SUBSTANCE EVALUATION REPORT

Background document for the purpose of substance evaluation under REACH

for

Dichloro(dimethyl)silane

EC No 200-901-0

CAS No 75-78-5

Evaluating Member State(s): Czech Republic

Dated: 30.11.2015

Evaluating Member State Competent Authority

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Conclusions of the most recent evaluation step*	Tick relevant box(es)
Concern not clarified; Need to request further information from the Registrant(s) with the draft decision	
Concern clarified; No need of further risk management measures	x
Concern clarified; Need for risk management measures; RMO analysis to be performed	
Other: fulfilment of standard information requirements according REACH	

**Include details in the executive summary.*

DISCLAIMER

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Executive summary

Grounds for concern

The substance was included into CoRAP according to Art. 44(1)(a), published on March 20, 2014, due to the concern for PBT properties and lack of data for terrestrial compartment and terrestrial organisms, concern for terrestrial compartment, lack of data on adsorption/desorption. This applies for both the mother substance and its hydrolysis products (the substance hydrolyses quickly). There are also concerns regarding the aggregated tonnage.

Procedure

Relevant data available in the CSR and the registration dossier were evaluated. Further information was obtained via a new literature research concerning both dichloro(dimethyl)silane and dimethylsilanediol (first hydrolytic product). Some supporting data were obtained using (Q)SAR methods.

Based on the gathered information, it was concluded that the data are sufficient for substance evaluation of this compound.

PBT/vPvB assessment was performed; as part of this assessment information about environmental degradation of dichloro(dimethyl)silane and dimethylsilanediol was evaluated, including assessment adsorption/desorption of dimethylsilanediol in soil, bioaccumulation potential and long-term toxicity to human (including reproduction toxicity) and environment.

The assessment of aggregated tonnage and exposure concentrations was processed using CHESAR software (version 2.3.0). The structure of exposure scenarios including descriptors was taken from registration dossier and CSR for dichloro(dimethyl)silane.

Conclusions

PBT/vPvB

PBT substances are simultaneously persistent, bioaccumulative and toxic, while vPvB substances are characterised by a particular high persistency in combination with a high tendency to bio-accumulate. Based on the available data, dichloro(dimethyl)silane meets the P/vP criterion but does not fulfil the B/vB or T criteria. For these reasons dichloro(dimethyl)silane cannot be considered as PBT/vPvB substance.

Aggregated tonnage

Exposure scenarios were processed using CHESAR software. The structure of exposure scenarios including descriptors was taken from registration dossier and CSR for dichloro(dimethyl)silane.

Estimated exposure concentrations are under control. The only exception when RCR > 1 was covered by measured exposure concentrations of related substance a (trichlorosilane). These measured concentrations of the related substance at identical conditions are two orders of magnitude lower than the estimated exposure values, RCRs based on them are below safe limit, therefore the risks can be considered as controlled.

Information on fate and behaviour

All the dichloro(dimethyl)silane is immediately decomposed into dimethylsilanediol and hydrogen chloride by reaction with water or atmospheric moisture. According to all available data, dimethylsilanediol is very hydrophilic substance with negligible potential to adsorption to soil or sediment. Therefore it could be that dimethylsilanediol will be become a part of aquatic systems. Further degradation of dimethylsilanediol to inorganic silicate in environment is very slow (several months). However, it can be assumed that dimethylsilanediol remains part of the aquatic environment throughout all its life-cycle. Short-term toxicity to the aquatic environment was not found in any trophy level (vertebrates, invertebrates and microorganisms), neither long-term toxicity to the environment (microorganisms) was not identified.

Direct contamination of soil with dichloro(dimethyl)silane under normal conditions is practically excluded. Indirect contamination can occur through rainfall or via activated sludge from STP. Dichloro(dimethyl)silane in the soil may exist only in the form of its hydrolysis products, dimethylsilanediol and hydrogen chloride. Hydrogen chloride, hydrogen and chloride ions respectively, are natural part of the environment. According to gathered knowledge, dimethylsilanediol does not have the tendency to adsorb to soil as its nature is very hydrophilic. Therefore, dimethylsilanediol is removed from soil by water and exposure concentrations can be considered negligible.

Dichloro(dimethyl)silane in the air will be rapidly converted into dimethylsilanediol and hydrogen chloride by the effect of atmospheric moisture. In contrast to dichloro(dimethyl)silane, dimethylsilanediol is not volatile and its gradual entry into an aqueous environment through rainfall, can be expected.

Based on their properties (hydrolysis, water solubility, partition coefficient) dichloro(dimethyl)silane and dimethylsilanediol, have a low potential to bioaccumulate, and entry into the food chain is not expected.

These indications show that dimethylsilanediol (or dimethylsilanediol as its metabolite) is not hazardous to the environment.

