not certain and would need to be studied beforehand, because hairdressing salons are usually very small companies and are numerous in EU.

It should be noted also that new data is currently being generated in the context of a CCH for the endpoints mutagenicity and reproductive toxicity. The data should become available by 2020. If on the basis of this new data, lower thresholds are identified, they would need to be taken into account in the derivation of the OEL.

B. REACH restriction (Annex XVII)

Although persulfates would theoretically meet the criteria to propose a restriction of the placing on the market of products containing persulfates where risks were identified, this is unfortunately not a suitable option to manage cosmetics. Indeed, cosmetics are exempted from the restriction procedure according to Article 67(2) of the REACH regulation, with regard to restrictions addressing the risks to human health.

C. Substance evaluation

The concerns regarding skin and respiratory sensitisation are already well-known and this is reflected in the classification under CLP as Skin Sens. 1, H317 (may cause an allergic skin reaction) and Resp. Sens. 1, H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled). This classification is not

⁶⁴ <https://www.cdc.gov/niosh/ipcsneng/neng0632.html> accessed 4 April 2018.

⁶⁵ Risk Assessment Committee.

questioned as it is widely supported by data and acknowledged by the scientific and industrial communities. Substance evaluation would not have any added value for this endpoint as sufficient data is already available.

Although no article in the REACH regulation explicitly exempts cosmetics from Substance Evaluation, the REACH registration dossiers do not contain any information on cosmetic use and related exposure assessment and risk characterisation for human, in accordance with Article 14(5)(b) which says that the CSR need not include consideration of the risks to human health from the end use in cosmetic products. Therefore no information would be available for the purpose of Substance Evaluation and therefore this procedure do not seem adequate to address the risks related to cosmetics.

However, it should be noted that new data is currently being generated in the context of a CCH for the endpoints mutagenicity and reproductive toxicity, and depending on the outcomes of these studies (to be available by 2020), if additional concerns are identified, Substance Evaluation could be a suitable option in the future for all other uses.

It is important to note also that disodium persulfate is currently being evaluated by Portugal in the framework of the Biocidal Product Regulation as an active substance in PT04 (disinfectants for food and feed area). In this context, a comprehensive evaluation of all hazards endpoints will be performed and the results of this evaluation could be used when available for consistency and efficiency.

D. REACH authorisation (Annex XIV) on the basis of the sensitising properties of persulfates

According to the recent discussions that occurred between ECHA, COM and Member States in the framework of the SVHC 2020 Roadmap, identification of persulfates as SVHC of equivalent level of concern in the frame of Article 57(f) should be feasible, since these substances are respiratory sensitisers and are among the most reported substances involved in occupational asthma after isocyanates and anhydrides.

Table 15: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	X*	
b) Registrations in accordance with Article 10?	X	
c) Registrations include uses within scope of authorisation?	X**	
d) Known uses <u>not</u> already regulated by specific EU legislation that provides a pressure for substitution?	X	

* 57(f) on the basis of the sensitising properties of the persulfates.

** other than biocidal and cosmetic uses

Consumers and professionals' exposure to these sensitisers is clearly demonstrated. There are substantial social and economic impacts for the persons involved (for example, some young apprentices have to be re-oriented and some hairdressers can no longer perform their original work).

Nevertheless, authorisation does not apply for uses in cosmetics within the scope of Directive 76/768/EEC according to Article 56(5)(a). Moreover, the problem is rather focused on the conditions of use and the form of the substance (powdered). In industrial settings where ventilation and personal protective equipment (PPEs) are normally better applied than in salons, only few cases of sensitisation have been reported. Authorisation could not be proportionate as the problem, according to the current knowledge, is clearly related to cosmetics end-uses by hairdressers and consumers which is out of scope of authorisation.

