SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Trimethoxy(vinyl)silane

EC No 220-449-8

CAS No 2768-02-7

Evaluating Member State(s): Sweden

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2013

Before concluding the substance evaluation a Decisions to request further information was issued on 4 July 2016.

Further information on registered substances here:

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

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

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

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Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

Trimethoxy(vinyl)silane (TMVS) was originally selected for substance evaluation in order to clarify concerns about:

-Suspected sensitiser

-Wide dispersive use

-Exposure of workers

-Exposure of sensitive population

-High RCR

-High (aggregated) tonnage

During the evaluation also other concerns were identified. The additional concerns were:

-Mutagenicity

-Derivation of DNELs

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A dossier evaluation was performed and a compliance check (CCH) decision was issued in May 2018. The requested studies included a pre-natal developmental toxicity study (OECD TG 414) and an extended one-generation reproductive toxicity study (OECD TG 443).

Harmonised classification as Skin Sens., Category 1B, was proposed by the Swedish CA in May 2017. The Risk Assessment Committee (RAC) opinion was adopted in September 2018, agreeing to this proposal.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State 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	X
Harmonised Classification and Labelling	X
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

A Mammalian alkaline comet assay, according to the OECD TG 489, was performed subsequent to the substance evaluation decision. The results were negative in the lung and

bone marrow and equivocal in the liver. The evaluating MSCA concluded that no further mutagenicity testing was needed.

Subsequent to the requests in the SEv decision the Registrant(s) provided information on the reasoning behind the choice of assessment factors used for derivation of DNELs. The Registrant(s) also provided further information on exposure estimations for the worker and consumer use of products containing the substance. The evaluating MSCA concluded that no further information request was needed for risk assessment.

4. FOLLOW-UP AT EU LEVEL

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

4.1.1. Harmonised Classification and Labelling

The concern for skin sensitisation was confirmed based on the evaluation of the available data. The SE CA submitted in May 2017 a classification dossier with the proposal Skin Sens. Category 1B, which was adopted in September 2018 in the Risk Assessment Committee.

4.1.2. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

Not 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

Trimethoxy(vinyl)silane was originally selected for substance evaluation in order to clarify concerns about:

-Suspected sensitizer

-Wide dispersive use

-Exposure of workers

-Exposure of sensitive population

-High RCR

-High (aggregated) tonnage

During the evaluation also other concerns were identified. The additional concerns were:

-Mutagenicity

-Derivation of DNELs

Table 2

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Skin Sensitisation	The available data was considered sufficient to conclude that the substance was a skin sensitiser. The evaluating MSCA submitted a CLH proposal, which led to harmonised classification of the substance as Skin Sens., Category 1B. No further action.
Genotoxicity	An *in vivo* Mammalian alkaline comet assay (OECD TG 489) was performed following a request in the SEv decision. The results were negative in the lung and bone marrow and equivocal in the liver. The genotoxicity concern was not confirmed in the bone marrow and lung. Results were inconclusive for the liver. No further action.
DNEL derivation	Justification for use of lower assessment factors than default for derivation of DNELs was provided, subsequent to a request in the SEv decision. No further action.
Worker and consumer exposure	Information on exposure for workers and consumers was updated in the registration(s). No further action.

7.2. Procedure

Trimethoxy(vinyl)silane was included in the Community Rolling Action Plan (CoRAP) for Substance Evaluation (SEv) in 2013, by the competent authority of Sweden. The scope of the evaluation was human health, targeted to concern for skin sensitisation, genotoxicity and exposure/risk assessment.

A SEv decision was issued on 4 July 2016, with request for information on genotoxicity (OECD TG 489), derivation of DNELs and exposure of consumers and professional users.

Based on the evaluation of the available information the evaluating MSCA concluded that data was sufficient for classification of the substance as a skin sensitiser. In May 2017 the Swedish CA submitted a classification dossier for TMVS with the proposal Skin Sens. Category 1B. In September 2018 the Risk Assessment Committee (RAC) opinion was adopted, agreeing to this proposal.

In February 2018 the registration(s) were updated. An *in vivo* Mammalian alkaline comet assay was provided. Also, information on derivation of DNELs and exposure assessment was updated. The evaluating MSCA assessed the new information in the follow-up evaluation and concluded that no further information request was necessary.

