



Justification Document for the Selection of a CoRAP Substance

Group Name:	Oximino Silanes Category
EC Numbers:	218-747-8, 245-366-4 2224-33-1, 22984-54-9
CAS Numbers:	
Authority:	Italian CA
Date:	20/03/2018

Cover Note

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

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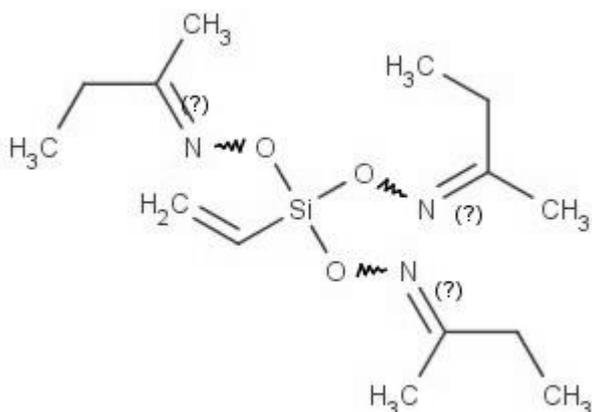
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1 IDENTITY OF THE SUBSTANCES

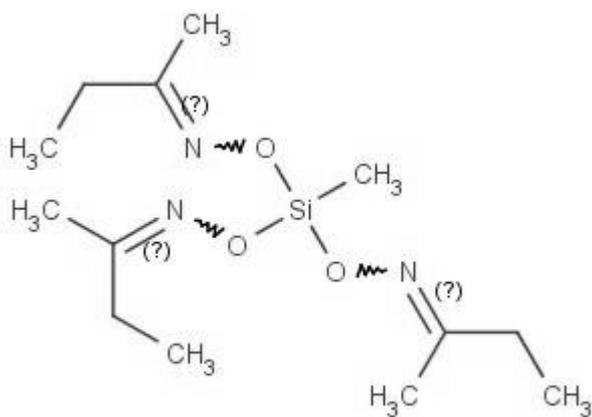
1.1 Identifiers of the substances within the group

EC/List number	CAS number	Public Substance Name	Index number in Annex VI of the CLP Regulation	Type of substance (mono-, multi-constituent, uvcb)
218-747-8	2224-33-1	Butan-2-one O,O',O''-(vinylsilylydyne)trioxime	-	Mono constituent
245-366-4	22984-54-9	Butan-2-one O,O',O''-(methylsilylydyne)trioxime	-	Mono constituent

Structural formulas:



Butan-2-one O,O',O''-(vinylsilylydyne)trioxime
EC 218-747-8



Butan-2-one O,O',O''-(methylsilylydyne)trioxime
EC 245-366-4

Other relevant information about substance composition

Confidential information

1.2 Similar substances/grouping possibilities

Has read-across been used by the registrant for the concern related endpoints? Yes No

Is the substance a member of a category? Yes No

The oximino silanes undergo rapid hydrolysis in the presence of water; the hydrolysis of Butan-2-one O,O',O''-(methylsilylidyne)trioxime (MOS) is expected to produce 3 moles of methylethylketoxime (CAS 96-29-7; MEKO) and 1 mole of methylsilanetriol. The hydrolysis of Butan-2-one O,O',O''-(vinylsilylidyne)trioxime (VOS) produce 3 moles of MEKO and 1 mole of vinylsilanetriol. The similarity assessment has been performed on the basis of process information, structural features, physicochemical properties, environmental behavior and toxicological and ecotoxicological profiles. The list of the structural analogues or surrogates for read-across is composed of three substances: methylethylketoxime (CAS 96-29-7; MEKO); dichloro(methyl)(vinyl)silane (CAS 124-70-9); phenylsilanetriol (CAS 3047-74-3).

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

For the substance Butan-2-one O,O',O''-(vinylsilylidyne)trioxime, there is a TPE .

Table: Completed or ongoing processes

other processes	RMOA	REACH process			Authorisation		Restriction	h C&L	process under other EU legislation		previous legislation		Stockholm convention	other processes EU legislation
		CCH	TPE	SEV	candidate list	Annex XIV			Annex XVII	Annex VI (CLP)	PPP	BPR		
EC entries														
218-747-8			X											

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Both the category members are not currently listed on Annex VI of CLP Regulation ((EC) No 1272/2008).