E. Improvement of the hairdressers' training (including for apprentices) to raise awareness on risks related to exposure to persulfates, on organisational prevention measures and on collective and personal protective equipments

A European Framework Agreement on the protection of occupational health and safety in the hairdressing sector was signed on 26 April 2012⁶⁶ by the European social partners in the hairdressing sector (Coiffure EU⁶⁷ and UNI Europa Hair & Beauty⁶⁸) and is supported by the European Agency for Safety and Health at Work (EU-OSHA), the International Labour Organization (ILO) and the World Health Organization (WHO), as reported in the EU-OSHA report on Occupational health and safety in the hairdressing sector (2014)⁶⁹. It endorses the principles of **prevention** in general under Directive 89/391/EEC and applies to employers, workers and self-employed hairdressers. The intention is to have it assessed by the European Commission in view of its implementation at national level through a Council decision so that it becomes legally binding. In parallel and to support this Framework Agreement, Coiffure EU and UNI Europa Hair & Beauty adopted a 'Declaration on health and safety in the hairdressing sector' on 17 May 2016⁷⁰, which states, under paragraph 20: "The Parties urge that **staff be given regular training on the correct and safe use of the products.**" An essential prerequisite to make it possible is that cosmetic products placed on the market are compliant with the cosmetics regulation, and in particular that they include appropriate information on the conditions of safe use.

The effectiveness of education and training in the use of hazardous substances in salons was addressed by Lee and Nixon (2001) who surveyed 184 hairdressers and 193 hairdressing students in Melbourne, Victoria, Australia (see also Nixon *et al.*, 2006). Approximately 10% of students could not recall learning about skin problems and 95% of students did not understand the term "allergy". Approximately 4% of students said they had received no occupational health and

⁶⁶ European Commission (2012), DG EMPL. Hairdressing sector agrees on new measures to boost health and safety. News of the 26/04/2012, available at <http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=1286&furtherNews=yes>.

⁶⁷ <http://www.coiffure.eu/>.

⁶⁸ <http://www.uniglobalunion.org/sectors/hair-beauty/about-us>.

⁶⁹ European Agency for Safety and Health at Work (EU-OSHA) (2014). Eeckelaert L., Dontas S., Georgiadou E., Koukoulaki-Elinyae T., Munar L. Based on an input from the Topic Centre – Occupational Safety and Health (TC-OSH). Occupational health and safety in the hairdressing sector. ISSN: 1831-9343. ISBN: 978-92-9240-278-5 doi: 10.2802/86938. Available at https://osha.europa.eu/en/tools-and-publications/publications/literature_reviews/occupational-health-and-safety-in-the-hairdressing-sector.

⁷⁰ Declaration of the European Social Partners on Health and Safety in the Hairdressing Sector (2016). http://www.uniglobalunion.org/sites/default/files/files/news/20160517_declarationhs_hairdressingsdc_final_0.pdf.

safety training, 49% had received "some" and 46% said they had received "quite a bit" or "a lot". The study identified a number of areas where the training of hairdressers in colleges was deficient. These included knowledge relating to: skin disorders, damaging substances used in hairdressing, how substances damage the skin and understanding MSDS and appropriate glove use (NICNAS, 2001). In France, a survey was conducted with apprentices in first year of hairdressing schools (Girardin *et al.*, 2010). 50% said that they use gloves with holes or unclean gloves, 20% that they never use gloves for hair coloring, 40% that they use the inside-out technique during their work, 50% already had hand dermatosis, and 60% had had preventative advice (including 20% from a doctor). This illustrates a lack of awareness on chemical risks among apprentices. In United Kingdom, a survey was conducted with 121 trainee hairdressers from 2 hairdressing colleges (Ling and Coulson, 2002) and showed that 17% of the trainees currently suffered from hand dermatitis, 2/3 of trainees were not aware that atopic eczema predisposed to hand dermatitis, gloves were being worn by only 9% when shampooing and 58% when perming. One of the conclusions of this study was also that prevention of hand dermatitis by education and pre-employment counseling is of fundamental importance. In United Kingdom still, a campaign entitled "Bad Hand Day?" was launched in 2006 to raise awareness of work-related dermatitis in the hairdressing industry, targeting 20 000 hairdressers. HSE, local Authorities, government appointed standards setting body of hair and beauty industry (Habia) and professional organisations (NHF⁷¹ and HBSA⁷²) have worked together to raise awareness and promote good hand care, including the use of the correct type of gloves. In the Netherlands, a national plan has been put in place in order to reduce the prevalence of hand eczema among hairdressers with encouraging results (Terwoert *et al.*, 2002). The efficiency of evidence-based education with trained supervisors has been shown to be an efficient tool for skin-protection programs (Bregnhøj, 2011). All these examples highlight that the improvement of the hairdressers training is feasible and a very positive complementary tool.

Material available in the context of SafeHair project⁷³ may prove useful for that purpose.