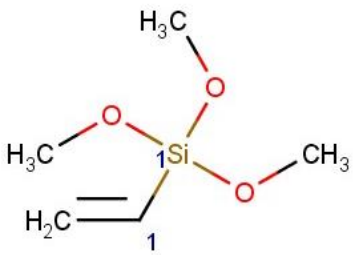
7.3. Identity of the substance

Table 3

SUBSTANCE IDENTITY	
Public name:	Trimethoxy(vinyl)silane
EC number:	220-449-8
CAS number:	2768-02-7
Index number in Annex VI of the CLP Regulation:	014-049-00-0
Molecular formula:	C5H12O3Si
Molecular weight range:	148,23 g/mol
Synonyms:	VINYLTRIMETHOXYSILANE

Type of substance: Mono-constituent

Structural formula:



7.4. Physico-chemical properties

Table 4

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Liquid
Vapour pressure	12 790 Pa at 20°C
Water solubility	1000 000 mg/L at 20°C
Partition coefficient (Log Kow)	-0,82
Flammability	Flammable liquid
Flash point	25,5-26°C at 1013 hPa
Explosive properties	Non-explosive
Oxidising properties	Non-oxidising

7.5. Manufacture and uses

7.5.1. Quantities

Table 5

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 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

Table 6

USES	
	Use(s)
Formulation	Formulation or re-packing at industrial sites and in manufacturing Coatings, sealants and adhesives
Uses at industrial sites	Laboratory chemical Coatings, adhesives and sealants products Monomer, intermediate Non-metal surface treatment
Uses by professional workers	Coatings, adhesives and sealants products Intermediate, monomer Non-metal treatment solutions Building and construction work
Consumer Uses	Adhesives and sealants Coating products Laboratory reagent

The information was collected from the ECHA dissemination site on 2020-04-16.

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

None. Skin Sens. Category 1B was agreed in RAC (RAC opinion 2018).

7.6.2. Self-classification

In the registration(s):

Flam. Liq. 3	H226
Acute Tox. 4	H332 (Harmful if inhaled)

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

Skin Irrit. 2	H315
Eye Dam. 1	H318
Eye Irrit. 2	H319
STOT SE 3	H335 (Kidney and bladder)
STOT RE 2	H373 (Bladder)
Skin Sens. 1B	H317
Flam Liq. 2	H225

7.7. Environmental fate properties

Not evaluated.

7.8. Environmental hazard assessment

Not evaluated.

7.9. Human Health hazard assessment

7.9.1. Toxicokinetics

Not evaluated. See section 7.9.9. for an overview of toxicokinetics information.

7.9.2. Acute toxicity and Corrosion/Irritation

Not evaluated.

7.9.3. Sensitisation

The concern for skin sensitisation was based on the available animal data on trimethoxy(vinyl)silane.

A positive *in vivo* Buehler test (OECD TG 406) with trimethoxy(vinyl)silane was available. This study was performed according to GLP with reliability 1 (Klimisch scoring). Doses used were 100% for the induction and 25% for the challenge. The study resulted in a clear response, where 13 out of 20 animals showed positive reactions. None of the animals in the negative control group showed positive reactions.

Two Guinea pig maximisation tests with trimethoxy(vinyl)silane showed negative results. However, the design of these studies was not sufficient to detect sensitisation. For the key study there was a concern regarding the dose selection: for the intradermal induction 3% solution in Freund's complete adjuvant (FCA) and 5% solution in mineral oil was used. For the topical induction 5% solution in mineral oil was used. The concentration of 5% in mineral oil was the highest tested, but caused no irritation. According to the OECD TG 406

the concentration used for the induction should cause mild to moderate skin reaction. Therefore, the results of this test was deemed unreliable. In the supporting study positive controls were missing and too few animals were tested. Based on these limitations this study was considered not reliable.

The Registrant(s) provided a summary report on information from human exposure to TMVS. The report stated that only acute slight redness, but no case of skin sensitisation was observed and that based on the experience of the plant managers and the application experts with direct relations to the customers there is no indication/information of sensitising properties of trimethoxy(vinyl)silane or mixtures containing the substance. The Registrant(s) concluded that the substance did not have skin sensitisation potential.

However, in the evaluating MSCA's view the information provided on human exposure was not satisfactory to address the skin sensitisation potential. The report did not include methodical analysis of the populations exposed to trimethoxy(vinyl)silane at work or as consumers, but rather referred to a lack of information. Regarding the available animal data, the Registrant(s) did not justify why the positive results from the Buehler test was disregarded.

