Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Trimethoxy(metyl)silane
Chemical Group:	
EC Number:	214-685-0
CAS Number:	1185-55-3
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

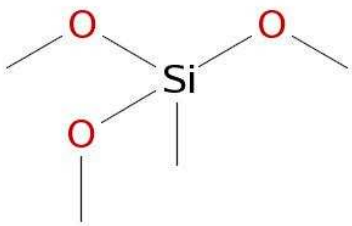
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Trimethoxy(methyl)silane
EC number:	214-685-0
EC name:	Trimethoxy(methyl)silane
CAS number (in the EC inventory):	1185-55-3
CAS number:	1185-55-3
CAS name:	
IUPAC name:	Trimethoxy(methyl)silane
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C4H12O3Si
Molecular weight or molecular weight range:	136.2218
Synonyms:	Methyltrimethoxysilane, Silane, trimethoxymethyl-

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 classified

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not proposed

2.3 Self classification

For physical-chemical properties:	
Flammable liquids:	Flam. Liquid 2 (Hazard statement: H225: Highly flammable liquid and vapour.)
For health hazards:	
Skin sensitisation:	Skin Sens. 1 (Hazard statement: H317: May cause an allergic skin reaction.)

Opt out for sensitisation potential registrations -

Skin sensitisation:	Reason for no classification: conclusive but not sufficient for classification

According to DSD:

F; R11: Highly flammable; Highly flammable.

Xi; R43: May cause sensitisation by skin contact.

The following self classifications are in addition notified to the Classification and Labelling Inventory:

Acute Tox. 4; H302: Harmful if swallowed.

Acute Tox. 4; H332: Harmful if inhaled.

Skin Irrit. 2; H315: Causes skin irritation.

Eye Irrit. 2; H319: Causes serous eye irritation.

STOT SE 3; H335: May cause respiratory irritation.

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 concern is due to: 1) no first choice skin sensitization provided and lack of motivation for performing other study (as required by REACH Annex VII); 2) ambiguity of the results in the provided study (Buehler test); 3) ambiguity of the overall evidence; 4) suspected sensitization properties in connection to exposure of workers and customers (wide spread use).

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		

Please provide further details

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

Please provide further details

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)	

Please provide further details

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)	

The proposed substance evaluation process aim to clarify the targeted concern i.e. suspected sensitization potential.

As a first step the compliance with the data requirement would be evaluated including requesting and evaluation of motivation on why registrant(s) did not provide the first choice sensitization study LLNA as required in REACH Annex VII, but performed another type of test or registered studies analyzing similar substances.

Dependent the outcome of this part of evaluation in connection to clarification of the main concern the additional study e.g LLNA sensitization study maybe further requested.

3.6 Potential follow-up and link to risk management

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

The following step includes evaluation of all information including possible new data on sensitisation potential and the exposure data indicating wide spread use and/or consumer exposure for consideration of proposal for harmonised classification as skin sensitizer.