If the cosmetic regulation has been adequately implemented, this risk management option is relevant to prevent risks related to skin and respiratory sensitization due to persulfates for hairdressers, also taking into account all other possible hazards in this occupation, and should also efficiently reduce risks for consumers (clients of hair salons).

F. Enforcement of OSH (occupational safety and health) legislation by the labour inspectorate.

Diammonium and dipotassium persulfates have harmonised classification as Acute Tox. 4*, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2, Resp. Sens. 1 and STOT SE 3, and disodium persulfate meets the same criteria for classification. Hence they are considered as "hazardous chemical agents" according to Article 2(b)(i) of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. By application of Article 5 of this Directive, risks to the health and safety of workers at work involving hazardous

⁷¹ National Hairdressers' Federation.

⁷² Hairdressing and Beauty Suppliers Association.

⁷³ <http://www.safehair.eu/safehair/homepage.html>.

chemical agents shall be eliminated or reduced to the minimum. In view of the numerous occupational disease cases in hairdressing salons, this Directive is not properly implemented.

In accordance with Directive 94/33/EC on the protection of young people at work, young persons under 18 are prohibited to use sensitizing substances according to Article 7 and Annex I of this Directive. In France, young people can start an apprenticeship for hairdressing from 14 years old. Therefore apprentices should not use persulfates. However RNV3P data show that 25.3% of occupational diseases recorded in the database affect apprentices, which reveals that this Directive is not properly implemented.

It should be noted, however, that cosmetic products in their finished state are exempted from classification and labelling (Article 1(5)(c) of the CLP Regulation) and from information to the supply chain (Article 02(6)(b) of the REACH regulation), which means that employers/users may not even be aware of the sensitizing properties of the products that they handle. Employers cannot implement OSH legislation if the information is not made available to them by the persons responsible for the placing on the market of the cosmetic products. Adequate implementation of the cosmetics regulation is therefore an essential prerequisite to ensure that products placed on the market are safe, and that information on the conditions of safe use are available.

The National Enforcement Authorities (labor inspectorate) are recommended to enforce Directive 98/24/EC and Directive 94/33/EC in hairdressing salons if the cosmetics regulation has been adequately implemented and enforced (see section G) but fails to manage the risks.

G. Regulation of persulfates in the frame of Regulation (EC) 1223/2009 on cosmetic products

In accordance with Article 2(1)(f) of the Cosmetic Regulation (EC) 1223/2009 which has come into force on 11 July 2013, consumers and professionals who uses cosmetic products are both defined as a "end users": "'end user' means either a consumer or professional using the cosmetic product". Thus, the consumers and the professional users (hairdressers) who are exposed to persulfates while manipulating the cosmetic products are both in the frame of this regulation. This is also confirmed in ECHA factsheet "Interface between REACH and Cosmetic regulations"⁷⁴.

According to Article 3 of this Regulation, "a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use". There are numerous and strong evidences that the placing on the market of cosmetic products containing persulfates are not compliant with the Regulation. According to Article 23(4) and (5), "Where end users or health professionals report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information on the cosmetic product concerned to the competent authorities of the other Member States and to the responsible person. Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27." In case of

⁷⁴ ECHA factsheet "Interface between REACH and Cosmetic regulations". ECHA-14-FS-04-EN. ISBN: 978-92-9244-819-6 - DoI: 10.2823/64527. October 2014. Accessible at https://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf.

non-compliance by the responsible person, which is the case here, according to Article 25, the responsible person can be requested by the Competent Authorities to take appropriate measures and in case of failure to do so, **“the competent authority shall take all appropriate measures to prohibit or restrict the making available on the market of the cosmetic product or to withdraw the product from the market or to recall it”** (Article 25(5)).

Therefore, the cosmetic regulation is the appropriate framework for managing the risk identified for persulfates use in hair bleaching products by professionals (hairdressers) and by consumers.

As highlighted by the European Agency for Safety and Health at Work (EU-OSHA) in 2014⁶⁹, “It is of major importance that the products used have been designed and manufactured in compliance with the EU Cosmetics Regulation (EC Regulation No 1223/2009)”.

In the ‘Declaration on health and safety in the hairdressing sector’ adopted in May 2016 by the social partners Coiffure EU and UNI Europa Hair & Beauty (see option E), the hair cosmetic industry and the manufacturers of the other substances used in the sector are called upon “to step up their research into the use of the substances which are less harmful to the skin and respiratory tract” and to substitute “hair cosmetics (e.g. blonding agents, dyes) releasing dust into the air”. Also, under paragraph 18, **“The Parties call upon the European Commission to take account of occupational hazards linked to the professional use of cosmetic products when approving substances under the cosmetic legislation”**.