Based on the available information the evaluating MSCA concluded that the substance was a skin sensitiser. Consequently, the evaluating MSCA submitted a CLH dossier with the proposal Skin Sens. Category 1B, which was agreed on in the RAC.

7.9.4. Repeated dose toxicity

Not evaluated.

7.9.5. Mutagenicity

During the SEv the evaluating MSCA identified a concern for mutagenic potential of trimethoxy(vinyl)silane.

Negative results were reported from *in vitro* Bacterial reverse mutation assays and an *in vitro* Mammalian cell gene mutation test (OECD TG 476) using CHO cells. Thus, there was no concern for potential of the substance to induce point mutations.

Positive results for *in vitro* Mammalian chromosome aberration induction was reported in two studies. A follow up *in vivo* Erythrocyte micronucleus assay (chromosome aberration) was performed via intraperitoneal administration, according to the EPA Health effects guideline 560/6-83-001. The study that was assigned as reliable with restrictions by the Registrant(s) was negative. However, the result of this study was deemed unreliable as significantly lower number of cells were analysed compared to the guideline requirement. 1000 erythrocytes were scored for incidence of micronuclei, but the current guideline requires a minimum of 2000 cells to be analysed.

Thus, the *in vitro* data raised a concern for mutagenicity via induction of cytogenicity and the available *in vivo* micronucleus assay was not sufficient to clarify the concern. Therefore, another *in vivo* study was deemed necessary to clarify the concern for the potential of TMVS to cause cytogenicity.

In the SEv decision an *in vivo* Mammalian alkaline comet assay, according to the OECD TG 489, via the inhalation route was requested. The Registrant(s) carried out the comet assay. The substance was administrated as a vapour by nose only inhalation, for 6 hours on 2 consecutive days to male rats. Doses were 325, 650 and 1300 ppm. DNA damage was assessed in the lung, liver and bone marrow.

The % DNA tail for the negative control was within the historical range and for the positive control showed a statistically significant increase. No statistically significant increase in the

mean % tail DNA compared to the respective negative control was reported in the lung or bone marrow tissue.

In the liver tissue a statistically significant dose-dependent increase in the % tail DNA was reported, shown by regression analysis (P<0.01). The mean % DNA tail was 0,03 for the negative control and 0,02, 0,06 and 0,09 in the low, mid and high dose, respectively. All the values were indicated to be within the historical vehicle control range. The indicated vehicle control % tail DNA range for liver was 0,00-4,36 (0,98 at 95% confidence. 95% confidence was calculated by the mean of the median ± 2 standard deviations). The historical control data was collected 2015-2017 from male rats liver tissue, from all vehicles used and routes of administration (gavage, intraperitoneal, subcutaneous, inhalation or intravenous). According to the OECD TG 489 different tissues and different species, as well as different vehicles and routes of administrations, may give different negative control % tail DNA values. It is therefore important to establish negative control ranges for each tissue and species. Thus, the historical control data provided has limitations as data were not collecetd from studies with the same vehicle and route of administration as the performed study.

The evaluating MSCA noted that statistical analysis of the difference in the % tail DNA between each dose group and the concurrent negative control group by pairwise comparisons using one-sided statistical tests was not reported. The Registrant(s) were asked (informal communication) to clarify if such statistical analyses were performed and, if so, what P-values were obtained. In response the Registrant(s) provided the following information: the vehicle control and test article dose groups were subjected to one-way ANOVA (two-tailed significance test), Dunnett's post-hoc (comparison test) looking at a significance level of $p \leq 0,05$. In the liver data the one-way ANOVA value was p=0,036, but no significant differences were noted between the control and test groups within Dunnett's comparison.

According to the OECD TG 489 a test chemical is considered to be clearly positive if: (a) at least one of the test doses exhibits a statistically significant increase compared with the concurrent negative control, (b) the increase is dose-related when evaluated with an appropriate trend test and (c) any of the results are outside the distribution of the historical negative control data for a given species, vehicle, route, tissue, and number of administrations. When all of these criteria are met, the test chemical is then considered able to induce DNA strand breakage in the tissues studied in this test system. Further, according to the test guideline in case not all the criteria listed are met and in order to assist in establishing the biological relevance of a result, the data should be evaluated by expert judgement and/or further investigations if scientifically justified.

