LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Disodium metasilicate

EC No 229-912-9

CAS No 6834-92-0

Evaluating Member State(s): Latvia

Dated: 17 March 2016

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2015

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

Disodium metasilicate was originally selected for substance evaluation in order to clarify concerns about:

- suspected R,
- exposure for consumer use,
- high RCR,
- high tonnage.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Not applicable.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State Competent Authority (eMSCA) to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	Tick box
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	x

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

Not applicable.

4.1.1. Harmonised Classification and Labelling

Not applicable.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

4.1.3. Restriction

Not applicable.

4.1.4. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2

REASON FOR REMOVED CONCERN The concern could be removed because	Tick box
Clarification of hazard properties/exposure	x
Actions by the registrants to ensure safety, as reflected in the registration dossiers(e.g. change in supported uses, applied risk management measures, etc.)	

Initial grounds for concern to be clarified under Substance Evaluation were based upon an indication that the registered substance is widely used including different consumer products but the existing data on reproductive toxicity taken basically from OECD SIDS report (2004) was considered to be limited. In addition, the combined RCR (inhalation, dermal, and oral) for the consumer exposure was close to 1 (0.8).

The concern of reprotoxicity was clarified following reassessment of the available data. The Latvian CA as eMSCA concludes that irrespective of certain limitations (e.g. use of non-guideline studies, etc.) the available data can be used with sufficient level of certainty for DNEL derivation and for the purpose of this substance evaluation. In addition, this conclusion is based upon a lack of other effects on reproductive organs observed in the available repeated dose toxicity studies.

The concern of exposure to consumers with respect to reprotoxicity was clarified by calculating the relevant DNEL for fertility and developmental effects taking into account all exposure routes (dermal, inhalation, oral). A combined risk assessment was carried out for all exposure routes and reproduction endpoints. The combined risk expressed as RCR for reprotoxicity is no more than 0.5 considering even exposure from cosmetic products which is out of the scope of REACH in accordance of REACH regulation Article 14 (5) (b). Thus with the available information there is sufficient level of certainty to consider if the use of the substance would warrant further regulatory risk management actions. Furthermore, the eMSCA is of the opinion that the most critical endpoint is repeated dose toxicity which was already assessed by the applicant during registration process of substance leading to omit reprotoxicity issues.

Latvia as eMSCA concludes that no further regulatory follow up at EU level is needed.

5.2. Other actions

No applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

Disodium metasilicate was originally selected for substance evaluation in order to clarify concerns about:

- suspected R,
- exposure for consumer use,
- high RCR,
- high tonnage.

Within their registration dossier, the Registrant referred to an OECD SIDS report on soluble silicates. This report included a 4-generation toxicity study in rats using a structurally related substance at dose of 79 and 159 mg /kg bw/day (reliability 2, not GLP compliant, and no data on guideline).

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. However, severe limitations of the study and inter-current deaths, including controls made it difficult to draw any firm conclusion from this study. Overall, the OECD SIDS report indicated that the availability of data on toxicity to reproduction is limited. Furthermore, the combined RCR (inhalation, dermal, and oral) for the consumer exposure is close to 1, and the registered substance has wide dispersive uses, including consumer exposure.

Consequently, the substance was selected for Substance Evaluation to clarify the potential reproductive toxicity and the exposure concerns.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Reprotoxicity - fertility	Concern not substantiated. No further action needed (see Tables 11 and 12)
Reprotoxicity – developmental effects	Concern not substantiated. No further action needed (see Tables 11 and 12)

Exposure for consumer use (and related risk characterisation)	The combined risk expressed as RCR for reprotoxicity is no more than 0.5.

7.2. Procedure

The substance was included in the CoRAP for Latvian competent authority to start the evaluation on 17 March 2015.

The reprotoxicity endpoint, exposure for consumer use and high RCR were evaluated by eMSCA. The evaluation was based upon the available data provided in the registration dossier(s), the Chemical Safety report (CSR) and OECD SIDS (2004) (included in CSR). During the evaluation process, the information relating to analytical data, submitted in a non-EU language, was identified and clarified by the registrant(s).

