Justification for the selection of a substance for CoRAP inclusion

– UPDATE –

Substance Name (Public Name):	3-trimethoxysilylpropyl methacrylate
Chemical Group:	-
EC Number:	219-785-8
CAS Number:	2530-85-0
Submitted by:	Health and Safety Authority, Ireland
Date:	20/03/2013 Update 26/03/2014 Update 17/03/2015

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

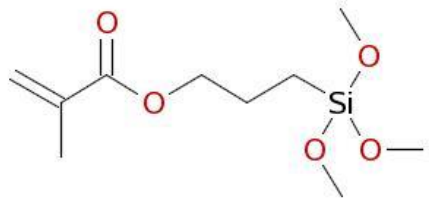
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	3-trimethoxysilylpropyl methacrylate
IUPAC name:	3-trimethoxysilylpropyl 2-methylprop-2-enoate
Index number in Annex VI of the CLP Regulation	Not listed in Annex VI of CLP
Molecular formula:	C10H20O5Si
Molecular weight or molecular weight range:	248 g/mol
Synonyms/Trade names:	

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.

2.2 Self classification

- In the registration data:
  - Not classified.

- In addition, the following hazard classes are notified among the self classifications in the C&L Inventory:
  - Acute Toxicity 4; H302: Harmful if swallowed
  - Skin Irritation 2; H315: Causes skin irritation
  - Eye Irritation 2; H319: Causes serious eye irritation
  - Specific target organ toxicity single exposure (STOT SE) 1; H370: Causes damage to organs
  - Specific target organ toxicity single exposure (STOT SE) 3; H335: May cause respiratory irritation
  - Specific target organ toxicity repeated exposure (STOT RE) 1; H372: Causes damage to organs through prolonged or repeated exposure
  - Specific target organ toxicity repeated exposure (STOT RE) 2; H373: May cause damage to organs through prolonged or repeated exposure

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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	
☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System
The substance is used in non-metal surface treatment and in coatings and sealants, as an industrial intermediate, a monomer and as laboratory chemical.			

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

☐ Compliance check, Final decision	☐ 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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
The registration data contains a testing proposal for an "OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)"	

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)

☐ Article 45(5) (Member State priority)

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[1]	
☐ 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)

A guinea-pig maximization test (GPMT) study is available for the registered substance which showed a "weakly positive" effect. However, it is concluded in the registration data that the results of the study are ambiguous since some positive reactions were also observed in the control group (cottonseed oil), but to a lesser degree than those observed in the test group. Negative GPMT studies on analogous substances are also reported in the registration data but no justification is provided for the proposed read-across. It is noted that other methacrylate substances are classified for skin sensitisation in Annex VI of CLP. Further evaluation of the available data is required to conclude on the sensitisation endpoint.

With respect to repeated dose toxicity, the registrants have used a weight of evidence approach based on a number of rat inhalation studies with durations from 4 to 14 weeks to aerosol atmospheres of aqueous solutions of the registered substance and one 9 day inhalation study to a vapour of the registered substance. A NOAEC of 15 mg/m^3 was identified for local effects based on the formation of laryngeal granulomas and a LOAEC of 50 mg/m^3 based on decreases in body weight. Further evaluation of the repeated dose toxicity data is required to evaluate the adequacy of the available data set and the robustness of the DNELs for workers and consumers for repeated dose toxicity.

A prenatal developmental toxicity study in rat with the registered substance is available. An increase in total and soft tissue malformations was observed at 2 and 5 ml/kg bw/day, which were also maternally toxic doses. Therefore, given the aggregated tonnage and the potential for worker and consumer exposure, further evaluation of the available data is required in order to determine whether a second prenatal developmental study with another species is required.

The identified uses in the registration data indicate potential dermal and inhalation exposure to both workers and consumers. Further assessment of the exposure assessment and risk characterisation is required in order to confirm that risks are adequately controlled.

[1] 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

5.4 Preliminary indication of information that may need to be requested to 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)

Following evaluation of the existing data, additional data to clarify the identified concerns for skin sensitisation, repeated dose toxicity and developmental toxicity may be requested.

Further information on use, exposure and existing risk management measures may be requested.

5.5 Potential follow-up and link to risk management

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

If the skin sensitisation hazard is confirmed, a proposal for a harmonized classification for skin sensitisation will be considered. Additional follow up actions will be considered depending on the outcome of the evaluation.