Considering the criteria given in the test guideline a robust conclusion, indicating clearly negative (or positive) result could not be drawn for the comet assay with the substance. Thus, the Comet assay was inconclusive.

A recent Mammalian alkaline comet assay with the analogue substance Trimethoxy(methyl)silane (EC number 214-685-0), in which DNA damage was assessed in lung, liver and bone marrow showed negative results.

The evaluating MSCA concluded that the mutagenicity concern was unresolved (based on the inconclusive results from the liver tissue), but that further mutagenicity testing could not be justified.

7.9.6. Carcinogenicity

Not evaluated.

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

Not evaluated.

Information on reproductive toxicity was identified as a potential data gap for a standard information requirement. The substance was "handed over" to ECHA for CCH.

7.9.8. Hazard assessment of physico-chemical properties

Not evaluated.

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

In the registration(s) DNELs for long-term systemic effects are derived for the inhalation, dermal and oral route. The dermal and inhalation DNELs are based on NOAEC=605 mg/m^3 from a subchronic whole-body inhalation study in rats. The effects observed included cystitis in the bladder submucosa at 14 weeks and submucosal mastocytosis at 18 weeks. Renal lesions, including papillary necrosis, interstitial edema and/or papillary hyperplasia of the transitional epithelium was observed at 2421 mg/m^3. The oral DNEL is derived from the NOAEL=62,5 mg/kg bw/day from a Combined repeated dose toxicity and reproduction/developmental toxicity screening study, according to the OECD TG 422. The substance was administrated via gavage at up to 1000 mg/kg bw/day. The effects observed included histopathological changes in the urinary bladder and decreased thymus weights at 250 mg/kg bw/day.

During the SEv the evaluating MSCA noted that for DNEL derivation the assessment factor (AF) used for the intraspecies extrapolation was lower than ECHA's guidance recommendation. AF 2.2 for workers and 3.2 for the general population was used, instead of 5 and 10, respectively. This resulted in less conservative DNELs and brought some of the RCR values below 1.

The Registrant(s) argued that the intraspecies AF takes account for the variability between individuals. The default AFs can be broken down into factors accounting for toxicodynamic and toxicokinetic differences. The intraspecies factor of 10 is composed of two identical factors of $\sqrt{10}$ = 3.2 and for workers $\sqrt{5}$ = 2.2. As the conversion of siloxanes to silanols and their excretion proceeds without enzymatic involvement, individual differences was without effect. As a result, the toxicokinetic components could be eliminated from these AFs.

The evaluating MSCA concluded that since no study of the metabolism of the substance was available further information was needed to support this assumption. Therefore, under SEv further justification for the use of lower than default AFs was requested.

In response to this request the registration(s) were updated with a justification for the use of modified AFs, based on toxicokinetics information. Physiologically based pharmacokinetic and toxicokinetic (PBTK) models were used to predict absorption, distribution, metabolism and excretion properties of TMVS. Using these models predictions were made that the substance is hydrolysed, absorbed and excreted rapidly. In moist medium the substance hydrolyses with a half-life of 0.1 hours at pH 7 and 20-25°C, to vinylsilanetriol and methanol. Following oral exposure, at pH 2 the substance is predicted to hydrolyse within 5 seconds. TMVS and its hydrolysis products are absorbed after inhalation or oral exposure, based on their molecular weight and water solubility. Systemic availability is supported in the acute and repeated dose toxicity studies. The soluble fraction of TMVS in blood is about 92% and of vinylsilanetriol >99%, suggesting that once absorbed, both substances are likely to be excreted via urine.

It could therefore be concluded that the substance and its hydrolysis products are not recognised by the mammalian metabolic systems. Since hydrolysis occurs without

enzymatic involvement, it was considered appropriate to reduce the intraspecies assessment factor by exclusion of the toxicokinetic element of the AF.

The evaluating MSCA concluded that no further information request on derivation of DNELs was needed.

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

The substance is a skin sensitiser and there is a RAC opinion for harmonised classification as Skin Sens. Category 1B.

Based on the evaluated available information, no further classification is warranted for the substance.

7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

7.11. PBT and VPVB assessment

Not evaluated.