CONTENTS

TABLES

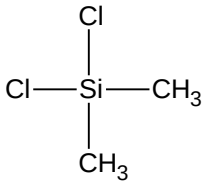
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	dichloro(dimethyl)silane
EC number:	200-901-0
EC name:	dichloro(dimethyl)silane
CAS number (in the EC inventory):	75-78-5
CAS number:	75-78-5
CAS name:	dichlorodimethylsilane
IUPAC name:	dichloro(dimethyl)silane
Index number in Annex VI of the CLP Regulation:	014-003-00-X
Molecular formula:	$C_2H_6Cl_2Si$
Molecular weight:	129.06 g/mol
Synonyms:	dimethyl-dichlorosilane Inerton AW-DMC Inerton DW-DMC

Structural formula:



1.2 Composition of the substance

Stated in Confidential Annex.

Name: dichloro(dimethyl)silane

Description: mono-constituent substance

1.3 Physico-chemical properties

Table 2: Overview of physicochemical properties

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	liquid	
Melting/freezing point	–76.1°C	
Boiling point	70.2°C	1013 hPa
Vapour pressure	14600 Pa	20°C
Water solubility	n/a	contact with water leads to immediate degradation
Partition coefficient n-octanol/water (log value)	n/a	
Flash point	–8°C	
Flammability	highly flammable	
Explosive properties	not explosive	
Oxidising properties	not oxidising	
Auto flammability	425°C	

Experimental values reported herein are not included in registration dossier. The registration dossier contains only the estimated values obtained via (Q)SAR calculation. As these values are very useful for derivation some other properties (bioaccumulation, adsorption ability etc.), it is appropriate to be noted at this point.

Water solubility

Substance: dimethylsilanediol (CAS: 1066-42-8)

Value: 245 g / 100 g water

Reference: Hyde J.F., Silanol Derivatives of the Dimethyl Substituted Organosilicon Compounds, Journal of the American Chemical Society, **75**(9), p. 2166-2167 (1953).

Partition coefficient n-octanol/water (log value)

Substance: dimethylsilanediol (CAS: 1066-42-8)

Value: –0.41 (log Kow)

Reference: Xu S., Kropscott B., Method for simultaneous Determination of Partition Coefficients for Cyclic Volatile Methylsiloxanes and Dimethylsilanediol, American Chemical Society, **84**(4), p. 1948-1955 (2012).

2 MANUFACTURE AND USES

2.1 Quantities

Table 3: Aggregated tonnage (per year)

1 – 10 t	10 – 100 t	100 – 1000 t	1000 - 10 000 t	10 000-50 000 t
50 000 – 100 000 t	100 000 – 1 000 000 t	> 1 000 000 t	Confidential	

2.1.1 Manufacturing processes

Not relevant for this evaluation.

2.2 Identified uses

2.2.1 Uses by workers in industrial settings

Non-metal surface treatment agent

Manufacture of semiconductors/photovoltaics

Monomer in the production of polydimethylsiloxane polymers (PDMS)

Chemical intermediate in the production of other organic silicon-containing chemicals

Manufacture of silicon wafers for the semiconductors industry, including photovoltaics

2.2.2 Use by professional workers

Not used.

2.2.3 Uses by consumers

Not used.

3 CLASSIFICATION AND LABELLING

3.1 Harmonised Classification in Annex VI of the CLP Regulation

Index number: 014-003-00-X

CAS number: 75-78-5

EC number: 200-901-0

Name: dichloro(dimethyl)silane

Classification: Flam. Liq. 2 (H225)
Skin Irrit. 2 (H315)
Eye Irrit. 2 (H319)
STOT SE 3 (H335)

3.2 Self classification

Self classification was based on the test results presented in registration dossier and CSR.

Classification: Flam. Liq. 2 (H225)
Acute Tox. 3 (H331)
Acute Tox. 4 (H302)
Skin Corr. 1A (H314)
Eye Dam. 1 (H318)

(For the purpose of labeling, the classification should be extended by supplemental hazard information.)

EUH014 - Reacts violently with water.
EUH071 - Corrosive to respiratory tract.

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Abiotic degradation

4.1.1.1 Hydrolysis

In contact with water dichloro(dimethyl)silane immediately hydrolyses to dimethylsilanediol and hydrogen chloride. This hydrolysis is practically independent of pH and its half-time is shorter than one minute.

4.1.1.2 Phototransformation/photolysis

4.1.1.2.1 Phototransformation in air

Not relevant for this evaluation.

4.1.1.2.2 Phototransformation in water

Not relevant for this evaluation.

4.1.1.2.3 Phototransformation in soil

Not relevant for this evaluation.

