Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	A mixture of: propan-2-one-O,O'(methoxyvinylsilandiyl)dioxime; propan-2-one-O-(dimethoxyvinylsilyl)oxime; propan-2-one-O,O',O''-(vinylsilantriyl)trioxime
EC Number:	458-680-3
CAS Number:	797751-44-1
Authority:	ES MSCA
Date:	22/03/2016

Note

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

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1 IDENTITY OF THE SUBSTANCE

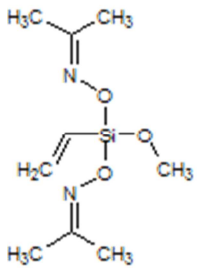
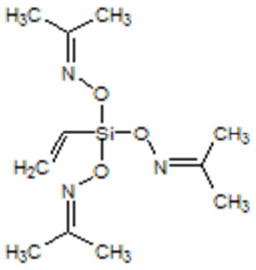
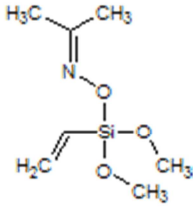
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	A mixture of: propan-2-one-O,O'(methoxyvinylsilandiyl)dioxime; propan-2-one-O-(dimethoxyvinylsilyl)oxime; propan-2-one-O,O',O''-(vinylsilantriyl)trioxime
IUPAC name (public):	Reaction mass of : Propan-2-one-O,O'(methoxyvinylsilandiyl)dioxime; Propan-2-one-O-(dimethoxyvinylsilyl)oxime; 2-Propanone, O,O',O''-(ethenylsilylidyne)trioxime
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	
Molecular weight or molecular weight range:	
Synonyms:	WASOX-VMAC2

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

Structural formula:

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		X Testing proposal: ECHA has made a final decision on 10 August 2011 requesting viscosity of liquids (OECD TG 114). Result of this study is included in the registration dossier.
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric -tion	☐ Annex XVII
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other (provide further details below)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

None.

3.1.2 Self classification

- In the registration:

Not classified.

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

  None

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

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4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per 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

4.2 Overview of uses

Table: Uses

Part 1:

☐ Manufacture	☒ Formulation	☐ Industrial use	☒ Professional use	☒ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses by professional workers	The substance is used as silicone sealant by professionals and consumers. Consumer use includes wide dispersive indoor and outdoor use resulting in inclusion into or onto a matrix and wide dispersive indoor and outdoor use of long-life articles and materials with low release.
Consumer Uses	

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)

[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

The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII, i.e. It has a relatively high tonnage (100-1000 t/a) and is used as a silicone sealant. Therefore, an environmental exposure is likely.

The substance hydrolyses rapidly. It is not readily biodegradable, indicating that the reaction products of hydrolysis are potentially persistent.
Due to rapid hydrolysis, testing on bioaccumulation was waived for the parent substance.
However, the PBT/vPvB assessment of the registrant does not account adequately for the identity and the PBT/vPvB properties of potential degradation products. As even structure and identity of the transformation products are not unambiguously defined, it is not possible to assess whether they might be bioaccumulative or not. Therefore, the transformation products are considered to be potentially bioaccumulative.
No long-term studies on aquatic ecotoxicology are available. The available short-term studies on aquatic ecotoxicology have not been assessed in detail, but their results indicate that the substance is not toxic.

In summary, the transformation products of the substance fulfill the PBT/vPvB screening criteria.

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)

The properties of the potential transformation products have to be assessed further. Further information on identity and physico-chemical properties is required to clarify whether the transformation products are potentially bioaccumulative.

Depending on the outcome, further evaluation and, if necessary, further testing is required to clarify whether the transformation products are persistent/ very persistent and bioaccumulative/ very bioaccumulative.

5.5. Potential follow-up and link to risk management

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

If the substance is identified as a substance forming PBT/vPvB substances, an analysis of risk management options will be carried out, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List with or without Authorisation, but also Restriction.