Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	diisotridecyl adipate
Chemical Group:	
EC Number:	247-660-8
CAS Number:	26401-35-4
Submitted by:	ES CA for Environment
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:	diisotridecyl adipate
EC number:	247-660-8
EC name:	diisotridecyl adipate
CAS number (in the EC inventory):	
CAS number:	26401-35-4
CAS name:	-
IUPAC name:	bis(11-methyldodecyl) adipate
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C32H62O4
Molecular weight or molecular weight range:	510.8323
Synonyms:	Dioctyl adipate; Octyl adipate; Di(2-ethylhexyl)adipate; Bis(2-ethylhexyl) hexanedioate; Hexanedioic acid, dioctyl ester; Hexanedioic acid, bis(2-ethylhexyl) ester; Adipic acid bis (2-ethylhexyl) ester; Hexanedioic acid bis(2-ethylhexyl) ester

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

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not given.

2.3 Self classification

There is no self classification for this substance.

All notifications to the Classification and Labelling Inventory is with "Not Classified".

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)	

Environment/Clarification of P, B, aquatic and terrestrial toxicity; Exposure/Lack of exposure assessment

The substance is not readily biodegradable (Key study according to OECD Guideline 301F, reliability1, GLP, 2003. Result: 58.5% after 28 d), however the value from the key study is close to the criteria. Independent tests show that the substance is not readily biodegradable, based on tests the registrant claims that the substance is inherently biodegradable. The simulation test(s) have been waived because the substance is highly insoluble in water. The hydrolysis test has not been performed because the substance is highly insoluble in water. The substance is not B. Log Kow is 11.7.

While there are acute toxicity tests for Fish and Algae for the substance, the tests have performed above the water solubility of the substance (0.001 mg/l) and are therefore invalid. There is a read-across for the endpoint, short-term toxicity test for aquatic invertebrates. However the test was performed above the water solubility of the read-across substance (3.2 x 10^{-3} mg/l) and is therefore invalid.

There is a chronic toxicity test for *Daphnia magna* performed with the read-across substance (NOEC ≥ 0.77 mg/L). However all concentrations were above the water solubility and the test is therefore invalid.

In summary, there are no valid acute or chronic aquatic ecotoxicity tests for the substance and all terrestrial tests have been waived.

Additional concerns are that the substance is not classified by the registrant and there is no exposure assessment provided.

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		
Please provide further details		

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

Industrial uses: Formulation & (re)packing lubricants, use in lubricant (ind), manufacture of DTDA, distribution of DTDA, compounding (dry-blends), compounding (plastisols), polymer processing, (mainly closed systems).

Professional workers: Use in lubricants (prof). (Wide dispersive indoor use of processing aids in open systems)

Consumer use: service life of plastic articles (indoor and outdoor) (wide dispersive use).

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)	
None that we know about	

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)	
Further information is needed especially on the chronic aquatic environment and terrestrial as well as related information on exposure.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)
Follow-up regulatory actions will be set depending on the outcome of the evaluation. That is, further information is needed on the preparation of Annex XV dossier either for authorization or restriction.			