4.1.2 Biodegradation

4.1.2.1 Biodegradation in water

4.1.2.1.1 Estimated data

Biodegradation probability of dimethylsilanediol was estimated using the (Q)SAR calculation methods:

Biodegradability = 0.846 (BIOWIN 2, Non-Linear Model)
Biodegradability = 2.669 (BIOWIN 3, Ultimate Biodegradaton Model)
Biodegradability = 0.476 (BIOWIN 6, MITI Non-Linear Model)
Substance: dimethylsilanediol (CAS: 1066-42-8)

These values were utilized for PBT/vPvB assessment (see chapter 8.1.1). Program EPI Suite (ver. 4.1), module BIOWIN (ver. 4.10) was used for estimation of parameters of biodegradability.

4.1.2.1.2 Screening tests

Using read-across approach with trimethylsilanol (CAS: 1066-40-6) as analogue substance, biodegradability is very low. Under OECD 310 test conditions (Ready biodegradability – CO_2 in sealed vessels (Headspace test)), 0 % degradation of the test substance was observed after 28 days (based on inorganic carbon analysis).

Trimethylsilanol is structurally very similar to dimethylsilanediol; it has the same central atom (silicon) and identical substituents (methyl-groups and hydroxyl-groups). It can be expected to have similar behavior and properties both dimethylsilanediol, and trimethylsilanol.

4.1.2.1.3 Simulation tests (water and sediments)

No data are available.

4.1.2.1.4 Summary and discussion of biodegradation in water and sediment

Biodegradation in water was assessed on the basis of published results of experimental study of trimethylsilanol (analogue substance for read-across approach). This substance decomposes very slowly. It can be expected that degradation of trimethylsilanol is slower than dimethylsilanediol as the rate of decomposition is determined by the rate of oxidation of methyl-groups and cleavage of Si-C bonds. Nevertheless, it can be concluded that biodegradability of dimethylsilanediol is low.

The results of (Q)SAR methods used as supporting arguments to PBT/vPvB assessment are not conclusive. While Non-Linear model (BIOWIN 2) and Ultimate Biodegradation model (BIOWIN 3) predicts rapid biodegradability, MITI Non-Linear model (BIOWIN 6) estimates slow biodegradability.

For the assessment of biodegradability of dimethylsilanediol in water and sediment, an experimental result of degradation of trimethylsilanol applied by read-across method was used.

4.1.2.2 Biodegradation in soil

Tests on biodegradability of dichloro(dimethyl)silane in soil are not available. Data from literature cited in CSR suggest that biodegradability of dimethylsilanediol in soil is very slow (only a few percent per month). However, it was found that certain soil microorganisms (*Fusarium oxysporum* (fungus), *Arthrobacter sp.* (bacteria)) accelerate decomposition.

4.1.3 Summary and discussion on degradation

First step of degradation of dichloro(dimethyl)silane is hydrolysis with water. Reaction with water proceeds almost immediately (half-time of this reaction is several seconds) to give dimethylsilanediol and hydrogen chloride. Hydrogen chloride is inorganic and degradation is not applicable to this compound.

Biodegradability of dimethylsilanediol in water was evaluated on the basis of read-across to trimethylsilanol as source substance. Biodegradation rate was found as negligible.

Biodegradability of dimethylsilanediol in soil is the subject of several studies published in the scientific literature. Various types of soil and duration of tests were applied; biodegradation rate was no more than a few percent per month.

All available sources suggest that biodegradation of dimethylsilanediol in water, soil or sediment is very slow.

4.2 Environmental distribution

4.2.1 Adsorption/desorption

Adsorption/desorption screening test is required for substances manufactured in quantities above 10 tonnes per year. According to Regulation (EC) No. 1907/2006, Annex VIII, section 9.3.1, column 2, this test does not need to be performed if (based on the physicochemical properties) the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient), or the substance and its relevant degradation products decompose rapidly.

Dichloro(dimethyl)silane can not be tested as this substance rapidly hydrolyses in contact with water. A hydrolytic product of this reaction, dimethylsilanediol, is a non-ionising and considerably hydrophilic substance (water solution 245 g / 100 g water; log Kow = –0.41). Such compounds, in accordance with ECHA methodology (Guidance on information requirements and chemical safety assessment, Chapter R.7a: Endpoint specific guidance, version 3.0 (2014)), are considered as having low adsorption potential.

The result of (Q)SAR software (program EPI Suite (ver. 4.10), module KOCWIN (ver. 2.00)) support this conclusion. This software included two computational models for calculation of the adsorption coefficient of organic carbon (Koc). The first method used to estimate the first order molecular conductivity index (MCI – molecular descriptor), and the second method is based on the logarithm of the partition coefficient octanol-water (log Kow):

Koc = 43.89 L/kg (MCI)
Koc = 0.440 L/kg (log Kow)
Substance: dimethylsilanediol (CAS: 1066-42-8)

Both of these results are below limit 500 – 1000 L/kg, indicating a substance which is poorly adsorbable to sediment[4].

There is no indication that dichloro(dimethyl)silane, resp. dimethylsilanediol tends to adsorb to soil/sediment.