Increased regulatory pressure on these cosmetics ingredients could promote the development of alternatives and substitution of the substances.

In France, Anses is not in charge of the assessment of cosmetics as this activity is in the scope of ANSM. In addition, cosmetics totally escape the REACH regulation when risks for human health are identified, as they are exempted from information to the supply chain, from assessment in a CSR, from restriction and from authorisation, according to:

- Article 02(6)(b): “The provisions of Title IV [information to the supply chain] shall not apply to the following mixtures in the finished state, intended for the final user (...) cosmetic products”,
- Article 14(5)(b): “The chemical safety report need not include consideration of the risks to human health from the following end uses (...) cosmetic products”,
- Article 56(5)(a): “In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) [CMR 1A/1B] or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article [authorisation granted] shall not apply to the following uses (...) uses in cosmetic products”,
- Article 67(2): “Paragraph 1 [A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.(...)] shall not apply to the use of substances in cosmetic products, as defined by Directive 76/768/EEC, with regard to restrictions addressing the risks to human health within the scope of that Directive.”

According to our information, the Committee of cosmetic products of DG SANTE from the European Commission can request the SCCS (Scientific Committee on Consumer Safety) to evaluate a substance in view of a restriction under Article

25. Therefore, **Anses urges the Competent Authorities in charge of Cosmetics to request SCCS to assess this risk for end-users (professionals and consumers) and to take adequate action under the Cosmetics Regulation to ensure that products placed on the market are safe for the users.** Several options to restrict for example the type of formulation and packaging are proposed (see 5.1), but only the appropriate evaluation and risk management in the framework of the Cosmetics Regulation can identify the adequate conditions for restriction.

H. Harmonised Classification and Labelling for disodium persulfate

Disodium persulfate is the only substance of the persulfate category that is not classified in the Annex VI of CLP. France initially added disodium persulfate on the Registry of Intention for classification in October 2012. However, realising that Portugal was evaluating this substance in the framework of the Biocidal Product Regulation (as active substance in PT04), and following confirmation by Portugal that they would evaluate the need of a classification in the frame of their biocidal evaluation, this intention was withdrawn. A proposal of harmonised classification is therefore expected in the near future.

The classification threshold according to Annex I (3.4) of CLP Regulation imply that mixtures containing (skin/respiratory) sensitizing substance above 0.1% must be labelled with EUH208 – ‘Contains {name of sensitizing substance}. May produce an allergic reaction’ according to Annex II (2.8), and mixtures containing (skin/respiratory) sensitizing substance above 1% must be classified as respiratory and skin sensitizer.

It should be noted however that although dipotassium and diammonium persulfates already have harmonised classification and disodium persulfate is self-classified, available cosmetovigilance data show that all three persulfates are still causing adverse effects due to the use as cosmetics. Classification alone is not sufficient to manage the risks for cosmetics and to inform end-users, since **cosmetic products are exempted from information to the supply chain (Article 02(6)(b) of the REACH regulation) and from classification and labelling as mixture (Article 1(5)(c) of the CLP Regulation).** Only adequate implementation of the Cosmetics Regulation can make labelling of cosmetic products containing persulfates as “sensitisers” mandatory.

I. Improvement of exposure scenarios in Chemical Safety Reports (CSR) and extended Safety Data Sheets (eSDS)

The exposure scenarios include a description of the uses, of the operational conditions (OCs) and of the risk management measures (RMMs) in order to achieve safe use.

A CCH was undertaken by ECHA (Decision of 8 September 2016) since the registration dossiers for the 3 persulfates were not compliant to Annex I, 5 and 6 of REACH, as safe use was not demonstrated regarding skin and respiratory sensitization. The registrants were requested to provide a qualitative exposure assessment demonstrating the likelihood that effects of inhalation and skin sensitisation are avoided for all worker and consumer exposure scenarios and detail the operational conditions and risk management measures and revise the exposure assessment and risk characterisation accordingly.