3.1.2 Self classification

- In the registration:

Both the group members

Eye Damage 1 H318

Skin Sens. 1B H317

STOT Rep. Exp. 2 H373

(Affected organs: cardiovascular / hematological: hematopoiesis)

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

substance EC 218-747-8

Skin Sens. 1 H317

Skin Irrit. 2 H315

Eye Irrit. 2 H319

STOT SE 3 H335

Acute Tox. 3 H301

Acute Tox. 4 H302

Acute Tox. 4 H312

Acute Tox. 4 H332

STOT SE 3 H336

Aquatic Chronic 3 H412

Skin Corr. 1B H314

Skin Corr. 1A H314

substance EC 245-366-4

Skin Sens. 1 H317

Eye Irrit. 2 H319

Skin Irrit. 2 H315

Acute Tox. 4 H312

Aquatic Acute 1 H400

Aquatic Chronic 1 H410

Aquatic Chronic 3 H412

Not Classified
 STOT SE 3 H335
 Acute Tox. 4 H332
 Acute Tox. 4 H302
 Acute Tox. 1 H312

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Status

Table: Tonnage and registration status

From ECHA dissemination site (12/05/17) EC 218-747-8 and EC 245-366-4		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input checked="" type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
EC 218-747-8 has 3 active registrations under REACH, 1 Joint Submission and 1 Individual Submission. Tonnage band: 100-1000		
EC 245-366-4 has 6 active registrations under REACH, 1 Joint Submission and 1 Individual Submission. Tonnage band: 1000-10000		

4.2 Overview of uses

Table: Uses

Part 1:

EC 218-747-8

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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¹ Please provide here the date when the dissemination site was accessed.

EC 245-366-4

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

EC 218-747-8

	Use(s)	Technical function
Uses as intermediate	This substance has an industrial use resulting in manufacture of another substance (use of intermediates).	
Formulation	This substance is used in the following products: adhesives and sealants. Release to the environment of this substance is likely to occur from industrial use: formulation of mixtures.	
Uses at industrial sites	<p>This substance is used in the following products: adhesives and sealants and laboratory chemicals.</p> <p>This substance has an industrial use resulting in manufacture of another substance (use of intermediates).</p> <p>This substance is used in the following areas: scientific research and development and building & construction work.</p> <p>This substance is used for the manufacture of: electrical, electronic and optical equipment, machinery and vehicles and chemicals.</p> <p>Release to the environment of this substance is likely to occur from industrial use: in the production of articles, as an intermediate step in further manufacturing of another substance (use of intermediates) and as processing aid. Other release to the environment of this substance is likely to occur from: indoor use as reactive substance.</p>	
Uses by professional workers	This substance is used in the following products: adhesives and sealants. This substance is used in the following areas: building & construction work. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners) and outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives).	
Consumer Uses		

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Article service life		
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EC 245-366-4

	Use(s)	Technical function
Uses as intermediate	This substance has an industrial use resulting in manufacture of another substance (use of intermediates).	
Formulation	This substance is used in the following products: coating products, adhesives and sealants, polymers and semiconductors. Release to the environment of this substance is likely to occur from industrial use: formulation of mixtures.	
Uses at industrial sites	<p>This substance is used in the following products: coating products, adhesives and sealants, polymers, semiconductors and laboratory chemicals.</p> <p>This substance is used in the following areas: building & construction work, formulation of mixtures and/or re-packaging and scientific research and development.</p> <p>This substance is used for the manufacture of: machinery and vehicles, chemicals and electrical, electronic and optical equipment.</p> <p>Release to the environment of this substance is likely to occur from industrial use: in the production of articles and for thermoplastic manufacture.</p>	
Uses by professional workers	This substance is used in the following products: coating products, adhesives and sealants. This substance is used in the following areas: building & construction work, public domain (administration, education, entertainment, services, craftsmen). Other release to the environment of this substance is likely to occur from: indoor use (e.g. paints and coating or adhesives) and outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives).	
Consumer Uses	This substance is used in the following products: coating products. Other release to the environment of this substance is likely to occur from: indoor use (e.g. paints and coating) and outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings).	
Article service life		

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

Total regional releases are calculated for the hydrolysis product methylethylketoxime (CAS 96-29-7; MEKO).

