Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Sodium hydroxymethanesulphinate
EC Number:	205-739-4
CAS Number:	149-44-0
Authority:	NL MSCA
Date:	22/03/2016

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):	sodium hydroxymethanesulphinate
IUPAC name (public):	sodium hydroxymethanesulphinate
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	CH4O3S.Na
Molecular weight or molecular weight range:	118.09.
Synonyms:	Sodium hydroxymethane sulphinate (anhidrous form) Sodium Formaldehyde Sulfoxylate, corresponds to sodium hydroxymethane sulphinate with 2 eq of crystal water

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

Structural formula:

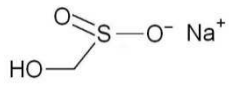


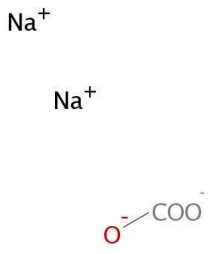
Table: Impurity

EC number:	231-175-3
EC name (public):	Zinc
CAS number:	7440-66-6
CAS name (public):	Zinc
IUPAC name (public):	Zinc
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	Zn
Molecular weight or molecular weight range:	65.37
Synonyms:	

Table: Additive

EC number:	207-838-8
EC name (public):	sodium carbonate
CAS number:	497-19-8
CAS name (public):	
IUPAC name (public):	disodium carbonate
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	CH2O3.2Na
Molecular weight or molecular weight range:	105.99
Synonyms:	

Structural formula:



1.2 Similar substances/grouping possibilities

Structural formula:

No data.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

<table>
<tr><td>RMOA</td><td colspan="2">☐ Risk Management Option Analysis (RMOA)</td></tr>
<tr><td rowspan="5">REACH Processes</td><td rowspan="3">Evaluation</td><td>☐ Compliance check, Final decision</td></tr>
<tr><td>☒ Testing proposal

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following proposed tests using the indicated test method:

a) Sub-chronic toxicity study in the rat via the oral route (Annex IX 8.6.2, test method: EU B.26/ OECD 408);

b) Pre-natal developmental toxicity study in the rat via the oral route (Annex IX, 8.7.2, test method: EU B.31/ OECD 414); and

c) Long-term toxicity testing on invertebrates (Annex IX, 9.1.5, test method: EU C.20/ OECD 211).

Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant shall carry out the following additional test using the indicated test method:

d) Long-term toxicity testing on fish (Annex IX, 9.1.6., test method: OECD 210 (Fish, Early-life Stage Toxicity Test)</td></tr>
<tr><td>☐ CoRAP and Substance Evaluation</td></tr>
<tr><td rowspan="2">Authorisation</td><td>☐ Candidate List</td></tr>
<tr><td>☐ Annex XIV</td></tr>
<tr><td>Restri -ction</td><td>☐ Annex XVII</td></tr>
<tr><td>Harmonised C&L</td><td colspan="2">☐ Annex VI (CLP) (see section 3.1)</td></tr>
</table>

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)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonized Classification and Labelling is available, although that in the IUCLID file on ECHA dissemination site is indicated, that C&L is according to EU implementation.

3.1.2 Self classification

- In the registration:

Muta. 2; H341: Suspected of causing genetic defects
Repr. 2; H361: Suspected of damaging fertility or the unborn child
EUH032: Contact with acids liberates very toxic gas.

- 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

  STOT SE 3, Respiratory system

  Resp. Sens. 1, H334

  Aquatic Chronic 3, H412

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration statusFrom 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
Joint Submission		

4.2 Overview of uses

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Formulation	PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 32: Polymer preparations and compounds PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids PC 35: Washing and cleaning products (including solvent based products) PC 23: Leather tanning, dye, finishing, impregnation and care products PC 19: Intermediate PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids
Uses at industrial sites	PC 20: Products such as pH-regulators, flocculants, precipitants, neutralisation agents PC 32: Polymer preparations and compounds PC 34: Textile dyes, finishing and impregnating products; including

	bleaches and other processing aids PC 35: Washing and cleaning products (including solvent based products) PC 23: Leather tanning, dye, finishing, impregnation and care products PC 19: Intermediate PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids
Uses by professional workers	PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 23: Leather tanning, dye, finishing, impregnation and care products PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids PC 32: Polymer preparations and compounds PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids PC 35: Washing and cleaning products (including solvent based products)
Article service life	AC 5: Fabrics, textiles and apparel AC 6: Leather articles AC 8: Paper articles AC 10: Rubber articles AC 13: Plastic articles

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[1]	
☐ 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)

[1] 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

The available data shows that this substance is mutagenic *in vivo* and indicates that it may have carcinogenic properties. In addition, the substance has some concern for developmental toxicity. As the substance is used by workers and may be present in consumer articles including textiles, there is a concern for both workers and consumers.

5.4 Preliminary indication of information that may need to be requested t 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)
Further information may be requested related to the toxicokinetic properties of the substance to determine the bioavailability and systemic exposure to the substance. This may indicate the likelyhood that the substance may reach the germ cells and thus whether testing for germ cell mutagenicity is warranted. If the systemic exposure is limited and no germ cell mutagenicity can be expected also the concern for local carcinogencity will be adressessed. The exposure assesment will focus on presence of the substance in articles and the possible exposure during the article service life.	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Depending on the outcome of the substance evaluation and additional information that may be requested via substance evaluation, harmonised classification is considered a relevant step also required for substances fulfilling the CMR criteria. Other actions depend on the category of the CMR classification and on the level of exposure.			