Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Trimethoxyvinylsilane
Chemical Group:	
EC Number:	220-449-8
CAS Number:	2768-02-7
Submitted by:	Swedish Chemicals Agency
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

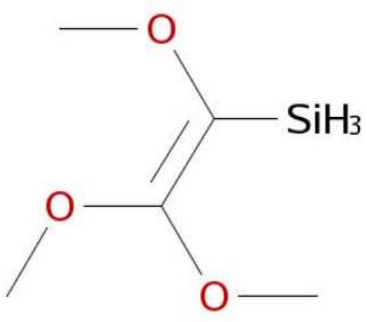
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Trimethoxyvinylsilane
EC number:	220-449-8
EC name:	trimethoxyvinylsilane
CAS number (in the EC inventory):	2768-02-7
CAS number:	2768-02-7
CAS name:	N/A
IUPAC name:	Ethenyl(trimethoxy)silane
Index number in Annex VI of the CLP Regulation	Not applicable.
Molecular formula:	C5H12O3Si
Molecular weight or molecular weight range:	148.2325
Synonyms:	Vinyl trimethoxy silane, (Trimethoxysilyl)ethylene (Trimethoxysilyl)ethene Ethenyltrimethoxysilane

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed in Annex VI of CLP

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

No CLH proposal available.

2.3 Self classification

Self classification in the registrations:

CLP:

Flam. Liquid 3, H226: Flammable liquid and vapour.

Acute Tox. 4, H332: Harmful if inhaled.

DSD:

R10 Flammable

Xn; R20 Harmful; Harmful by inhalation.

In addition are the following classifications included in the Classification and labelling inventory:

Flam. Liq. 2; H225: highly flammable liquid and vapour.
Asp. Tox. 1; H304: May be fatal if swallowed and enters airways.
Skin Irrit. 2; H315: Causes skin irritation.
Eye Irrit. 2; H319: Causes serious eye irritation.
STOT SE 3; H335: May cause respiratory irritation.
Muta. 1B; H340: May cause genetic defects.
Carc. 1B; H350: May cause cancer.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☒ Article 44(1) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

3.2 Grounds for concern

☐ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☒ (Suspected) Sensitiser	☐ Consumer use	☒ High RCR
☐ (Suspected) PBT	☒ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☒ Other (provide further details below)	

The Registrant has provided four studies on skin sensitization from which one is a key study and the three remaining are supportive studies. Three out of four studies have been performed with the registered substance and one with a read-across substance (supportive study) vinylsilanetriol where only common name was provided in the endpoint study record.

Three out of the four studies were negative, including the key study and one was positive. The negative studies were performed according to the OECD 406 using the Guinea Pig Maximation Test (GPMT). The positive study was performed according to the OECD 406 using the Buehler test. The registrant has not justified soundly why the positive results from the Buehler test can be disregarded. Moreover, the Buehler test can be regarded as less sensitive than the GPMT (or LLNA).

The Buehler study was performed in 1993, according to GLP and with reliability 1 (Klimish scoring) and resulted in clearly positive response where 13 out of 20 animals showed positive reactions, none of the animals in the negative control group showed reactions. Doses used in the study were 100% for induction and 25% for challenge (corn oil used as a vehicle).

The Key study (GPMT) was performed in 2000, according to GLP and with reliability 1. There are some concern in the dose selection for challenge, because for the intradermal induction 3% solution with FCA and mineral oil was selected and for the topical induction 5% in mineral oil. The concentration for the topical challenge was chosen to be 5% in mineral which was the highest non-irritant concentration. However, according to the GPMT (OECD 406) the concentration for the induction should cause mild to moderate skin reaction, therefore it is not clear how why they have used 5% concentration for the topical induction if that concentration does not cause skin reactions.

The substance has a wide dispersive use and high exposure to workers. There is also high potential for exposure via inhalation route to workers and consumers (PROCS 7 and 10) in Exposure scenario (ES) 5 to 8, 10 and 12 where the Risk characterization ratios (RCRs) are above 0.5. The substance is a medium fugacity substance with vapor pressure 1190 Pa, hence inhalation exposure is relevant for this substance, especially if substance is considered to be a sensitiser.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☒ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Industrial use: monomers, chemical intermediates, sealants, laboratory chemical, non-metal surface treatments and non-aqueous polymer preparation and in coatings.

Professional use: sealants and coatings

Consumer use: sealants and coatings

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☒ Other (provide further details below)
☐ Annex XVII (Restriction)	

Substance has been evaluated under OECD in 2009 (report published in 8/2010) and the conclusion for the human health part was

"VTMS may present hazard for human health (potential for skin sensitization, oral repeated-dose toxicity and developmental toxicity (only at the high concentration via inhalation). Adequate screening-level data are available to characterize the human health hazard for the purposes of the OECD HPV Chemicals Programme."

VTMS is a synonym for trimethoxyvinylsilane.
Link to the OECD substance site
http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?Key=05e9b072-9f4a-4e65-bea5-f4c4e0b629f8&idx=0

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☒ Other (provide further details below)	

Further data not necessarily needed, since the substance has already some data for the sensitisation endpoint. However, the registrant has not given sound justification why the other test has been taken over the clearly positive Buehler test. If new data would be requested the choice of test would be the LLNA.

If concluded that the substance is a skin sensitiser, the potential for respiratory sensitisation could be examined in addition due to the potential exposure via inhalation route e.g. by performing cytokine fingerprinting.

3.6 Potential follow-up and link to risk management

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

If concluded that substance is a sensitiser, to consider a proposal for harmonized classification.