Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Diallyl phthalate
Chemical Group:	
EC Number:	205-016-3
CAS Number:	131-17-9
Submitted by:	Ministry of Health, Social Services and Equality, Spain
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

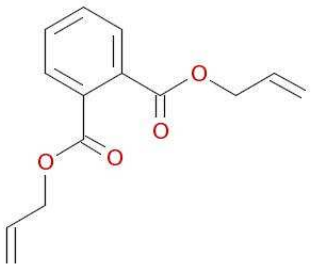
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Diallyl phthalate
EC number:	205-016-3
EC name:	Diallyl phthalate
CAS number (in the EC inventory):	131-17-9
CAS number:	288-32-4
CAS name:	diallylphthalate
IUPAC name:	1,2-Benzenedicarboxylic acid, di-2-propenyl ester
Index number in Annex VI of the CLP Regulation	607-086-00-4
Molecular formula:	C14H14O4
Molecular weight or molecular weight range:	246.2586
Synonyms:	

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

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

According to Regulation (EC) No 1272/2008 Annex VI Table 3.1, the substance is classified as:

Acute Tox. 4 (H302: Harmful if swallowed)
Aquatic Acute 1 (H400: Very toxic to aquatic life)
Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects)

According to Regulation (EC) No 1272/2008 Annex VI Table 3.2, the substance is classified as:

Xn; R22 (Harmful if swallowed)
N; R50-53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classification by the lead registrant is consistent with harmonised classifications and additionally includes the following classifications;

Acute Tox. 4 H332: Harmful if inhaled.

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

Muta. 2 H341: Suspected of causing genetic defects.

Route of exposure: Oral appears to be mutagenic after metabolization (in the presence of S9 fraction), indicating that oral uptake is the most hazardous route.

STOT Rep. Exp. 1 H373: May cause damage to organs through prolonged or repeated exposure.
Affected organs: Liver
Route of exposure: Oral Classification is only based on animal studies, more specifically rat. Significant histological changes were observed in rats at oral dose levels as low as 50 mg/kg bw/day.

In addition to the harmonised classification, the following classifications for other endpoints are notified to the Classification and Labelling Inventory:

Acute Tox. 3 (H301: Toxic if swallowed).
Aquatic Chronic 4; H413: May cause long lasting effects to aquatic life.
Carc. 2 (H351: Suspected of causing cancer).

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 diallyl phthalate is self classified as Muta. 2 (H341: Suspected of causing genetic effects), based on positive results in several *in vitro* studies and a positive result in an *in vivo* mammalian chromosome aberration test.

In view of the positive genotoxic response in somatic cells *in vivo*, the potential to affect germ cells should be considered. Based on this, there is concern that the substance should be classified as Muta 1. Therefore further information to clarify the mutagenic potential of the substance and exposure may be needed.

3.3 Information on aggregated tonnage and uses

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

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

The substance is used by workers in industrial settings. The use pattern is described as follows:

- Polymer manufacture
- Formulation of insulating varnishes
- Industrial application of insulating varnishes
- Laboratory use

Consumer use is also identified as service use of varnishes.

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)	
See section 2.1.	

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)	
Depending on the outcome of the substance evaluation further testing may be required in order to clarify the mutagenic potential of the substance. Further information on exposure could be relevant to clarify the risk that the substance may pose to workers and consumers.	

3.6 Potential follow-up and link to risk management

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

1. Harmonised classification and labeling:

   Once the hazard is clarified, a revision of the harmonized C&L could be needed

2. Authorisation

   If the substance is confirmed to be a CMR category 1, identification as substance of very high concern and subsequent authorization may be relevant.