4.2.2 Volatilisation

Volatilisation from water cannot be considered as dichloro(dimethyl)silane is a readily hydrolysable substance. Henry's Law constant for dichloro(dimethyl)silane is 1.87×10^{3} Pa·m^3/mol, and for dimethylsilanediol is 1.17×10^{-3} Pa·m^3/mol (program HenryWin, version 3.20). These values indicate that dichloro(dimethyl)silane is volatile whilst dimethylsilanediol has very low volatility.

4.2.3 Distribution modelling

The distribution of dichloro(dimethyl)silane has been estimated using the program CHESAR (version 2.3). Results are listed in Table 39 (Chapter 10.2.1.1). Due to the rapid hydrolysis of dichloro(dimethyl)silane, the distribution is based on its hydrolysis product - dimethylsilanediol.

Based upon experience with related substance, it can be assumed that the actual amount of dichloro(dimethyl)silane released into the air is considerably lower (see Chapter 9.1.5.2).

4.2.4 Summary and discussion of environmental distribution

Due to the rapid hydrolysis of dichloro(dimethyl)silane and the Henry's law constant of dimethylsilanediol, volatilisation from the water surface is not expected to be an important fate path.

Dichloro(dimethyl)silane released into air is rapidly transformed to dimethylsilanediol due to atmospheric moisture.

Since the log Kow value for the hydrolytic product of dichloro(dimethyl)silane is less than 3, dimethylsilanediol has a low potential for adsorption to soil, sediment, and suspended solids. Therefore it could be estimated that dimethylsilanediol will predominantly distribute into aquatic systems.

4.3 Bioaccumulation

Due to rapid hydrolysis of the dichloro(dimethyl)silane and due to the presence of water in biological tissues, it is not relevant to consider this substance as bioaccumulative.

The subsequent hydrolytic product – dimethylsilanediol – is a very hydrophilic substance (log Kow = –0.41) that has no potential for bioaccumulation[3] (see Chapter 8.1.2).

4.3.1 Aquatic bioaccumulation

Bioaccumulation potential is not expected.

4.3.2 Terrestrial bioaccumulation

Bioaccumulation potential is not expected.

4.3.3 Summary and discussion of bioaccumulation

Bioaccumulation potential is not expected.

4.4 Secondary poisoning

Due to rapid hydrolysis dichloro(dimethyl)silane and due to the presence of water in biological tissues, it is not relevant to consider this substance as bioaccumulative.

The subsequent hydrolytic product – dimethylsilanediol – is a very hydrophilic substance (log Kow = –0.41) that has no potential for bioaccumulation[3] (see Chapter 8.1.2).

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Dichloro(dimethyl)silane is decomposed to dimethylsilanediol and hydrogen chloride immediately after entry into the organism. Hydrogen chloride causes severe acute local irritation/corrosion of skin and mucous membrane. In aqueous medium, hydrogen chloride dissociates into hydrogen cation and chloride anion. Both ions are a normal part of the metabolic processes. Dimethylsilanediol is highly hydrophobic substance (see Chapter 6) and in accordance with the low partition coefficient Kow may be assumed to remain dissolved in the plasma and gradually is excreted in urine.

Any study describing in detail the distribution of dimethylsilanediol in the organism was not found.

Absorption of dichloro(dimethyl)silane is very limited due to its hydrolysis and release of corrosive hydrogen chloride. Dichloro(dimethyl)silane in contact with skin or mucous membranes of the respiratory or digestive tract causes severe damage. These effects are observed and described in a number of tests gathered in the registration dossier.

Adverse local effects of dichloro(dimethyl)silane are identical to those caused by hydrogen chloride. Acute exposure may result in respiratory tract irritation, sneezing, choking, laryngitis, dyspnea, and chest pain. Higher exposure can cause pulmonary edema, bleeding of nose and gums, ulceration of the nasal and oral mucosa, chronic bronchitis, and pneumonia may also occur. Eye contact with dichloro(dimethyl)silane causes irritation, pain, swelling, corneal erosion, and blindness may result. Dermal exposure causes dermatitis (red, inflamed skin), severe burns, eschar formation, and necrosis damaged skin.

The dermal absorption test was conducted to determine the degree of skin permeability. Penetration rate of dimethylsilanediol was determined 11.7 µg/cm^2/d (11.4 % applied dose). It can be expected that the application of dichloro(dimethyl)silane would provide a different result due to skin damage.

Systemic effects were studied by using dimethylsilanediol in order to prevent interference with acute local effects. During long-term toxicity tests several adverse effects were found with varying degrees of severity. From systemic effects were among the most serious symptoms increased liver weight in connection with the centrilobular hypertrophy. Liver enlargement itself does not necessarily mean a specific manifestation of toxicity of dichloro(dimethyl)silane or dichlorosilanediol; this effect can be a common response to uptake of extraneous substance. The developmental toxicity test showed at higher doses of dimethylsilanediol more frequent occurrence of foetal malformations. However, these effects are observed only at higher doses of dimethylsilanediol; in real treatment of dichloro(dimethyl)silane such high doses are not absorbable due to corrosivity this substance.

