Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Ethylene Carbonate
Chemical Group:	Organic
EC Number:	202-510-0
CAS Number:	96-49-1
Submitted by:	Latvia
Date:	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

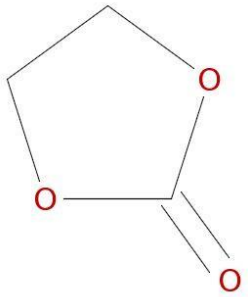
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Ethylene carbonate
IUPAC name:	1,3-dioxolan-2-one
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C3H4O3
Molecular weight or molecular weight range:	88.06
Synonyms/Trade names:	*Ethylene carbonate*

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

Structural formula:



1.2

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

2.2 Self classification

- In the registration

  Eye Irrit. 2; H319: Causes serious eye irritation
  Acute Tox.4; H302: Harmful if swallowed
  STOT RE 2; H373: May cause damage to organs (Kidney, oral)

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

  Eye Dam. 1; H318: Causes serious eye damage
  STOT SE 3; H335: May cause respiratory irritation
  Skin Irrit. 2; H315: Causes skin irritation

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
☒ 1000 + tpa		☐ Confidential

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Use in cleaning agents
Use in agrochemicals
Use as lubricant
Consumer uses: waterborne latex wall paint
Consumer uses: remover

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)	

Compliance check final decision (Decision number: CCH-D-2114290256-46-01/F):

1. In vitro gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102, as specified in section III.B.1 below;

2. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats;
3. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route;
4. Growth inhibition study aquatic plants (Annex VII, 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD 201);
5. Short-term toxicity testing on fish (Annex VIII, 9.1.3.; test method: Fish, acute toxicity test, EU C.1./OECD 203).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised DNELs for workers and for the general population using the recommended assessment factors by ECHA and deriving a DNEL long-term local inhalation for workers

or

A full justification for not using the recommended assessment factors in DNEL derivation and a qualitative assessment of local inhalation effects (Annex I, 1.4.1. of the REACH Regulation), as specified in section III.B.1;

2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn when handling the substance need to be specified clearly (Article 14(6), Annex I, 5.1.1.)

3. Revised exposure assessment and risk characterisation for workers via dermal route or a justification why the efficiency values used for gloves are considered appropriate (Art. 41.1(c) of the REACH Regulation and Annex I, Section 5.2.4 and 5.2.5).

4. Revised consumer exposure assessment and risk characterisation:
a. Taking into account the consumers' activities and the duration and frequency of their exposure (Annex I, Sections 5 and 6).
b. Using the fraction released to air recommended by ECHA Guidance R.15 (Annex I, Section 5.2.4) or a full justification for not using the recommended values in the consumer exposure estimates.

Deadline: 2 January 2017.

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)

[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

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)

Eye irritation of the substance could be considered during SEV since 25 notifiers have indicated Eye Dam. 1 classification. Two tests (reliability 2) comparable with OECD 405 are available indicating irreversible effects on the eye. One test (reliability 1) performed according to OECD 405 indicated reversibility of the all irritative effects on eye.

There is no reliable Repeated Dose Toxicity study for the substance of concern. An OECD 452 Repeated Dose Toxicity study on the metabolite affected kidneys. The metabolite has harmonised classification Acute Tox. 4 however the substance is notified in the C&L Inventory as STOT RE 2 oral kidney damage. Therefore specific target organ toxcicity of the substance and if necessary due to the metabolite should be investigated in depth during the SEV.

No reliable data on fertility is available on ethylene carbonate, data from the metabolite is used for the risk characterization of ethylene carbonate. It is stated in the dossier that the substance is rapidly metabolised to ethylene glycol, measurements of the whole blood levels of ethylene carbonate and ethylene glycol in rats treated with ethylene carbonate revealed blood levels of ethylene glycol approximately 100-fold higher than levels of ethylene carbonate in the same animal, indicating rapid conversion of ethylene carbonate to ethylene glycol. The half-life of ethylene carbonate is 0.25h and the half-life of ethylene glycol in blood of 2h. However, there is no justification why a half-life of 0.25h would exclude any toxic effects of non-metabolised ethylene carbonate and thus would allow predicting the reprotoxicity of ethylene carbonate from data available on ethylene glycol.
Reproductive toxicity study with the metabolite indicated weak effects on fertility.

In an OECD 414 prenatal toxicity study (realiability 2) animals were treated from days 6-15 of gestation rather than administered daily from implantation (e.g., day 5 post mating) to the day prior to the scheduled caesarean section. Statistically significant decreases were observed in the group mean fetal body weights in the 1500 and 3000 mg/kg dose groups. These decreases were considered biologically significant and related to the administration of the test substance.
Thirty three fetuses with malformations were detected during the study. Malformations were observed in one control fetus (0.3 %) from one litter (3.8 %), one low dose fetus (0.3 %) from one litter (3.8 %) and thirty one high dose fetuses (9.2 %) from eleven litters (45.8 %). Additionally from the fertility studies with the metabolite some facial anomalies were noted in the offspring of mice at the high concentration of the metabolite. Skeletal examination revealed a pattern of reduction in the size of bones in the skull, fused ribs, and abnormally shaped sternebrae and vertebrae.
Toxicity to reproduction should be clarified under SEV.

Exposure should also be assessed during SEV since the substance is having high tonnage, wide dispersive, professional and consumer uses.

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)
Reproductive toxicity study	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Eye irritiation/damage, specific target organ toxicity (STOT RE) and reprotoxicity are the endpoints to consider after SEV for CLH process.			