Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Potassium permanganate
EC Number:	231-760-3
CAS Number:	7722-64-7
Authority:	France
Date:	21/03/2017

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

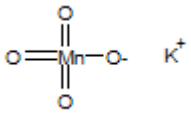
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Potassium permanganate
IUPAC name (public):	K-permanganat Kálium-permanganát Potasodium permanganate Potassium manganate (vii) Potassium manganate(VII) Potassium manganesoylolate Potassium oxido(trioxo)manganese Potassium permanganat Potassium Permanganate
Index number in Annex VI of the CLP Regulation:	025-002-00-9
Molecular formula:	HMnO4.K / KMnO4
Molecular weight or molecular weight range:	158.03g/mol
Synonyms:	POTASSIUM PERMANGANATE POTASSIUM PERMANGANATE AWWA-Free Flowing POTASSIUM PERMANGANATE, pureneedles

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Other manganese compounds.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	

Other processes / EU legislation	☐ Other (provide further details below)
Further details	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

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)		
025-002-00-9	potassium permanganate	231-760-3	7722-64-7	Ox. Sol. 2 Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H272 H302 H400 H410		

3.1.2 Self classification

- In the registration:

In addition to the harmonized classification:
- Skin Corr 1C – H314
- STOT RE. 2 – H373 (liver, oral)

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Skin Irrit. 2 – H315
  - Eye Irrit. 2 – H319
  - Skin Corr. 1A – H314
  - STOT SE 3 – H336
  - Muta. 2 – H341
  - Carc. 1B – H350
  - Aquatic Chronic 3 – H412

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

A CLH report was submitted by France for reproductive endpoint in 2015, with a proposal to classify the substance as Repro 1B – H360Df. This proposal was discussed

during the RAC 39 (December 2016). In fine, RAC proposed the following harmonised classification: Repr 2 – H361d.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
1 joint submission		

4.2 Overview of uses

Potassium permanganate is a highly oxidative agent. Its primary uses consist in control of odour and taste, remove colour, control biological growth and remove iron and manganese (EPA, 1999). According to the registration dossier, potassium permanganate is used by industrials, professionals and consumers. Various sectors of end use are identified: agriculture, forestry and fishing (SU 1); mining (SU 2a); offshore industries (SU 2b); printing and reproduction of recorded media (SU 7); building and construction work (SU 19); health services (SU 20); manufacture of various products (SU 4, 5, 6a, 6b, 8, 9, 12, 15, 16, 17, 18); formulation of preparation (SU 10); electricity, steam, gas water supply and sewage treatment (SU 23); scientific research and development (SU 24).

[1] *Dissemination site was accessed 7 March 2017.*

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	
Formulation	Waste water decontamination Blending, solution, industrial Repacking, industrial Production in batch design Water treatment, oxidant Blending, solution, repacking industrial
Uses at industrial sites	Production in continuous design Waste water decontamination Use in jeans bleaching Production in batch design Use in chemical synthesis Use in water treatment Repacking, industrial Use in soil remediation Water treatment, oxidant
Uses by professional workers	Use in water treatment Use as laboratory chemicals Waster water decontamination Spraying water solution Water treatment, oxidant
Consumer Uses	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor) Widespread use of reactive processing aid (no inclusion into or onto article, indoor)
Article service life	

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☐ Article 44(2) (refined prioritisation criteria for substance evaluation)

☒ Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

☒ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☒ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☒ Consumer use	☒ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

[2] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

In 2011, the registrants of the substance submitted a Testing proposal for a 2-generation study. This Testing Proposal was rejected considering that there was sufficient evidence to classify potassium permanganate as reprotoxic on the basis of the available one-generation study and a prenatal developmental study.

In this context, France submitted a CLH report with the proposed classification: Repro Cat. 2 for fertility (based on testicular effects and a decrease of the gestation index) and Cat. 1B for development (based on post-implantation loss and effects in pups brain). The proposal was discussed during the RAC-39 meeting. Despite the effets observed, the RAC only agreed on a classification as Repro 2 for development and no classification for fertility considering that the studies available were not sufficiently reliable.

Some additional reprotoxic concerns are reported with other manganese compounds (reduced fertility, number of implants and viable fetuses, neurodevelopmental toxicity) which support that a reprotoxic concern is raised for potassium permanganate and that the classification agreed at the RAC level may not be sufficient.

Overall, a reprotoxic concern (both fertility and development) still exists for potassium permanganate based on data available with this substance and based on effects seend with other manganese compounds. However, in their discussions during the meeting, RAC emphasized that available data are not of sufficient quality to conclude firmly on this endpoint.

An adequate and firm conclusion on the CMR properties of the substance is essential considering the uses identified and available on ECHA dissemination website. Although only limited information is available, widespread exposure is expected. In particular general population may be exposed due to consumer uses listed for the substance or via the environment (e.g. after water treatment). Therefore, in addition to the reprotoxic concern to be clarified, it is needed to have more information on the potential exposure of sensitive populations such as pregnant women and/or infants.

5.4. Preliminary indication of information that may need to be requested to clarify the concern

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☒ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

An EOGRTS with at least a developmental neurotoxicity cohort could be required on the basis of the reprotoxic concerns identified in the available data for the substance and the other manganese coumponds and on the lack of fully reliable data. This is also consistent with the Testing Proposal submitted by the registrants in 2011.

Only limited information on relevant uses is available in the dissemination website and in the registration dossier necessiting further clarifications, in particular regarding potential exposure of sensitive populations.

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)

Depending on results of the required data, update of the current harmonized classification could be needed for fertility and development.

In addition, considering the notified classifications, an update of the harmonized classification for other endpoints (e.g acute toxicity, irritation/corrosivity, repeated dose toxicity) could be necessary.