5.2 Acute toxicity

Not relevant for this evaluation for considering further testing.

5.3 Irritation

Not relevant for this evaluation for considering further testing.

5.4 Corrosivity

Not relevant for this evaluation for considering further testing.

5.5 Sensitisation

Not relevant for this evaluation.

5.6 Repeated dose toxicity

Study of sub-acute inhalation toxicity after repeated doses of dichloro(dimethyl)silane showed that local irritant/corrosive effects overlap any systemic effects. NOAEC for long-term systemic toxicity in this study was not identified.

The subacute oral toxicity study of dimethylsilanediol was performed. Based on the NOAEL of 250 mg/kg/day was identified, which is based on adverse effects in liver. However, chemical properties of dichloro(dimethyl)silane suggest that this daily dose of dichloro(dimethyl)silane can not be absorbed under normal circumstances.

250 mg Dimethylsilanediol is molarly equal to 350 mg dichloro(dimethyl)silane. By hydrolysis of dichloro(dimethyl)silane is formed 198 mg hydrogen chloride. This means that intake of 250 mg/kg dimethylsilanediol per day is also intake of 198 mg/kg hydrogen chloride per day. According to ECHA guidance (Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health, ECHA, 2012) may be inhalation exposure derived from oral exposure (route-to-route extrapolation). By application of this mechanism, the concentration (for workers) of dichloro(dimethyl)silane for inhalation exposure is 617 mg/m^3. In literature a concentration of dichloro(dimethyl)silane of 13 ppm (cca 20 mg/m^3) is reported as life threatening at 8-hour exposure[5]. This is due to local corrosive effects of hydrogen chloride. It is therefore obvious that repeated exposure at a thirty times higher concentration of dichloro(dimethyl)silane is practically inconceivable.

Information on the long-term toxicity have been complemented by study of subchronic inhalation toxicity of hydrogen chloride, which is also the product of hydrolysis (primary degradation) dichloro(dimethyl)silane and is responsible for its corrosive properties. NOAEC established for hydrogen chloride (NOAEC = 20 ppm) was derived on the basis of the same symptoms as in subacute inhalation toxicity dichloro(dimethyl)silane. This confirms the theory that local irritation is caused by the hydrogen chloride formed by hydrolysis of dichloro(dimethyl)silane.

On the basis of available information, the eMSCA concludes that classification for repeated dose toxicity is not warranted.

5.7 Mutagenicity

Seven *in-vitro* studies of mutagenicity of dichloro(dimethyl)silane were available. These studies include all the tests required by Annexes VII and VIII of Regulation (EC) 1907/2006 (REACH). Results of all these tests are negative; the only exception is test *in-vitro* chromosome aberration, the result of which is inconclusive.

In-vivo chromosome aberration test was also performed (Mammalian Bone Marrow Chromosome Aberration Test). Results of this test is negative too.

No positive result was observed in mutagenicity tests of dichloro(dimethyl)silane. The eMSCA concludes that based on these results, classification for mutagenicity is not warranted.

5.8 Carcinogenicity

Carcinogenicity studies of dichloro(dimethyl)silane or dimethylsilanediol are not available.

Mutagenicity tests showed no mutagenic properties of the test substance. Histopathological findings in repeated dose toxicity test showed no tendency to form neo-plastic changes. The molecular structure contains no structural alert associated with carcinogenicity. There were no assumptions leading to a conclusion that dichloro(dimethyl)silane or its hydrolysis product dimethylsilandiol have carcinogenic potential.

On the basis of available information, the eMSCA concludes that there is no indication that dichloro(dimethyl)silane would be a carcinogen.

5.9 Toxicity for reproduction

Testing of the reproductive/developmetal toxicity was conducted on the basis of read-across approach due to corrosivity of dichloro(dimethyl)silane.

Adverse effect on fertility of dimethylsilanediol was not observed (NOAEL > 500 mg/kg/day). Maternal NOAEL mentioned in CSR (NOAEL = 250 mg/kg/day) is not based on reproductive parameters.

In the test of developmental toxicity of dimethylsilanediol, some adverse effects were observed (NOAEL = 250 mg/kg/day, foetal malformations and variations). However, chemical properties of dichloro(dimethyl)silane suggest that this daily dose of dichloro(dimethyl)silane can not be absorbed under normal circumstances.