The registrants updated the section 11 in IUCLID and section 9.0.2 of the CSR to include a qualitative assessment. However, the conditions of use (operational

conditions (OCs) and risk management measures (RMMs)) reported in the exposure scenarios (sections 9.1 to 9.8) still enable only to manage the risks related to long-term exposure. In other terms, the conditions of use which were derived following the qualitative assessment were not included in the exposure scenarios. Therefore, the information communication along the supply chain via the extended Safety Data Sheets (eSDS) would either be only the conditions of use related to systemic long-term effects, which would be incomplete, or either two sets of conditions of use (for systemic effects on one hand and for sensitization of the other hand) at the same time, which would be confusing.

Therefore, the exposure scenarios must be updated in the CSR and the eSDS to describe for each exposure scenario **one unique set of OCs and RMMs** able to manage the risks related to both sensitization and systemic long-term effects.

Although no need for specific EU-wide action (additional to the standard REACH requirements) was identified yet for the manufacture of persulfates, formulation of products, industrial and professional (non-cosmetic) use of persulfates and products containing persulfates (see 5.1), this improvement – which is also a REACH requirement! – would contribute to improve workers safety (except for cosmetics end-uses as they are out of scope according to Article 2(6)(b) of the REACH regulation).

J. Enforcement of REACH regulation on exposure scenarios in extended Safety Data Sheets (eSDS)

Exposure scenarios describing the registered uses and adequate OCs and RMMs must be communicated via the extended SDS to downstream users.

Some cases of occupational allergies were reported for workers manufacturing persulfates and formulating products (including formulating cosmetics). This shows that the exposure scenarios may not be properly communicated and/or implemented. Deficiencies were noted (NICNAS, 2001; Keegel *et al.*, 2004 and 2007) in the reporting of information on sensitizers on safety data sheets.

In addition, consumer exposure scenarios were removed following the CCH and a survey conducted by the registrants to their downstream users. Nevertheless, some consumer uses are recorded in the SPIN database, which raise questions and highlights the need to make sure that all downstream users in the supply chain, for those who might be concerned, must either completely stop using these substances to formulate products intended for consumers, or must provide a Downstream User report to demonstrate safe use. In any case, the change in the consumer exposure scenarios must be communicated to the supply chain and enforcement authorities should be made aware that consumer uses other than cosmetics are not expected.

Altogether, National Enforcement Authorities are recommended to enforce the exposure scenarios in eSDS for persulfates and products containing persulfates, in order to ensure that the requirements of REACH are properly implemented and safe use is ensured, and be should be made aware that consumer uses other than cosmetics are not expected.

5.3 Conclusions on the most appropriate (combination of) risk management options

Table 16: Summary of the risk management options

Management Options	Risk identified for end-uses as cosmetics		Remarks
	Professionals	Consumers	
A Occupational exposure limit (OEL) at EU level	Questionable	Not relevant	Would be beneficial to increase workers safety
B Restriction under REACH	Out of scope because identified risks are related to human health [Article 67(2) of the REACH regulation]	Out of scope because identified risks are related to human health [Article 67(2) of the REACH regulation]	/
C Substance evaluation under REACH	Inadequate/not necessary	Inadequate/not necessary	May be considered after completion of CCH, for other endpoints and non-cosmetic uses
D Authorisation under REACH	Out of scope because persulfates meet the criteria in Article 57(f) for hazards to human health [Article 56(5)(a)]	Out of scope because persulfates meet the criteria in Article 57(f) for hazards to human health [Article 56(5)(a)]	Not proportionate for other uses
E Training to raise awareness on risks related to exposure to persulfates, on organisational prevention measures and on collective and personal protective equipments.	Adequate option as a follow-up to G	Adequate option as a follow-up to G	/
F Enforcement of OSH (occupational safety and health) legislation	Adequate option as a follow-up to G and E	Adequate option as a follow-up to G and E	Would be beneficial to increase workers safety
G Regulation in the frame of Cosmetics Regulation (EC) 1223/2009	Preferred option	Preferred option	/
H Harmonised Classification and Labelling for sodium persulfate	Out of scope because cosmetics are exempted [Article 1(5)(c) of the CLP Regulation] Labelling of cosmetics is to be implemented under G	Out of scope because cosmetics are exempted [Article 1(5)(c) of the CLP Regulation] Labelling of cosmetics is to be implemented under G	Would be beneficial to increase workers safety (except for cosmetic end-uses), but efficiency of this RMO is questionable
I Improvement of exposure scenarios in Chemical Safety Reports (CSR) and Safety	Out of scope because cosmetics are exempted	Out of scope because cosmetics are exempted	Would be beneficial to increase workers safety (except for