A meeting with the registrant(s) was held in Riga on 21th of October 2015 to clarify questions on the endpoints of concern that were raised during the eMSCA's evaluation. The original publications regarding the reprotoxicity endpoint were provided by registrant(s) after the discussions and taken into account by the eMSCA in their assessment.

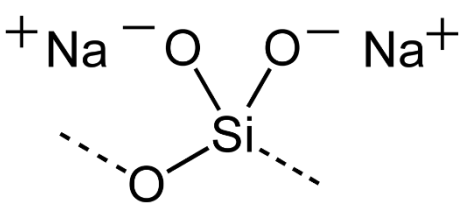
7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	Disodium metasilicate
IUPAC name	Disodium oxosilanediolate
EC number:	229-912-9
CAS number:	6834-92-0
Index number in Annex VI of the CLP Regulation:	014-010-00-8
Molecular formula:	$H_2O_3Si.2Na$
Molecular weight range:	101.1
Synonyms:	Silicic acid (H_2SiO_3), disodium salt Sodium metasilicate

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

Structural formula:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES		
Property	**Value**	**Remarks**
Physical state at 20°C and 101.3 kPa	solid	The physical state is evident from the appearance of the substance. No study needed.
Vapour pressure	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted if the melting point is above 300°C.
Water solubility	210 g/L at 20 °C	Safety Data Sheet.
pH	12.7 at concetration 1% (w/w)	Safety Data Sheet.
Partition coefficient n-octanol/water (Log Kow)	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted, if the substance is inorganic. Further, disodium metasilicate is insoluble in alcohol. The octanol/water partition coefficient is therefore not applicable.
Flammability	study scientifically unjustified	The study does not need to be conducted, since the substance is inorganic. Pyrophoricity is not a concern based on the chemical structure and the experience in handling and use. Soluble silicates do not spontaneously ignite when in contact with air.
Auto flammability	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted, if preliminary results exclude self heating of the substance up to 400°C.
Explosive properties	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted, if there are no chemical groups associated with explosive properties present in the molecule.
Oxidising properties	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted, if the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure.
Granulometry	Powder: 0.005 - 2000 µm Granule: 200 - 1250 µm	Handbook data.
Stability in organic solvents and identity of relevant degradation products	study scientifically unjustified	In accordance with column 2 of REACH Annex IX, the study does not need to be conducted if the substance is inorganic.

Dissociation constant	pKa ≥9.9 and ≤ 12 at 30 °C	Handbook data.
Melting point	1089 °C	Handbook data.
Boiling point	100 °C	Handbook data. However, in accordance with column 2 of REACH Annex VII, the study does not need to be conducted for solids which either melt above 300°C.
Flash point	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted, if the substance is inorganic.
Density	1.75 g/cm^3 at 20 °C	Determined in a pyknometer using kerosene as the immersion liquid.
Surface tension	study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted, if based on structure, surface activity is expected or can be predicted.
Viscosity	study scientifically unjustified	Disodium metasilicates are solid substances. Testing is only appropriate for liquids.

7.5. Manufacture and uses

7.5.1. Quantities

Tonnage band: 10 00-100 000 tonnes per annum.

7.5.2. Overview of uses

Table 6

USES	Use(s)
Manufacture	Manufacture of soluble metasilicates
Uses as intermediate	Not applicable
Formulation	Formulation of solutions (detergents, adhesives, binders, surface technologies, other applications); Industrial uses. Use of solutions and powders in artists supply and hobby preparations: Manufacture of artists supply and hobby preparations; Manufacture of Detergents (solutions & powders): Fabric washing detergents, dishwasher detergents, industrial cleansing agents, hard surface cleaning and disinfecting agents; Industrial formulation of cosmetic products; Industrial uses. Use of powders for processing aid: developers for photographic plates; Industrial uses. Use of powders in Lithographic: Processing

