Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate
Chemical Group:	-
EC Number:	219-207-4
CAS Number:	2386-87-0
Submitted by:	Health & Safety Authority, Ireland
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

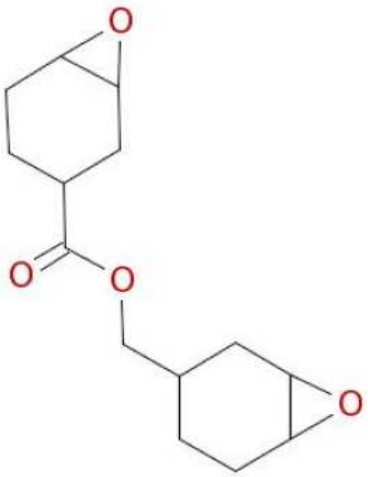
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate
EC number:	219-207-4
EC name:	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate
CAS number (in the EC inventory):	219-207-4
CAS number:	2386-87-0
CAS name:	-
IUPAC name:	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate
Index number in Annex VI of the CLP Regulation	Not listed on Annex VI of CLP
Molecular formula:	C14H20O4
Molecular weight or molecular weight range:	252.3062
Synonyms:	7-Oxabicyclo 4.1.0 heptane-3-carboxylic acid, 7-oxabicyclo 4.1.0 hept-3-ylmethyl ester. Trade name: CELLOXIDE 2021P

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

There are no proposals listed on the Registry of Intentions.

2.3 Self classification

In the registration data:

- CLP Criteria:

  Skin Sens. 1; H317: May cause an allergic skin reaction.

- DSD Criteria:

  R43: May cause sensitization by skin contact.

  Xi: Irritant.

C&L Inventory:

The following additional classifications have been notified to the C&L Inventory:

Hazard class	**Hazard statement**
STOT RE 2	H373: May cause damage to organs.
Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	H315: Causes skin irritation.
Eye Irrit. 2	H319: Causes serious eye irritation.
Muta. 2	H341: Suspected of causing genetic defects.
STOT SE 3	H335: May cause respiratory irritation.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☒ Article 44(1) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

3.2 Grounds for concern

☒ (Suspected) CMR	☐ Wide dispersive use	☐ Cumulative exposure
☒ (Suspected) Sensitiser	☐ Consumer use	☒ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☐ Aggregated tonnage
☐ Suspected endocrine disruptor	☒ Other (provide further details below)	

The substance is self-classified as Skin Sens. 1 H317: May cause an allergic skin reaction. However it is not listed in Annex VI of CLP. A number of identified uses indicate the possibility for dermal exposure, e.g. PROCs 10, 11, 13 and 19. Therefore, the adequacy of risk management measures should be further evaluated.

The registration data contains several *in vitro* mutagenicity studies which are positive. There is one negative *in vivo* UDS and one negative *in vivo* mouse micronucleus study; both reported with limited details in the registration data. No carcinogenicity studies are available. In addition, the substance has positive structural alerts for mutagenicity and carcinogenicity using a number of QSAR models. Further review of the mutagenic, and possibly carcinogenic, potential of the substance is proposed.

In a study according OECD Guideline 414 (Prenatal Developmental Toxicity Study) effects observed in the high dose group included reduced mean foetal body weight, increased skeletal developmental variations in the form of reduced mean litter proportion of cervical centrum no. 1 ossified, which were statistically significant and an increase in the mean litter proportions of unossified sternebrae, which although not statistically significant, were above the maximum values in the historical controls. These observed effects were considered evidence of a developmental delay. However, a decrease in maternal body weight and food consumption was also observed at this dose and it was concluded in the registration data that the effects were secondary to maternal toxicity. Clarification of the significance of the observed maternal toxicity with respect to developmental delay is required.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☒ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 50,000 tpa	☐ 50,000 – 100,000 tpa
☐ 100,000 – 500,000 tpa	☐ 500,000 – 1000,000 tpa	☐ > 1000,000 tpa
☐ Confidential		

Tonnage band is indicated on ECHA's dissemination website.

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

The following uses are indicated on ECHA's dissemination website:

1. Formulation/packaging/mixing/blending (including formulation of coatings) – industrial
2. Intermediate use – industrial
3. Monomer use - industrial
4. Application and use - industrial
5. Formulation/packaging/mixing/blending (including formulation of coatings) – professional
6. Application and use - professional

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

☐ Compliance check	☐ 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Please provide further details	

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☒ Other (provide further details below)	

The clarification of data with relevance to sensitization, mutagenicity and reproductive toxicity is needed (see 3.2). Possible request for additional exposure information for processes where concern about exposure and further refinement of the exposure estimate may be appropriate.

3.6 Potential follow-up and link to risk management

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

A proposal for harmonised classification for skin sensitization, and for other endpoints if required, may be considered.
If it is confirmed that the risk to workers is not adequately controlled using the currently applied risk management measures, a proposal for additional EU wide or national risk management measures will be considered, depending on the concern identified.