Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	dimethoxydimethylsilane
EC Number:	214-189-4
CAS Number:	1112-39-6
Authority:	BE MSCA
Date:	22/03/2016

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

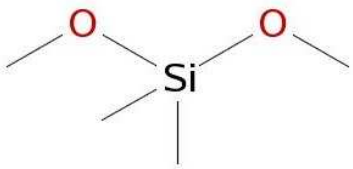
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	dimethoxydimethylsilane
IUPAC name (public):	dimethoxy(dimethyl)silane
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$C_4H_{12}O_2Si$
Molecular weight or molecular weight range:	120.2224
Synonyms:	DOW CORNING(R) Z-6194 SILANE Silane, dimethoxydimethyl-

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

Structural formula:



Other relevant information about substance composition

Dimethoxydimethylsilane has a short half-life in water (<0.6h at 25°C). The hydrolysis gives following degradation products: dimethylsilanediol (EC 213-915-7)(which is not registered) and methanol (EC 200-659-6).

1.2 Similar substances/grouping possibilities

For the ecotoxicological endpoints, read-across is proposed in the registration dossier with **dimethylsilanediol (EC 213-915-7)**

For the toxicity tests, read-acrosses are provided in the registration dossier with following substances:
Trimethoxy(methyl)silane (EC 214-685-0)
Triethoxy(methyl)silane (EC 217-983-9)
Dimethoxydimethylsilane (EC 214-189-4)
Diethoxy(dimethyl)silane (EC 201-127-6)
and **Dichloro(dimethyl)silane (EC 200-901-0)**

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: Completed or ongoing processes for dimethoxydimethylsilane

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[1]
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	

[1] Please specify the relevant entry.

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)

Testing proposal: (ongoing)

Sub-chronic toxicity (90-day) via the inhalation route: public consultation end 2014.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The substance has no harmonised classification

3.1.2 Self classification

- In the registration:
    - Flam. Liquid 2, H225: Highly flammable liquid and vapour.
    - Repr. 2, H361: Suspected of damaging fertility or the unborn child

Remark: in the registration dossier, for the classification, the substance has been given 3 different names, with only one being self-classified as repr.2.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
    - 'Not classified'
    - Acute tox.4, H302
    - Acute tox.2, H300
    - Eye irrit.2, H319
    - Skin irrit.2, H315
    - STOT SE 3, H335 (inhalation)

- STOT SE 1, H370
- STOT RE 1, H372
- Repr.1B, H360

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

There is currently no proposal for harmonised classification.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table 3: 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
Joint submission		

4.2 Overview of uses

Table 4: Uses

Part 1:

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

[2] *the dissemination site was accessed on 20 May 2015.*

Remark: in the registration dossier, no article service life is mentioned as such. However, various chemical product categories are provided. In addition, different 'subsequent service lifes' are mentioned as relevant for different end use sectors.

Part 2:

	Use(s)
Uses as intermediate	Not mentioned in the registration dossier (see however uses at industrial sites. Intermediate in the sense of REACH or monomer?)
Formulation	Formulation of sealants, formulation of non-metal surface treatment solutions/dispersions, formulation and process of non-aqueous polymer preparation, formulation in mold-making, , formulation for use in semiconductor manufacture
Uses at industrial sites	Use of dimethoxydimethylsilane as an intermediate at downstream industrial sites, industrial use of sealants, use in non-metal surface treatment, processing of non-aqueous polymer preparation, use in semiconductor manufacture, industrial use as a laboratory reagent, use in non-metal surface treatment, production of dimethoxydimethylsilane and its on-site use as an intermediate/monomer
Uses by professional workers	Professional use during mold-making, exposure to methanol during end-use of products containing dimethoxydimethylsilane
Consumer Uses	Not mentioned in the registration dossier
Article service life	Not mentioned in the registration dossier

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)

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[3]	
☐ 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)

[3] 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

R :

In an OECD 422 test (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test – oral (gavage) – 28 day exposure), rats were exposed to 0, 50, 250 and 1000 mg/kg bw/day. Male rats were administered the test substance for 29 consecutive days, while female rats were administered the test substance up to 51 days in total. Female rats were exposed for a two-week pre-mating phase, a 1-14 day mating phase, and through day post-partum, up to 51 days in total.

Following observations were made at 1000 mg/kg bw/day: increase in post-implantation loss, decrease in live pups, decrease in the total viable pups/total, decrease in final litter weight, decrease in final average pup weight and increase in the % of post-natal loss. No grossly external abnormalities were observed for the pups. However, in this test, soft tissue, skeletal or head examinations are not performed.

The developmental concern has to be further evaluated.

The result of the OECD 413 (subchronic toxicity study (90-day) in rats), when available, will provide additional information with regard to reproductive endpoints. Indeed, additional reproductive endpoints will be covered. These could include but are not limited to "Examination of reproductive organs, sperm parameters, and oestrus cycle". Those results are therefore awaited before performing the evaluation of the substance.

In the OECD 422 test, following results were observed at 1000 mg/kg bw/day in males: hepatic protoporphyrin accumulation, adrenal cortical atrophy, kidney protein droplet nephropathy, testicular seminiferous tubule degeneration with epididymides involvement, and in females rats: periportal vacuolation. Based on these results no clear concern for ED can be established.

Other : ECOTOX

For acute fish and algae tests, the read-across with the degradation product dimethylsilanediol does not take into account the methanol degradation product. No explanation is given to not consider it.

For acute Daphnia tests, results for dimethoxydimethylsilane and dimethylsilanediol are available. Comparison of both NOECs indicates a possible higher sensitivity against the parent substance, dimethoxydimethylsilane (NOEC-48h<10mg/L) compared to the degradation substance, dimethylsilanediol (NOEC (96h)>=120 mg/L (limit test)).

Moreover, no long term tests (fish, daphnia) are available.

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)

5.5 Potential follow-up and link to risk management

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