USES	
	Use(s)
	of lithographic plates; Industrial uses. Use of powders as adhesives and binders:in manufacture of building boards and prefabricated parts based on organic materials; Industrial uses. Use of powders in Textile and textile fibre processing: Bleach and dye stabiliser; Industrial uses. Use of powders in Textile and textile fibre processing: Fire retardant; Production uses. Production of soluble silicates - dried powders & granules (Metasilicate); Industrial uses. Use of powders as adhesives and binders in manufacture of bricks, ceramics and other construction materials; Industrial uses. 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 of building boards and prefabricated parts based on inorganic materials; Industrial uses. Use of powders as Adhesives and binders in manufacture and use of plasters and mortars; Industrial uses. Use of powders in Manufacture of Cosmetics: Hair treatment (bleaching and dying formulations); Industrial uses. Use of powders in Ceramics & minerals: Deflocculant in cement & clay suspensions; Industrial uses. Use of powders in Enhanced Oil Recovery:oil flow improvers; Formulation of solutions (detergents, adhesives, binders, surface technologies, other applications); Formulation of powders (detergents, adhesives, binders, surface technologies, other applications); Industrial uses. Use of powders in Ceramics & minerals: Component of porcelain slips and ceramic masses; Production uses. Production of soluble silicates - Solutions (Metasilicate); Formulation of powders (detergents, adhesives, binders, surface technologies, other applications); Production uses. Production of soluble silicates - Lumps (Metasilicate); Industrial uses. Use of powders as Adhesives and binders in manufacture of foundry moulds and cores.
Uses at industrial sites	Use of solutions and powders in Ceramics & minerals: Flotation agent in mineral processing; Industrial uses. Use of powders in Ceramics & minerals: Component of porcelain slips and ceramic masses; Use of powders in Textile and textile fibre processing: Fire retardant;

USES	Use(s)
	Use of powders in Textile and textile fibre processing: Bleach and dye stabiliser.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 bricks, ceramics and other construction materials; Use of powders as Adhesives and binders in manufacture of refractory cements and other refractory masses/mixes; 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 organic materials; Use of powders as adhesives and binders in manufacture of building boards and prefabricated parts based on inorganic materials; Use of solutions and powders in artists supply and hobby preparations: Manufacture of artists supply and hobby preparations; Use of solutions (detergents, adhesives, binders, surface technologies, other applications); Use of powders (detergents, adhesives, binders, surface technologies, other applications); Use of powders in Civil Engineering: Soil sealing and stabilisation in drilling, tunnelling and mining, sealing of landfills, building pits, buildings, coastline stabilisation; Manufacture of Detergents (solutions & powders): Fabric washing detergents, dishwasher detergents, industrial cleansing agents, hard surface cleaning and disinfecting agents; Use of powders as Surface Coatings: Coatings for fire-proof construction materials; Use of solutions and powders as Surface Coatings: Concrete; Use of powders in Enhanced Oil Recovery: oil flow improvers; Use of powders in Pulp and paper manufacture: Deinking and bleaching (recycled wastepaper); Use of powders for processing aid: developers for photographic plates.
Uses by professional workers	Use of powders (detergents, adhesives, binders, surface technologies, other applications); Use of powders in Cosmetics: Hair treatment (bleaching and dying formulations); Use of solutions (detergents, adhesives, binders, surface technologies, other applications); Use of Detergents (solutions & powders): Fabric washing detergents, dishwasher detergents, industrial cleansing agents, hard surface cleaning and disinfecting agents.
Consumer Uses	Use of powders (detergents, adhesives, binders, surface

USES	Use(s)
	technologies, other applications); Use of solutions (detergents, adhesives, binders, surface technologies, other applications); Use of powders as Adhesives and binders in plasters and mortars; Use of solutions and powders in artists supply and hobby preparations; 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). Use in cosmetic products.
Article service life	Article life of powders (adhesives and binders).