Data Sheets (SDS)	[Article 2(6)(b) of the REACH regulation]	[Article 2(6)(b) of the REACH regulation]	cosmetic end-uses)
Enforcement of REACH regulation on exposure scenarios in extended Safety Data Sheets (SDS)	Out of scope because cosmetics are exempted [Article 2(6)(b) of the REACH regulation]	Out of scope because cosmetics are exempted [Article 2(6)(b) of the REACH regulation]	Would be beneficial to increase workers safety (except for cosmetic end-uses)

This RMOA was initially started to investigate risk management options for known sensitizers not yet regulated, and in the course of the work, risks were clearly identified for one specific use which turned out to be out of the scope of REACH, i.e. the use of persulfates in cosmetics. Therefore, other options were investigated to trigger action from the Competent Authorities in charge of cosmetics and OSH (occupational safety and health).

The risks related to sensitizing effects of persulfates have been known since the 1930s and for hairdressers since the 1960s (if not even earlier), but obviously, no adequate prevention has been implemented yet. Products available on the market are still not safe, and no regulatory binding action has ever been taken. Between the last version of this RMOA (Anses opinion published in February 2014) and the current report, about 530 new cases of occupational diseases were reported in RNV3P for hairdressers⁷⁵. This is not an acceptable situation in EU and therefore it is urgent to take actions.

Anses concludes that persulfates should be regulated in the framework of the Cosmetics Regulation (EC) 1223/2009 as a first step. Indeed, the necessary basis for adequate prevention in hair salons is to ensure that cosmetic products placed on the market are safe and that all necessary information regarding hazards and risk prevention are made available (Article 3 of the cosmetics regulation) to all users (professional users and consumers) by the person responsible for the placing on the market. Therefore, adequate regulation under the Cosmetics Regulation (EC) 1223/2009 is an essential prerequisite, especially as cosmetics are exempted from classification and labelling (under CLP) and information to the supply chain via safety data sheets (under REACH). Then a combination of better prevention at workplace, of training of professionals, and of enforcement of occupational safety and health (OSH) legislation would be made possible as a further management option.

Anses is not in charge of cosmetics in France, and therefore may not be aware of all the available, practical and efficient options to manage risks related to cosmetics. Consequently, the choice of the most adequate risk management option(s) should not be limited to the ones presented in this RMOA, but could usefully be supplemented with any other options found relevant by the Competent Authorities in charge primarily of cosmetics (and then OSH), who are in the best position to identify the best risk management options for cosmetics.

Therefore, Anses urges the Competent Authorities in charge of cosmetics to take actions and regulate end-uses of persulfates in cosmetics under the Cosmetics Regulation (EC) 1223/2009.

Complementary actions should be also be envisaged by OSH Competent Authorities regarding the uses of persulfates.

⁷⁵ The previous version included RNV3P data from 2001 to 2009 and the current version includes RNV3P data from 2001 to 2015. 617 cases of persulfates-related occupational diseases were identified for the period 2001-2009 (97.7% for hairdressers), and 1144 for the period 2001 to 2015 (97.9% hairdressers).

Anses also points out that, on a general basis, risk management at workplace for persulfates would benefit from improvement and enforcement of exposure scenarios in Chemical Safety Reports (CSR) and extended Safety Data Sheets (eSDS) and from establishing a harmonised OEL. Anses also recommends the National Enforcement Authorities to be vigilant for any consumer use other than cosmetics which are not supported by the REACH registrations.

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Notes on the references:

A literature search was performed on PubMed (131 publications retained); in addition, other publications and reports were collected from preliminary work, from previous assessment by other organisations and from the industry. All references cited in the RMOA are listed under "References cited in the RMOA" below, which includes the publications obtained from the search on PubMed (identified with an (*)) and the other references.

The other publications retained from the search on PubMed, but not cited in the RMOA, are listed under "Additional references, not cited in the RMOA, obtained from the search on PubMed" below, for information purpose.

Method for the literature search:

- Database: PubMed
- Date of query: 30 March 2018
- Query: (persulfate*[Title/Abstract] OR persulphate*[Title/Abstract]) AND (allerg*[Title/Abstract] OR asthma[Title/Abstract] OR eczema[Title/Abstract] OR dermatitis[Title/Abstract] OR urticaria[Title/Abstract] OR rhinitis[Title/Abstract] OR hair*[Title/Abstract] OR hairdresser*[Title/Abstract] OR hypersensi*[Title/Abstract] OR sensitis*[Title/Abstract]). 135 publications were identified.
- 11 publications were removed after reading the abstracts because they were considered not relevant in the context of the RMOA.
- 7 publications obtained elsewhere were added (older publications not found on PubMed, publications in other languages).

