

Justification for the selection of a substance for CoRAP inclusion

| | |
|--------------------------------------|-----------------------|
| Substance Name (Public Name): | Disodium metasilicate |
| Chemical Group: | Inorganic |
| EC Number: | 229-912-9 |
| CAS Number: | 6834-92-0 |
| Submitted by: | Latvia |
| Date: | 17/03/2015 |

Note

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

Contents

| | | |
|-----|---|---|
| 1 | IDENTITY OF THE SUBSTANCE..... | 3 |
| 1.1 | Other identifiers of the substance | 3 |
| 1.2 | Similar substances/grouping possibilities | 4 |
| 2 | CLASSIFICATION AND LABELLING..... | 5 |
| 2.1 | Harmonised Classification in Annex VI of the CLP | 5 |
| 2.2 | Self classification | 5 |
| 2.3 | Proposal for Harmonised Classification in Annex VI of the CLP | 5 |
| 3 | INFORMATION ON AGGREGATED TONNAGE AND USES | 6 |
| 4 | OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION..... | 7 |
| 5 | JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE .. | 7 |
| 5.1 | Legal basis for the proposal | 7 |
| 5.2 | Selection criteria met (why the substance qualifies for being in CoRAP) | 7 |
| 5.3 | Initial grounds for concern to be clarified under Substance Evaluation | 8 |
| 5.4 | Preliminary indication of information that may need to be requested to clarify the concern | 8 |
| 5.5 | Potential follow-up and link to risk management | 9 |

1 IDENTITY OF THE SUBSTANCE

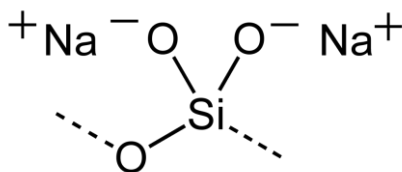
1.1 Other identifiers of the substance

Table 1: Substance identity

| | |
|---|---|
| EC name: | Disodium metasilicate |
| IUPAC name: | Disodium oxosilanediolate |
| Index number in Annex VI of the CLP Regulation | 014-010-00-8 |
| Molecular formula: | H ₂ O ₃ Si ₂ Na |
| Molecular weight or molecular weight range: | 101.1 |
| Synonyms/Trade names: | Silicic acid (H ₂ SiO ₃), disodium salt Sodium Metasilicate |

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Table 2: Silicic acid, sodium salt

| | |
|---|--|
| EC name: | Silicic acid, sodium salt |
| EC number: | 215-687-4 |
| IUPAC name: | sodium hydroxy(oxo)silanolate |
| Index number in Annex VI of the CLP Regulation | n/a |
| Molecular formula: | $\text{Na}_2\text{O} \cdot n\text{O}_2\text{Si}$ |
| Molecular weight or molecular weight range: | 100.0814 |
| Synonyms/Trade names: | <i>Silicic acid, sodium salt</i> |

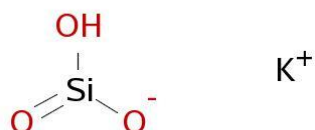
Structural formula:



Table 3: Silicic acid, potassium salt

| | |
|---|---|
| EC name: | Silicic acid, potassium salt |
| EC number: | 215-199-1 |
| IUPAC name: | potassium hydroxy(oxo)silanolate |
| Index number in Annex VI of the CLP Regulation | n/a |
| Molecular formula: | $\text{K}_2\text{O} \cdot n\text{O}_2\text{Si}$ |
| Molecular weight or molecular weight range: | 116.1899 |
| Synonyms/Trade names: | |

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

CLP criteria:

Skin Corr. 1B; H314: Causes severe skin burns and eye damage.
STOT SE 3; H335: May cause respiratory irritation.

DSD criteria:

C; R34: Causes burns.

Xi; R37: Irritating to respiratory system.

2.2 Self classification

- In the registration

CLP criteria: In addition to the harmonised classifications are the following self classifications given in the registrations:

Met. Corr. 1; H290: May be corrosive to metals.

Eye damage 1; H318: Causes serious eye damage.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Asp. Tox. 1; H304: May be fatal if swallowed and enters airways.

Acute Tox. 4; H302: Harmful if swallowed.

Eye Irrit. 2; H319: Causes serious eye irritation.

STOT SE 3; H370: May cause damage to organs.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