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

Table 7

HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008)							
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)**		
014-010-00-8	Disodium metasilicate	229-912-9	6834-92-0	Skin Corr. 1B STOT SE 3	H314 H335	Not applicable	Not applicable

H314: Causes severe skin burns and eye damage

H335: May cause respiratory irritation

Signal Word: Danger

Pictograms:

7.6.2. Self-classification

- In the registration(s)*:*

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

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

Eye Dam. 1; H318: Causes serious eye damage

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

Acute Tox. 4; H302: Harmful if swallowed

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

Eye Irrit. 2; H319: Causes serious eye irritation

STOT SE 1; H370: Causes damage to organs

7.7. Environmental fate properties

Not applicable.

7.8. Environmental hazard assessment

Not applicable.

7.9. Human Health hazard assessment

7.9.1. Assessment of Read-Across

This read-across approach was considered in the SIDS Initial Assessment Report for Soluble Silicates, which concluded that:

'The soluble silicates are structurally very similar. Silicon-oxide tetrahedra as the basic structural units are linked with each other via Si-O-Si bonds resulting in an infinite three-dimensional network. The negative charge of unshared oxygen atoms is balanced by the presence of sodium or potassium cations which are randomly spaced in the interstices. The extent to which balancing alkali ions are present in a given silicate is defined by the molar ratio SiO2/M2O (M = Na or K). The higher the molar ratio, the less sodium or potassium ions are present in the silica network and consequently the less alkaline the silicates are. Whereas the sodium and potassium salts have an amorphous three-dimensional structure, the disodium salts (= metasilicate) are crystalline with penta- and nonahydrate differing from the anhydrous form only by their water of crystallisation. Once in aqueous solution, all soluble silicates are subject to the same molecular speciation resulting in a mixture of monomeric tetrahedral ions, oligomeric linear or cyclic silicate ions and polysilicate ions. At environmental pH values the soluble silicates are present as poorly soluble amorphous silica and monomeric silicic acid. The biological properties of soluble silicates are mainly governed by their intrinsic alkalinity. Based on the available data the members of the soluble silicates category exhibit a similar toxicological profile.'

Comparision of physicochemical properties of sodium silicate and disodium metasilicate is given in the Table 8 below.

Table 8

Property	Sodium silicate CAS No. 1344-09-8	Disodium metasilicate CAS-No. 6834-92-0	Notes
Physical State	Amorphous glass melt (lumps), aqueous solution or spray-dried powder with ca. 20 % of residual wate	Crystalline anhydrous Powder	
Melting Point	730 - 870 °C (flow point); aqueous solutions have a melting point only slightly lower than that of water	1089 °C	
Density	1.26 - 1.71 g/cm3 (solutions); 700 - 800 kg/m3 (bulk density;spray-dried powders)	2.61 g/cm3 1200 kg/m3 (bulk density)	
Vapour Pressure	0.0031 hPa at 1165 °C (solid, MR 2.0). 0.0016 hPa at 1172 °C (solid; MR 3.0)	0.0103 hPa at 1175 °C	At ambient temperatures the vapour pressure of soluble silicates is negligible.
Partition Coeff.	-	-	The oil/water partition coefficient is not relevant, as alkali silicates are ionisable inorganic compounds.
Water Solubility	Anhydrous solid dissolves extremely slow at ambient conditions; solutions are infinitely miscible with water; spray-dried solutions readily dissolve in water	210 g/l at 20 °C	Determination of quantitative water solubilities is not feasible. Aqueous solutions are characterised by a dynamic polymerisation/hydrolysis equilibrium of monomeric SiO2 (aq.), oligomeric silicate ions and polysilicate ions which is strongly pH-dependant. At pH below 9 silicates are present as amorphous silica (SiO2) whose water solubility is 115 mg/l at 25°C. At pH values above 9 undissolved amorphous silica rapidly diminishes, soluble polysilicate ions aggregate and solubility of monomeric silica increases to up to 300 mg/l.

Taking into account structural similarity of silicates in question as well as comparison of physicochemical properties and considerations on toxicokinetics outlined in the SIDS Initial Assessment Report it can be concluded that read-across approach is acceptable.

7.9.2. Toxicity to reproduction (effects on fertility and developmental toxicity)

No human information is available. One animals` key study on effects on fertility as well as one key study on developmental toxicity is provided based on OECD SIDS (2004). Taking into account the available information it is concluded that the criteria given in Regulation (EC) No 1272/2008 for classification in the hazard class reproductive toxicity are not fulfilled.