250 mg Dimethylsilanediol is molarly equal to 350 mg dichloro(dimethyl)silane. By hydrolysis of dichloro(dimethyl)silane is formed 198 mg hydrogen chloride. This means that intake of 250 mg/kg dimethylsilanediol per day is also intake of 198 mg/kg hydrogen chloride per day. According to ECHA guidance (Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health, ECHA, 2012) oral data can be used by application by route-to-route extrapolation to evaluate the inhalation exposure situations. By application of this mechanism, the concentration (for workers) of dichloro(dimethyl)silane for inhalation exposure is 617 mg/m^3. In literature a concentration of dichloro(dimethyl)silane of 13 ppm (cca 20 mg/m^3) is reported as life threatening at 8-hour exposure[5]. This is due to local corrosive effects of hydrogen chloride. It is therefore obvious that

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Information on the long-term toxicity have been complemented by study of subchronic inhalation toxicity of hydrogen chloride, which is also the product of hydrolysis (primary degradation) dichloro(dimethyl)silane and is responsible for its corrosive properties. NOAEC established for hydrogen chloride (NOAEC = 20 ppm) was derived on the basis of the same symptoms as in subacute inhalation toxicity dichloro(dimethyl)silane. This confirms the theory that local irritation is caused by the hydrogen chloride formed by hydrolysis of dichloro(dimethyl)silane.

Based on these information, classification of dichloro(dimethyl)silane for reproduction toxicity is not warranted.

5.10 Endocrine disrupting properties

Not relevant for this evaluation.

5.11 Other effects

5.11.1 Non-human information

5.11.1.1 Neurotoxicity

Not relevant for this evaluation.

5.11.1.2 Immunotoxicity

Not relevant for this evaluation.

5.11.1.3 Specific investigations: other studies

Not relevant for this evaluation.

5.11.2 Human information

Not relevant for this evaluation.

5.11.3 Summary and discussion of specific investigations

Not relevant for this evaluation.

5.12 Combined effects

Not relevant for this evaluation.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO CHEMICAL PROPERTIES

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

Although dichloro(dimethyl)silane is manufactured and used in large quantities, its penetration into the environment is very limited. Dichloro(dimethyl)silane immediately hydrolyses in contact with water and therefore it must be rigorously separated from the outside environment in order to ensure the product is not contaminated. Dichloro(dimethyl)silane is therefore produced and used under strictly controlled conditions and contact with the surrounding environment is significantly reduced.

Normally, dichloro(dimethyl)silane or its hydrolytic product dimethylsilanediol may enter the environment through wastewater or via air emissions that occur during filling or emptying of transport containers. According to reactivity of dichloro(dimethyl)silane with water and hydrophilic properties (water solubility, partition coefficient) of dimethylsilanediol, it can be expected that dimethylsilanediol will be concentrated in the aquatic environment.

Long-term toxicity to Daphnia magna was assessed from information based upon read-across from trichloro(ethyl)silane.

Aquatic toxicity was not found in any study.

7.1.1 Toxicity data

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

LC_{50} > 126 mg/l (96 h, *Oncorhynchus mykiss*)
Substance: dimethylsilanediol (CAS: 1066-42-8)
Method: OECD Guideline 203 (Fish, Acute Toxicity Test)
Conditions: freshwater, static

7.1.1.1.2 Long-term toxicity to fish

No data are available.

7.1.1.2 Aquatic invertebrates

7.1.1.2.1 Short-term toxicity to aquatic invertebrates

IC_{50} > 117 mg/l (48 h, *Daphnia magna*)
Substance: dimethylsilanediol (CAS: 1066-42-8)
Method: OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Conditions: freshwater, static

7.1.1.2.2 Long-term toxicity to aquatic invertebrates

Long-term toxicity to Daphnia magna was established using read-across on trichloro(ethyl)silane (CAS: 115-21-9):

NOEC ≥ 100 mg/l (21 d, *Daphnia magna*)
Substance: trichloro(ethyl)silane (CAS: 115-21-9)
Method: OECD guideline 211 (Daphnia magna Reproduction Test)
Conditions: freshwater, semi-static

Trichloro(ethyl)silane is structurally similar to dichloro(dimethyl)silane, it has the same central atom and very similar substituents. In contact with water, it rapidly hydrolyzes to give hydrogen chloride and alkylsilanepolyol. It can be expected to have similar behavior and properties both dichloro(dimethyl)silane, and trichloro(ethyl)silane.

7.1.1.3 Algae and aquatic plants

EC_{50} > 118 mg/l (72 h, *Pseudokirchnerella subcapitata*)
NOEC ≥ 118 mg/l (72 h, *Pseudokirchnerella subcapitata*)
Substance: dimethylsilanediol (CAS: 1066-42-8)
Method: OECD guideline 201 (Alga, Growth Inhibition Test)
Conditions: freshwater, static

This value can be used as long-term toxicity for aquatic species according to ECHA guidance (Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterisation of dose[concentration]-response for environment, May 2008 (2008)).

7.1.1.4 Sediment organisms

No data are available.

7.1.1.5 Other aquatic organisms

No data are available.

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

Toxicity was not identified.

7.1.2.2 PNEC sediment

Derivation of PNEC(sediment) was carried by registrant in accordance with the recommended methodology ECHA (equilibrium partitioning method).