n/a

3 INFORMATION ON AGGREGATED TONNAGE AND USES

| | | | |
|--|--|--|--|
| From ECHA dissemination site | | | |
| <input type="checkbox"/> 1 – 10 tpa | <input type="checkbox"/> 10 – 100 tpa | <input type="checkbox"/> 100 – 1000 tpa | |
| <input type="checkbox"/> 1000 – 10,000 tpa | <input checked="" type="checkbox"/> 10,000 – 100,000 tpa | <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 | |
| | | | |
| <input checked="" type="checkbox"/> Industrial use | <input checked="" type="checkbox"/> Professional use | <input checked="" type="checkbox"/> Consumer use | <input type="checkbox"/> Closed System |
| <p>Industrial use: Use of powders as adhesives and binders in manufacture of bricks, ceramics and other construction materials. Use of powders as Adhesives and binders in manufacture of refractory cements and other refractory masses/mixes. Industrial uses. Use of powders as Adhesives and binders in manufacture and use of plasters and mortars. Use of powders as Adhesives and binders in manufacture of foundry moulds and cores Use of powders as adhesives and binders in manufacture of building boards and prefabricated parts based on inorganic materials. Use of powders as adhesives and binders: in manufacture of building boards and prefabricated parts based on organic materials. Use of powders in Enhanced Oil Recovery: oil flow improvers. Use of powders in Textile and textile fibre processing: Bleach and dye stabiliser. Use of powders in Textile and textile fibre processing: Fire retardant. Use of powders in Ceramics & minerals: Component of porcelain slips and ceramic masses. Use of powders in Ceramics & minerals: Deflocculant in cement & clay suspensions. Use of solutions and powders in artists supply and hobby preparations: Manufacture of artists supply and hobby preparations. Use of powders for processing aid: developers for photographic plates. Use of powders in Lithographic: Processing of lithographic plates. Use of powders in Manufacture of Cosmetics: Hair treatment (bleaching and dying formulations).</p> <p>Professional use: Use of Detergents (solutions & powders): Fabric washing detergents, dishwasher detergents, industrial cleansing agents, hard surface cleaning and disinfecting agents. Use of powders in Cosmetics: Hair treatment (bleaching and dying formulations).</p> <p>Consumer use: Use of detergents (solutions & powders): Fabric washing detergents, dishwasher detergents, industrial cleansing agents, hard surface cleaning and disinfecting agents. Use of powders as Adhesives and binders in plasters and mortars. Use of solutions and powders in artists supply and hobby preparations. Use of powders in Cosmetics: Hair treatment (bleaching and dying formulations).</p> | | | |

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

| | |
|---|---|
| <input checked="" type="checkbox"/> Compliance check, Final decision | <input type="checkbox"/> Dangerous substances Directive 67/548/EEC |
| <input type="checkbox"/> Testing proposal | <input type="checkbox"/> Existing Substances Regulation 793/93/EEC |
| <input checked="" type="checkbox"/> Annex VI (CLP) | <input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC |
| <input type="checkbox"/> Annex XV (SVHC) | <input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012) |
| <input type="checkbox"/> Annex XIV (Authorisation) | <input type="checkbox"/> Other (provide further details below) |
| <input type="checkbox"/> Annex XVII (Restriction) | |
| <p>The registered substance is classified according to the annex VI (CLP), see section 2.1.</p> <p>There was compliance check on a dossier for the registered substance in 2011 and the final decision requested the following information:</p> <ul style="list-style-type: none"> - <i>In vitro</i> gene mutation study in bacteria (Annex VII, 8.4.1; EU methos B.13/14.). - Toxicokinetics (Annex VIII, 8.8; information on absorption, metabolism and distribution of the registered substances). <p>The current registration dossier is updated for these two endpoints.</p> | |

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R | Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R | <input type="checkbox"/> Potential endocrine disruptor |
| <input type="checkbox"/> Sensitiser | Suspected Sensitiser ¹ | |
| <input type="checkbox"/> PBT/vPvB | <input type="checkbox"/> Suspected PBT/vPvB ¹ | <input type="checkbox"/> Other (please specify below) |
| Exposure/risk based concerns | | |
| <input type="checkbox"/> Wide dispersive use | <input checked="" type="checkbox"/> Consumer use | <input type="checkbox"/> Exposure of sensitive populations |
| <input type="checkbox"/> Exposure of environment | <input type="checkbox"/> Exposure of workers | <input type="checkbox"/> Cumulative exposure |
| <input checked="" type="checkbox"/> High RCR | <input checked="" type="checkbox"/> High (aggregated) tonnage | <input type="checkbox"/> Other (please specify below) |
| <p>The registration dossier referred the OECD SIDS report. This report included a 4-generation toxicity study in rats using the structurally related substance at dose of 79 and 159 mg /kg bw/day (reliability 2, not GLP compliant, and no data on guideline).</p> <ul style="list-style-type: none"> The result indicated that the total number of offspring born at 79 mg/kg bw/d was reduced to 67 % and of offspring weaned to 46 % of the control. Severe limitations of the study and inter-current deaths, including controls make it however difficult to draw any firm conclusion from this study. <p>Generally the OECD SIDS report indicated that the availability of data on toxicity to reproduction is limited. (http://www.inchem.org/documents/sids/sids/SolubleSilicates.pdf)</p> <p>The combined RCR (inhalation, dermal, and oral) for the consumer exposure is close to 1 (0.8).</p> <p>The registered substance is in wide dispersive use including consumer exposure.</p> <p>Therefore the need for additional information on reproductive toxicity and the exposure concern can be further clarified during substance evaluation.</p> | | |

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

| | |
|---|---|
| <input type="checkbox"/> Information on toxicological properties | <input type="checkbox"/> Information on physico-chemical properties |
| <input type="checkbox"/> Information on fate and behaviour | <input type="checkbox"/> Information on exposure |
| <input type="checkbox"/> Information on ecotoxicological properties | <input type="checkbox"/> Information on uses |
| <input type="checkbox"/> Information ED potential | <input type="checkbox"/> Other (provide further details below) |
| Depends on the out-come of substance evaluation. | |

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

5.5 Potential follow-up and link to risk management

| | | | |
|--|--------------------------------------|--|--|
| <input type="checkbox"/> Harmonised C&L | <input type="checkbox"/> Restriction | <input type="checkbox"/> Authorisation | <input type="checkbox"/> Other (provide further details) |
| Depends on the out-come of substance evaluation. | | | |