Fertility

Experiments on Sprague-Dawley male and female rats were performed by Smith, G. S. et al (1973). During this multigenerational study marked as ”2” (reliable with restrictions but not performed according to any guideline) 79 and 159 mg/kg bw/day of_sodium silicate was administered through drinking water. Premating exposure period was 12 weeks between weaning and sexual maturity both for males and females for each generation F0, F1, F2, F3 and F4. The duration of the continuous test was 2,5 years. As no data on disodium metasilicate are available, a “read-across” approach to data obtained on sodium silicate was proposed. The eMSCA considers the proposed read-across to be acceptable on the basis of the chemical similarity and comparable physicochemical and toxicokinetic properties of both substances.

The NOAEL for parental animals was determined to be > 159 mg/kg bw/day. For the F1 generation no NOAEL was identified.

It is stressed that inter-current deaths, including controls and giving less survived control animals compared to treated test animals, make it difficult to draw any firm conclusion from this study. Nevertheless, additionally mentioned studies on repeated dose oral toxicity with rats and dogs did not reveal any treatment-related effects on reproductive organs by their macroscopic and microscopic examination (OECD SIDS - Newberne and Wilson, 1970). The NOAEL for rats and dogs was determined to be > 2400 mg/kg bw/day. Besides, no testicular effects of sodium silicate injected either subcutaneously or intratesticularly in male rats were demonstrated by Kamboj and Kar (1964)(OECD SIDS). Taking into account the additional supportive information and considerations of humanitarian nature, the eMSCA concludes that no additional test data is required.

Consequently, the NOAEL >159 mg/kg bw/day (rats) can be applied for further risk assessment.

Developmental toxicity

Experiments on JLC-TCR female mice by means of oral gavage were carried out by Saiwai, K. et al. (1980). 12.5, 50 and 200 mg/kg bw/day of disodium metasilicate was administered in pregnant mice from day 0 to day 18 of gestation followed by examination of fetuses and newborns. The respective study is indicated to be of reliabily “2”, however there was some uncertainty regarding whether the study was performed in accordance with any guideline.

No treatment-related effects were observed on body weight, organ weights or the number of pregnancies within all groups, however it is reported that two dams died in the middle and high dose groups. The observed skeletal malformations in neonates like cervical vertebrae, tail vertebrae and vomer adhesion occurred in the controls, too, and did not show a dosage correlation. No malformations of the skeleton or the inner organs of fetuses delivered by hysterectomy were observed. The frequency of malformations and abnormalities of the external integument (opened eyes, cleft palate and exencephaly) showed no significant deviations from controls. Furthermore, no effects on main organs were found compared to controls.

The NOAEL for developmental toxicity is determined to be > 200 mg/kg bw/day and can be used for further risk assessment.

7.9.3. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

Derivation and justification of respective DNELs for reproductive toxicity based on experimentally determined NOAELs both for fertility effects and developmental toxicity are reflected in the Table 9 below.

Table 9

CRITICAL DNELS/DMELS					
Endpoint of concern	**Type of effect**	**Critical study(ies)**	**Corrected dose descriptor(s) (e.g. NOAEL, NOAEC)**	**DNEL/ DMEL**	**Justification/ Remarks**
Reproductive toxicity	Fertility	Smith, G. S. et al (1973)	159 mg/kg bw/day (rats, oral route)	6.36 mg/kg bw/day	Applied AF: 2.5 (interspecies) x 10 (intraspecies) = 25
		*	159 mg/kg bw/day (rats, dermal route)	6.36 mg/kg bw/day	
		**	69.1 mg/m³ (rats, inhalation route)	2.76 mg/m³	
	Developmental effects	Saiwai, K. et al. (1980)	200 mg/kg bw/day (mice, oral route)	1.14 mg/kg bw/day	Applied AF: 7 (mouse) x 2.5 (interspecies) x 10 (intraspecies) = 175
		*	200 mg/kg bw/day (mice, dermal route)	1.14 mg/kg bw/day	
		**	59.5 mg/m³ (mice, inhalation route)	2.38 mg/m³	Applied AF[2]: 2.5 (interspecies) x 10 (intraspecies) = 25

