

## Justification for the selection of a substance for CoRAP inclusion

<b>Substance Name (Public Name):</b>	2,2'-oxydiethanol
<b>Chemical Group:</b>	primary alcohol with ether group
<b>EC Number:</b>	203-872-2
<b>CAS Number:</b>	111-46-6
<b>Submitted by:</b>	National Institute of Chemical Safety, Hungary
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### 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

<b>EC name:</b>	2,2'-oxydiethanol
<b>IUPAC name:</b>	2,2'-oxydiethanol
<b>Index number in Annex VI of the CLP Regulation</b>	603-140-00-6
<b>Molecular formula:</b>	C <sub>4</sub> H <sub>10</sub> O <sub>3</sub>
<b>Molecular weight or molecular weight range:</b>	106.1204 g/mol
<b>Synonyms:</b>	2,2'-oxybisethanol Ethanol, 2,2'-oxybis- Diethylene glycol

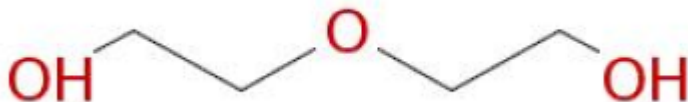
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**



### 1.2 Similar substances/grouping possibilities

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## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Acute Tox. 4 *	H302	H302		GHS07		
				Wng		

#### Hazard statement:

H302: Harmful if swallowed.

### 2.2 Self classification

- In the registration data:

In addition to the harmonised endpoint, has registrants given the following self classification:

STOT RE 2, H373: May cause damage to organs through prolonged or repeated exposure.

Affected organs: kidney    Route of exposure: Oral

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

Eye Irrit. 2, H319: Causes serious eye irritation.

Skin Irrit. 2, H315: Causes skin irritation.

STOT SE 3, H336: May cause drowsiness or dizziness.

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

- Not applicable

### 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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"/> 100,000 + tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
At least one registrant has claimed the tonnage confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p><u>Industrial use:</u>                      Production of Polymers, filled polymers, foams, coatings, adhesives, sealants                      Use in water-treatment chemicals                      Solvent                      Use as Process chemical                      Use in Paints/ Coatings                      Use in Cleaning agents                      Use in lubricants                      Use in metal-working fluids                      Use in/as functional fluids                      Use in laboratories                      Use as intermediate in chemical synthesis</p> <p><u>Professional use:</u>                      Use in Paints/Coatings/Adhesives/Sealants/Foams/Polymers/filled Polymers                      Use in Cleaning agents                      Use in metal-working fluids                      Use in/as functional fluids                      Use in/as de-icing/anti-icing applications/agents                      Use in laboratories                      Use in water-treatment chemicals                      Use as a fuel                      Solvent</p> <p><u>Consumer use:</u>                      Use in Paints/Coatings/Surface treatment products                      Use in Cleaning agents                      Use in heat transfer and hydraulic fluids                      Use in/as de-icing/anti-icing applications/agents                      Use in adhesives and sealants                      Production of rigid foam                      Use in Biocidal products                      Use as a fuel                      Solvent                      Use in agrochemicals</p>			

## 4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)  
 Article 45(5) (Member State priority)

### 4.2 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

### 4.3 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 <sup>1</sup> <input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input checked="" type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input 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)
<p>Carcinogenic potential of 2,2'-oxydiethanol has been investigated mostly in rodents. The data suggest a potential of the substance to induce bladder malignancies at higher doses after oral administration which are probably associated with the bladder stone formation. Human data are inconclusive due to either the relatively low number of cohorts studied or other methodological reasons. However, human carcinogenicity of the substance was not excluded. Recent data also suggest possible clastogenicity of the substance in vivo.</p> <p>The self-classification in the C&amp;L inventory suggests that the substance also has specific target organ toxic property arising from a repeated exposure. According to the available repeated dose studies the kidney is the target organ of toxicity.</p>		

<sup>1</sup> 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

#### 4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	

#### 4.5 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 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 ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Based upon the concerns identified further information to clarify carcinogenic, mutagenic and toxicological properties of the substance may be necessary. In particular, it might be useful to learn the mode of action and kinetics of the substance in order to clarify its effects on humans and particularly on kidney.</p>	

#### 4.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Depending on the outcome of the substance evaluation the amendment of the harmonized classification and labelling and also proposal for restriction of the substance are possible risk management measures.</p>			