Part 3: There is high potential for exposure of

<input checked="" type="checkbox"/> Humans	<input checked="" type="checkbox"/> Environment
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5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE OR GROUP

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 or group 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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² 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

PBT ASSESSMENT

The oximino silanes hydrolyse rapidly to produce 3 moles of methylethylketoxime (CAS 96-29-7; MEKO) and 1 mole of reactive vinyl- or methyl-substituted silanetriols, the latter can condense to form oligomers and polymers. Because the parent substances are hydrolytically unstable, biodegradation, bioaccumulation and the ecotoxicological profile were measured for the hydrolysis product MEKO and, by read-across, for the structurally analogous substance dichloro(methyl)(vinyl)silane (CAS 124-70-9).

PERSISTENCE

A reliable screening test for persistence with OECD Guideline 301A, showed that the structural analogue dichloro(methyl)(vinyl)silane was not readily biodegradable: 0% (-6.78%) degradation in 28 days. According to the "Rationale & Justification for the Grouping of the Oximino silanes", the hydrolysis products, silanetriol and condensed silanetriol materials, are not expected to be readily biodegradable and may persist in the environment.

The biodegradation for the hydrolysis product MEKO was tested with two tests on inherent biodegradability. The Registrants concluded that the substance was found to be inherently biodegradable in one test, and not inherently biodegradable in the second test. However, in the first test, following the OECD TG 302B, a 70 % mineralisation (DOC removal) was reached after 18 d, therefore it does not fulfill the condition of 7 days. Moreover the adaptation of the inoculum is not specified.

Therefore, on the base of the screening criteria, the oximino silanes and their hydrolysis products, are potentially P or vP, further information need to be provided to confirm persistence.

BIOACCUMULATION

The Registrants concluded that the oximino silanes have low potential for bioaccumulation, as the predicted log Kow values of their hydrolysis products were low (<3). The log Kow of vinylsilanetriol and methylsilanetriol were predicted to be -2.0 and -2.4 respectively, the log Kow of MEKO was reported as 0.59 - 0.65.

The measured BCFs for MEKO in fish ranged from 0.5 to less than 2.5, indicating low or no bioaccumulation potential. However, no information was provided on the test, which was performed in 1982, therefore is not possible to validate the BCF study. No bioaccumulation data on the other hydrolysis products (vinylsilanetriol and methylsilanetriol) were presented. Therefore, it cannot be completely excluded the bioaccumulation potential of the oximino silanes.

Moreover, log Koa were computed for both the group substances based on KOAWIN v3.01 program of EPIWEB v 4.1, and they were found to be 10.88 and 10.53. The estimated log Koa for the hydrolysis products, MEKO and methylsilanetriol, were 4 and 7.61, respectively. Therefore, based on estimated high log Koa values, a potential to bioaccumulate in terrestrial organisms cannot completely excluded.

TOXICITY

Both the group members are classified for specific target organ toxicity after repeated exposure (STOT-RE Cat 2, H373), therefore they meet the criteria for toxicity, in a PBT assessment.

Regarding the ecotoxicological profile, the available data do not meet the screening criteria for T for the environment.

EXPOSURE ASSESSMENT

The oximino silanes are used by consumers and by professional workers (widespread uses) as adhesives and sealants. The potential for releases to the environment is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners) and outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives).

Moreover, other potential releases to the environment are likely to occur from industrial use:

manufacturing of the substance and formulation of mixtures, in the production of articles, as an intermediate step in further manufacturing of another substance (use of intermediates) and as processing aid.

RISK CONSIDERATIONS

The oximino silanes pose a concern as suspected PBT substances, that need to be further examined and clarified under SEV. The substances have wide dispersive uses, therefore a potential risk for human health and for the environment is expected. The requested information under CoRAP process would lead to improvement of Risk management Measures for the oximino silanes group.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ED potential	<input type="checkbox"/> Other (provide further details below)

Definitive studies on biodegradability are required to conclude on the P property of the oximino silanes (simulation test in surface water, OECD TG 309, for the hydrolysis products).
 An experimental study on aquatic bioaccumulation (OECD TG 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure) and/or on terrestrial bioaccumulation (OECD TG 317: Bioaccumulation in Terrestrial Oligochaetes) could be necessary for a proper evaluation.

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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In case a PBT concern was confirmed, because the dossiers suggest that the uses are wide dispersive, a risk management option analysis (RMOA) could be necessary to decide on a potential regulatory RMO.