7.12. Exposure assessment

7.12.1. Human health

In the registration(s) exposure scenarios are presented for production and the following uses:

- Monomer in the production of silicone polymers or silicone resins
- Intermediate in the production of other organosilicon substances
- Coatings
- Non-metal surface treatment and non-aqueous polymer preparation
- Sealants
- Laboratory reagent in research and development

In the registrations(s) the exposure for several uses are estimated using CHESAR v3.1.1 with the inputs defined in the exposure scenarios. The exposure scenarios are based on information in the public domain or provided by the producer companies. Direct exposure of workers and the general population to the parent substance or its hydrolysis products may occur via the inhalation and dermal routes.

For some of the exposure scenarios, e.g. use of sealant products, it is indicated that the concentration of the monomeric silane in the products is lowered due to polymerisation, compared to the amount initially added to the formulation. Therefore, lower concentration than those initially added were used for the exposure estimations.

Subsequent to a request in the SEv decision the Registrant(s) provided information to support the use of lower concentrations. The provided studies described common sealant formulation processes and demonstrated that the residual concentration, at the point of use, of crosslinker (TMVS) in the sealant product is reduced. The reports are based on data from analysed samples across different formulations. The range of concentrations that were tested reflected the composition of the products on the market. In the report from 2010, measurements showed that the concentrations of the monomeric trimethoxy(vinyl)silane added to the formulation decreased from 2% to 0,65% and from 3% to 0,45% with the relative standard deviation of 5,6% and 9,3%, respectively.

Based on these studies the evaluating MSCA agreed that the concentration of the substance in the formulation is reduced at the time of exposure. However, it was noted that the study

had some limitations, e.g. no information was provided if the equilibrium between the monomeric and polymeric form of the silane in the sealant product could be affected significantly by additional factors such as temperature.

Consumer long-term exposure

In the registration(s) estimation of the long-term exposure of consumers from the short-term use, occurring 3 times per year was reported. The estimation was calculated by averaging uses over the whole year. This was considered not to be a proper approach. According to the ECHAs' Guidance on information requirements and chemical safety assessment: for products used infrequently, use frequency should not be used to average out exposure over a longer time period. In the first instance, exposure should be calculated for the actual duration of an event (event exposure) and then expressed as that concentration per day (ECHA 2012).

In the updated registration(s) for derivation of DNEL for infrequent inhalation exposure correction for exposure duration and exposure frequency was applied. ConsExpo daily average values were used instead of the yearly average. Thus, risks seem to be controlled.

7.12.2. Environment

Not evaluated.

7.12.3. Combined exposure assessment

Not evaluated.

7.13. Risk characterisation

The described use scenarios for trimethoxy(vinyl)silane result in exposure of workers and consumers/general population. The calculated Risk Characterization Ratios (RCRs) for the described uses are below 1.

In the SEv decision further information for the assessment of the risk characterisation for consumers was requested. Specifically, risk characterisation for consumers was based on acute DNELs. The evaluating MSCA noted that the expected consumer use pattern, i.e. duration and frequency of the use of products containing trimethoxy(vinyl)silane (and similar substances) indicated potential of repeated exposure over a period longer than acute / 24h. Considering the expected use patterns the risk assessment based on acute DNELs was regarded not sufficient to conclude that the risks were controlled.

In response to this request the registration(s) were updated. Long-term DNELs were used for RCR calculations for all the exposure scenarios (both acute and chronic). Thus, risks seem to be controlled.

7.14. References

ECHA 2012. *ECHA Guidance on information requirements and chemical safety assessment*. Chapter R.8 Characterisation of dose –response for human health. Version : 2.1 November 2012

References to the studies reported in the registration(s) can be found on the ECHA dissemination webpage http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

7.15. Abbreviations

AF	Assessment Factor
CAS	Chemical Abstracts Service
CCH	Compliance Check
CHESAR	CHEmical Safety Assessment and Reporting
CHO	Chinese Hamster Ovary
CLH	Harmonized classification
CLP	Classification, labelling and packaging (Regulation (EC) No 1272/2008)
CMR	Carcinogenic, Mutagenic or Reprotoxic
CoRAP	Community Rolling Action Plan
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
eMSCA	Evaluating Member State Competent Authority
EOGRTS	Extended One-Generation Reproductive Toxicity Study
FCA	Freund's Complete Adjuvant
MSC	Member State Committee
MSCA	Member State Competent Authority
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative, Toxic
PBTK	Physiologically Based Toxicokinetic
RAC	Risk Assessment Committee
RCR	Risk Characterization Ratio
TMVS	Trimethoxy(vinyl)silane