PNEC(sediment) = 1.21 mg/kg sediment wet weight

7.2 Terrestrial compartment

The direct contamination of soil with dichloro(dimethyl)silane under normal conditions is practically excluded. Indirect contamination can occur through rainfall or via activated sludge from STP. Dichloro(dimethyl)silane in the soil may exist only in the form of its hydrolysis products, dimethylsilanediol and hydrogen chloride. Hydrogen chloride, hydrogen and chloride ions respectively, are natural part of the environment. According to gathered knowledge, dimethylsilanediol does not have the tendency to adsorb to soil (see Chapter 4.2.1) as its nature is very hydrophilic. Therefore, dimethylsilanediol is removed from soil by water and exposure concentrations can be considered negligible.

Exposure in this compartment is unlikely.

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macro organisms

No data are available/needed.

7.2.1.2 Toxicity to terrestrial plants

No data are available/needed.

7.2.1.3 Toxicity to soil micro-organisms

No data are available/needed.

7.2.1.4 Toxicity to other terrestrial organisms

No data are available/needed.

7.2.2 Calculation of Predicted No Effect Concentration (PNEC soil)

Derivation of PNEC(soil) was carried out by the registrant in accordance with the recommended methodology ECHA (equilibrium partitioning method).

PNEC(soil) = 0.305 mg/kg soil wet weight

7.3 Atmospheric compartment

Air emissions of dichloro(dimethyl)silane occur during filling or emptying of transport containers. These leaks are converted into dimethylsilanediol and hydrogen chloride in a short time by atmospheric moisture. It can be assumed that dimethylsilanediol as well as hydrogen chloride are washed into the aqueous environment via rainfall.

Exposure in this compartment is unlikely.

7.4 Endocrine disrupting properties

Not relevant for this evaluation.

7.5 Microbiological activity in sewage treatment systems

7.5.1 Toxicity to aquatic micro-organisms

Not relevant for this evaluation. STP is not a part of the environment in the original meaning - it can be considered as part of the industrial unit.

7.5.2 PNEC for sewage treatment plant

Toxicity was not identified.

7.6 Non compartment specific effects relevant for the food chain (secondary poisoning)

Secondary poisoning is not expected as dichloro(dimethyl)silane (resp. dimethylsilanediol as its hydrolytic product) has no potential to bioaccumulation (see chapter 4.3).

7.7 Conclusion on the environmental hazard assessment and on classification and labelling

From the data obtained it can be concluded that dichloro(dimethyl)silane does not pose a risk to the environment.

8 PBT AND VPVB ASSESSMENT

8.1 Assessment of PBT/vPvB properties – Comparison with the criteria of Annex XIII

8.1.1 Persistence assessment

The evaluated substance, dichloro(dimethyl)silane, is easily hydrolysable compound and as such is not persistent. Its primary hydrolytic products are hydrogen chloride and dimethylsilanediol. Hydrogen chloride is an inorganic substance, so its persistent ability is not relevant.

Data collected in registration dossier suggest that dimethylsilanediol (DMSD) is degradable, but degradation process is slow. For example, several studies dealing with the decomposition of DMSD in soil report degradation rate in this environment in percent per month. This is much less than the required rate of biodegradation in this environment – required half-life in soil should be lower than 120 days (Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment, version 1.1 (20012)).

The study Ready biodegradability – CO_2 in sealed vessels (Headspace Test) was performed with trimethylsilanol (CAS: 1066-40-6) as tested substance (read-across). The test result demonstrated that trimethylsilanol does not decompose in water within 28 days. Trimethylsilanol in comparison with dimethylsilanediol is more lipophilic, less soluble in water and less capable of decomposition. This is due to one methyl group instead of a hydroxyl group in the molecule of trimethylsilanol. Binding to methyl group is less polar than to OH group and therefore it is more stable and less capable of decomposition. On the basis of Ready biodegradability study and read-across principles it can be assumed that dimethylsilanediol is not readily biodegradable substance.

Using the calculation methods (Chapter 4.1.2.1.1) was estimated degradability DMSD according to parameters recommended by ECHA (Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment, version 1.1 (2012)). Program EPI Suite (ver. 4.1), module BIOWIN (ver. 4.10), procedures BIOWIN2, BIOWIN3 and BIOWIN6 were used for estimation of parameters of biodegradability. The results of these computational models indicate that DMSD is degradable (conditions [BIOWIN 2 < 0.5 and BIOWIN 3 < 2.2] or [BIOWIN 6 < 0.5 and BIOWIN 3 < 2.2] are not fulfilled).

Based on all collected information, higher reliability was assigned to the experimental results, thus pursuant to results of the test Ready biodegradability – CO_2 in sealed vessels (Headspace Test) and decomposition of dimethylsilanediol in soil may be expected that this substance is not readily biodegradable and meets **P/vP** criteria.

8.1.2 Bioaccumulation assessment

Due to its rapid decomposition, dichloro(dimethyl)silane cannot be expected to bioaccumulate. Instead, bioaccumulation of the hydrolysis product (dimethylsilanediol) is considered.

