



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): 1,3-dioxolane

EC Number: 211-463-5

CAS Number: 646-06-0

Authority: German MSCA

Date: 22/03/2016

Note

This document has been prepared by the evaluating Member State 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):	1,3-dioxolane
IUPAC name (public):	1,3-dioxolane
Index number in Annex VI of the CLP Regulation:	605-017-00-2
Molecular formula:	C ₃ H ₆ O ₂
Molecular weight or molecular weight range:	74.0785 g/mol
Synonyms:	Formal glycol 1,3,5-DIOXOLANE

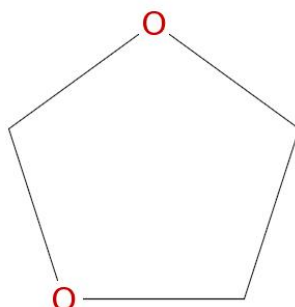
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input checked="" type="checkbox"/> Compliance check, Final decision http://echa.europa.eu/documents/10162/6986752/final_reg_public_cch-d-2114288006-49-01_en.pdf The document states "The other information requirement for two-generation reproductive toxicity study....is addressed in a separate decision although all requirements were initially addressed together in the same draft decision."
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	

(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment
	<input type="checkbox"/> In relevant Annex
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M- factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
605-017- 00-2	1,3-dioxolane	211- 463-5	646-06-0	Flam. Liq. 2	H225		

3.1.2 Self classification

- In the registration:
Eye Irrit. 2 H319
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
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3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonised classification and labeling is available.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<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 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 checked="" type="checkbox"/> >1000+ tpa		<input type="checkbox"/> Confidential
Joint submission		

4.2 Overview of uses

In industrial and professional settings, the substance is registered for the use as a monomer for the production of polymers, in the formulation of preparations, in laboratories as a lubricant and in metal working fluids or binders, release agents, binders, de-icing fluids, coatings, cleaning agents, washing products, thinners and paint removers. In addition, several registered uses for consumers exist which are disseminated below.

Table: Uses

Part 1:

<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 checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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¹ Data taken from ECHA dissemination site (accessed in May 2015)

Part 2:

	Use(s)
Consumer Uses	<p>Consumer end-use stage in coatings, cleaning agents, lubricants, de-icing and anti-icing applications</p> <p>PC 1: Adhesives, sealants</p> <p>PC 3: Air care products</p> <p>PC 4: Anti-freeze and de-icing products</p> <p>PC 9a: Coatings and paints, thinners, paint removes</p> <p>PC 9b: Fillers, putties, plasters, modelling clay</p> <p>PC 9c: Finger paints</p> <p>PC 15: Non-metal-surface treatment products</p> <p>PC 18: Ink and toners</p> <p>PC 23: Leather tanning, dye, finishing, impregnation and care products</p> <p>PC 24: Lubricants, greases, release products</p> <p>PC 28: Perfumes, fragrances</p> <p>PC 29: Pharmaceuticals</p> <p>PC 31: Polishes and wax blends</p> <p>PC 35: Washing and cleaning products (including solvent based products)</p> <p>PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products</p>
Article service life	<p>Monomer in imported polymer</p> <p>AC 01: Other (non intended to be released): Not applicable. Polymers are not defined as articles.</p>

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

- a) *in vitro*: ambiguous results have been obtained from two *in vitro* mammalian cell transformation assays (one with ambiguous results, one with positive results)
 b) *in vivo*: one *in vivo* micronucleus test was negative, another was positive

There is a concern with respect to reproductive toxicity.

Regarding the ticked box "exposure/risk based concerns: consumer exposure and exposure of sensitive populations": Some registrations indicate wide dispersive use and consumer exposure by the following uses (for details see chapter 4): adhesive, sealant, antifreeze, de-icing, finger paints, inks and toners, cleaning agent, lubricant, and coating. Therefore there is a concern with respect to consumer exposure. If the substance is used in e.g. finger paints, inks and toners the exposure of children as sensitive population cannot be excluded.

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

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

1) With respect to information on toxicological properties:

Further tests on *in vitro* and *in vivo* genotoxicity might be required. An extended one-generation reproductive toxicity study might be required.

2) With respect to information on exposure:

Further information on consumer use and exposure with special emphasis of exposure of children by use of finger paints and air care products might be required.

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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A possible follow-up of the evaluation process is the preparation of a proposal for harmonised classification and labeling.