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Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienist
ACToR	Aggregated Computational Toxicology Resource, USA
Anses	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety)
ANSM	Agence nationale de sécurité du médicament (French Agency for medical products)
BPR	Biocidal Product Regulation (EU) 528/2012
BUMAC	Building Material and Consumer Product Database, complemented with the data acquired in the framework of the EPHECT project
CAS	Chemical Abstract Service
CCH	Compliance Check
CDR	Chemical Data Reporting Rule under TSCA, USA
CESES	Consumer Exposure Skin Effects and Surveillance, NL
CIR	Cosmetic Ingredient Review
CLP	Classification, Labelling and Packaging (Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures))
COEH	Centre for Occupational and Environmental Health, University of Manchester, UK
CoRAP	Community Rolling Action Plan
CPCat	Chemical and Product Categories, USA
CSR	Chemical Safety Report
DK	Denmark
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
EPHECT	Emission, Exposure Patterns and Health Effects of Consumer Products in the EU
EPIDERM	Occupational Skin Surveillance scheme, UK
ERC	Environmental Release Category
eSDS	extended Safety Data Sheet
EU COM	European Commission
EU-OSHA	European Agency for Safety and Health at Work
FDA	Food and Drug Administration (USA)
FI	Finland
FR	France
GERDA	Groupe d'Etude et de Recherche en Dermato-Allergologie – group for study and research on dermal allergology (France)
HBSA	Hairdressing and Beauty Suppliers Association (UK)

HERA	Human and environmental risk assessment on ingredients of household cleaning products
HPV	High Production Volume
ILO	International Labour Organization
INCI	International Nomenclature of Cosmetic Ingredients
IPCHEM	Information Platform for Chemical Monitoring
IUCLID	International Uniform Chemical Information Database
IUR	Inventory Update Reporting, USA
IVDK	Information Network of Departments of Dermatology
JS	Joint submission
KEMI	Swedish Chemicals Agency
MEGA	Messdaten zur Exposition gegenüber Gefahrstoffen am Arbeitsplatz
MSCA	Member States Competent Authorities
MSDS	Material Safety Data Sheet
NACE	Nomenclature statistique des activités économiques dans la Communauté européenne (Statistical Classification of Economic Activities in the European Community)
NHF	National Hairdressers' Federation (UK)
NICNAS	Australian National Industrial Chemicals Notification and Assessment Scheme
NL	The Netherlands
NO	Norway
OC	Operational Condition
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Level
ONAP	Observatoire national des asthmes professionnels (national observatory for occupational asthma, France).
OPRA	Occupational Physicians Reporting Activity
OSH	Occupational safety and health
OSHA	Occupational Safety and Health Administration (USA)
PC	Product Category
PPE	Personal Protective Equipment
PROC	Process Category
RAC	Risk Assessment Committee
REVIDAL	Réseau de Vigilance en Dermato-Allergologie – vigilance network on dermal allergology (France)
RiME	Risk Management Expert Meeting
RIVM	National Institute for Public Health and the Environment of the Netherlands
RMM	Risk Management Measure
RMOA	Analysis of the most appropriate risk management option

RNV3P	French Workers' Health Surveillance and Prevention Network
SDS	Safety Data Sheet
SCCS	Scientific Committee on Consumer Safety
SCOEL	Scientific Committee on Occupational Exposure Limits
SE	Sweden
SICAP	Poison center information system, France
SIDS	Screening information datasets.
SIEF	Substance Information Exchange Forum
SPIN	Substances and preparations in Nordic countries
STOT SE	Specific target organ toxicity after single exposure
SVHC	Substance of Very High Concern
SWORD	Surveillance of Work-Related and Occupational Respiratory Disease, UK
THOR	The Health and Occupation Research network, UK
TSCA	Toxic Substances Control Act (USA)
TWA	Time-weighted average
UK	United Kingdom
UK HSE	UK Health and Safety Executive
USA	United States of America
WHO	World Health Organization

ANNEX I – CONFIDENTIAL INFORMATION

Refer to confidential version.