Generally, bioaccumulation is considered as a partitioning process between water and lipids. Other distribution processes in organism may be usually neglected (e.g. binding to the DNA or proteins).

Bioaccumulation ability of dimethylsilandiol is closely related to a partition coefficient n-octanol/water, resp. its logarithm. Logarithm of partition coefficient was determined experimentally: log Kow = –0.41[1]. This value indicates that dimethylsilanediol is very hydrophilic substance as evidenced by high solubility in water (245 g DMSD/100 g water[2]).

Due to rapid decomposition of dichloro(dimethyl)silane in water and the hydrophilic nature of dimethylsilanediol (log Kow = –0.41), both substances can be considered as **not B/not vB.**

8.1.3 Toxicity assessment

Toxicity of dichloro(dimethyl)silane need not be taken into account as this easily hydrolysable compound in contact with aqueous environment or animal tissues rapidly hydrolyses on dimethylsilanediol (DMSD) and hydrogen chloride. There are not known any long-term toxic effects of hydrogen chloride, on the other hand its acute local effects could mask the long-term toxicity effects of DMSD. Therefore, the evaluation of long-term toxicity of dichloro(dimethyl)silane is based upon testing of DMSD.

The dimethylsilanediol is not classified as CMR or long-term toxic substance according to criteria of Regulation (EC) 1272/2008 (CLP). The available information does not indicate that classification for mutagenicity, reproductive toxicity or carcinogenicity would be warranted. Chronic toxicity of dimethylsilanediol to environment has not been tested. The results of short-term toxicity to environment suggest that the toxicity of DMSD is not significant and in combination with hydrophilicity (log Kow = –0.41) indicates that long-term effects of DMSD are not expected.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.10: Characterisation of dose[concentration]-response for environment, May 2008 (2008) the NOEC (72 h) for algae can be used as long-term toxicity value. For dimethylsilanediol NOEC ≥ 118 mg/l (*Pseudokirchnerella subcapitata*, 72 h) was experimentally determined, therefore this value can be considered as long term toxicity to environment.

The registrant submitted long-term toxicity study on aquatic invertebrates for trichloro(ethyl)silane: NOEC ≥ 100 mg/l (Daphnia magna, 21 d) as read-across approach. Trichloro(ethyl)silane is structurally similar to dichloro(dimethyl)silane; it has both Si–Cl and Si–alkyl bonds and in contact with water hydrolyses to alkylsilanol. It is therefore appropriate to use as source substance for read-across.

On the basis of information presented above and in accordance with decision criteria (Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment, version 1.1 (2012)) dimethylsilanediol does not fulfil the conditions for toxicity and therefore is considered as **not T**.

8.1.4 Summary and overall conclusions on PBT and vPvB Properties

Pursuant to Regulation (EC) No. 1907/2006, Annex XIII, a substance is identified as a PBT substance if it fulfils the criteria P, B and T; a substance is identified as a vPvB substance if it fulfils the criteria vP and vB. Dichloro(dimethyl)silane and its first hydrolytic product dimethylsilanediol

respectively fulfil criteria P/vP, but they do not fulfil criteria B/vB and T. Therefore **dichloro(dimethyl)silane** can **not** be considered as **PBT/vPvB** substance.

9 EXPOSURE ASSESSMENT

Stated in Confidential Annex.

10 RISK CHARACTERISATION

Stated in Confidential Annex.

11 REFERENCES

1. Xu S., Kropscott B., Method for simultaneous Determination of Partition Coefficients for Cyclic Volatile Methylsiloxanes and Dimethylsilanediol, American Chemical Society, **84**(4), p. 1948-1955 (2012);

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3. ITC/U.S. EPA, Information Review No. 223 (draft), Chlorosilanes (1981);

4. Hill I.R., Mathiessen P., Heimbach F. (editors), Guidance Document on Sediment Toxicity Tests and Bioassays for Freshwater and Marine Environments: from the Workshop on Sediment Toxicity Assessment at Renesse, Netherlands on 8-10 November 1993, Society of Environmental Toxicology and Chemistry (SETAC), Brussel, Europe (1993);

5. U.S. EPA, Acute Exposure Guideline Levels (AEGLs) – Results for Dichlorodimethylsilane, http://www.epa.gov/oppt/aegl/pubs/results19.htm (available 7.11.2014);

12 ABBREVIATIONS

CAS	Chemical Abstract Services
CSR	chemical safety report
CoRAP	Community Rolling Action Plan
DMSD	dimethylsilanediol
ES	Exposure scenario
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
PBT/vPvB	persistent, bioaccumulative and toxic / very persistent and very bioaccumulative substances
(Q)SAR	quantitative structure-activity relationship
RCR	risk characterisation ratio
RMM	risk management measuring

ANNEX: This annex is confidential and not included in the public version of this report.