Risk Management Option Analysis Conclusion Document

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: 2019-06-02

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

			Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
RMOA		Risk Management Option Analysis (RMOA) other than this RMOA	☐	☐	☐
REACH Processes	Evaluation	Compliance check, Final decision	☒ Decision of 8 September 2016[2]: a follow-up according to Article 42 is available for the human exposure-related request (see confidential Annex I).	☒ Decision of 29 September 2014[3]: a follow-up accordinag to Article 42 is available (see confidential Annex I). Decision of 8 September 2016[4]: a follow-up according to Article 42 is available for the human exposure-related request (see confidential Annex I).	☒ Decision of 8 September 2016[5]: a follow-up according to Article 42 is available for the human exposure-related request (see confidential Annex I).
		Testing proposal	☐	☐	☐
		CoRAP and Substance Evaluation	☐	☐	☐
	Authori-sation	Candidate List	☐	☐	☐
		Annex XIV	☐	☐	☐
	Restriction	Annex XVII	☐	☐	☐
Harmonised C&L		Annex VI (CLP) (see section **Erreur ! Source du renvoi introuvable.**)	☒	☒	☐

[2] https://echa.europa.eu/documents/10162/734e2ae1-f446-e849-d7e0-3166853b82f8.

[3] Not found on ECHA website.

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

[5] https://echa.europa.eu/documents/10162/354ab374-b18f-bb8b-5ae9-57b6da7a1afa.

		Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
Processes under other EU legislation	Plant Protection Products Regulation Regulation (EC) No 1107/2009	☐	☐	☐
	Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	☐	☒ Listed in Annex I (*Active Substances identified as existing*) of the EU Regulation 1451/2007[6] (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.	☒ Listed in Annex I (active substances identified as existing) of the EU Regulation 1451/2007[6] (work programme for the review of biocidal active substances). Listed in Annex II (substance/product-type combinations[7]) for PT04 (food and feed area disinfectants) in the EU Regulation 1062/2014[8] (update of the work programme for the for the review of biocidal active substances). The 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)	☐	☐	☐
	Existing Substances Regulation	☐	☐	☐

[6] 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.

[7] 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.

[8] 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.

		Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
	Regulation 793/93/EEC (RAR/RRS)			
(UNEP) Stockholm convention (POPs Protocol)	Assessment	☐	☐	☐
	In relevant Annex	☐	☐	☐
Other processes/ EU legislation	Other (seedetails below)	☒	☒	☒
	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[9] (measured as [S_2O_8])	**Belgium, Ireland, Spain**: the 8-hour TWA[10] 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 is 4 mg/m^3 and the 8h- TWA is 2 mg/m^3	**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 mg/m^3
		United Kingdom: the 8-hour TWA is 1 mg/m^3 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." Until now, no occupational limit value (OEL) at Community level has been adopted by the Scientific Committee on Occupational Exposure Limits (SCOEL).[11] **OELs in non-EU countries:** - **Australia**: the short-term value (ceiling limit value) is 0.1 mg/m^3 - **USA**[12]**:** TLV (Threshold Limit Values): (as persulfates) 0.1 mg/m^3 as TWA (ACGIH[13] 2001).		
	EU Directive 94/33/EC on young people at work, as	Young persons under 18 are prohibited to use sensitizing substances according to Article 7 and Annex I of this Directive.		

[9] As available on http://limitvalue.ifa.dguv.de/ on 29 March 2018.

[10] Time-weighted average.

[11] As available on https://circabc.europa.eu/w/browse/3fea9535-be67-47b7-a7f7-ef9c41367d9c on 29 March 2018.

[12] https://www.cdc.gov/niosh/ipcsneng/neng0632.html accessed 4 April 2018.

[13] American Conference of Governmental Industrial Hygienists.

		Diammonium persulfate	Dipotassium persulfate	Disodium persulfate
	amended by Directive 2007/30/EC			
	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[14]	INCI name: AMMONIUM PERSULFATE 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). 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).	INCI name: POTASSIUM PERSULFATE Function: **OXI** (oxidising: changes the chemical nature of another substance by adding oxygen or removing hydrogen). This means that dipotassium 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).	INCI name: SODIUM PERSULFATE Function: **OXI** (oxidising: changes the chemical nature of another substance by adding oxygen or removing hydrogen). This means that disodium 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).
	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.			

Please provide a brief overview of completed/ongoing processes (including RMOA) and EU legislation relevant for the substance.

[14] http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple accessed 29 March 2018.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	X
Need for action other than EU regulatory action	
No action needed at this time	

Summary of the risk management options

This RMOA was initially started to investigate risk management options for known sensitisers not yet regulated. The persulfate category (3 substances) was prioritized based on dispersive uses and high tonnage. 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.

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.

Therefore, The French authorities urges the committee of cosmetics products of DG SANTE from the European commission to assess the risk for end-users (professionals and consumers) and to take actions and regulate end-uses of persulfates in cosmetics under the Cosmetics Regulation (EC) 1223/2009.

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

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Other Union-wide regulatory measures

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).

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, conjunctivis, 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.

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.

The hazards related to skin and respiratory sensitisation related to persulfates are very well known and acknowleged 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 and presented in the report

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). The french authorities conclude that the cosmetic regulation is one of the most appropriate framework for managing the risk identified for persulfates use in hair bleaching products by professionals

(hairdressers) and by consumers.

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