* Converted by route-to-route extrapolation according to the ECHA guidance document "Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health", May 2008. In the absence of any information on bioavailability, as is the case for disodium metasilicate, the same bioavailability for experimental

[2] As the specific standard respiratory volume for mice is already taken into account by derivation of inhalation NOAEL from oral NOAEL, no additional "mouse" AF shall be applied

animals and humans is assumed (default situation). This assumption results in an identical NOAEL for the oral and dermal exposure routes.

** Converted by route-to-route extrapolation according to the ECHA guidance document "Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health", May 2008. The conversion of an oral NOAEL into an inhalation NOAEL for the general population (24 h exposure) is performed using the following equations:

$$CorrectedinhalatoryN(L)OAEL = oralN(L)OAEL \times \frac{1}{sRVanimal} \times \frac{ABSoral}{ABSinhalation} \times \frac{ABSinhalation}{ABShuman}$$

$$= oralN(L)OAEL \times \frac{1}{sRVanimal} \times \frac{ABSoral}{ABShuman}$$

$$= oralN(L)OAEL \times \frac{1}{sRVanimal} \times \frac{1}{2}$$

where

ABS – absorbtion rate by route or species in question;

sRV – standard respiratory volume (for rats 1.15 m^3/kg bw during 24 h, for mice 1.68 m^3/kg bw during 24 h).

In the absence of route-specific information on absorption, a default factor of 2 (i. e. the absorption percentage of the starting route is half that of the end route) is used.

7.9.4. Conclusions of the human health hazard assessment and related classification and labelling

The available information does not trigger any classification for toxicity to reproduction according to criteria outlined in the CLP chapter 3.7: "Substances are classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, and where the evidence is not sufficiently convincing to place the substance in Category 1".

7.10. Exposure assessment

The eMSCA considered the exposure assessment provided by the registrant(s) in the Chemical Safety Report. In addition, the eMSCA and performed its own exposure assessment.

7.10.1. Human health

7.10.1.1. Worker

Not applicable.

7.10.1.2. Consumer

The eMSCA considered the exposure with respect to consumers` assessment provided by the registrant(s) in the Chemical Safety Report. In addition, the eMSCA performed its own exposure assessment in relation to consumers.

7.11. Risk characterisation

Risk assessment was carried out for all exposure routes and reproductivity endpoints followed by combined risk assessment. The combined risk expressed as RCR for reprotoxicity is no more than 0.5 considering even exposure from cosmetics which is out of the scope of REACH in accordance of REACH Regulation Article 14, point 5 (b). Furthermore, Latvia as eMSCA concludes that the most critical endpoint is repeated dose toxicity which was already assessed by the applicant during registration process of substance leading to omit reprotoxicity issues.

Indirect exposure of humans via the environment is not considered to be applicable due to the low hazard profile and negligible risks related to release into the environment.

At the same time soluble silicates, including disodium metasilicate, do not meet the criteria for classification as dangerous to the environment according to CLP Regulation and also 67/548/EEC. Furthermore, as high production volume substances, soluble silicates have been extensively reviewed for their exposure potential to the environment and the possible risks arising from their release (Van Dokkum et al. 2002 - OECD SIDS 2004, HERA 2005, and CEES 2003). It was concluded that soluble silicates are currently of low priority for further work because of their low hazard profile.

8. References

1. OECD SIDS (2004). Soluble Silicates. CAS No. 1344-09-8, 6834-92-0, 10213-79-3, 13517-24-3 and 1312-76-1. SIDS Initial Assessment Report for SIAM 18 Paris, France 20-23 April, 2004.
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9. Abbreviations

CoRAP	Community Rolling Action Plan
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
eMSCA	The Evaluating Member State Competent Authority
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
R	Reproduction toxicity
RCR	Risk Characterisation Ratio
TRA	Targeted Risk Assessment