Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Diundecyl phthalate
EC Number:	222-884-9
CAS Number:	3648-20-2
Submitted by:	Danish Environmental Protection Agency
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

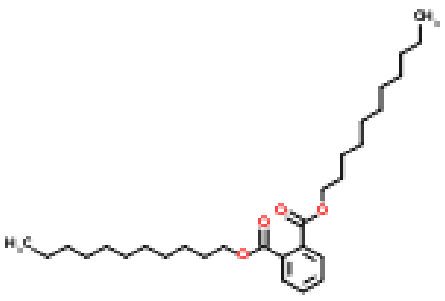
Table 1: Substance identity [1]

EC number:	222-884-9
EC name:	Diundecyl phthalate
CAS number (in the EC inventory):	3648-20-2
CAS number:	3648-20-2
CAS name:	N.A.
IUPAC name:	Diundecyl benzene-1,2-dicarboxylate
Index number in Annex VI of the CLP Regulation	N.A.
Molecular formula:	C30H50O4
Molecular weight or molecular weight range:	474.7156
Synonyms:	DIPLAST L 11 (trade name)

[1] Information has been derived from the public available registration on the ECHA website.

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

None proposed.

2.3 Self-classification

The substance is not classified by the registrants.

There is one notification to the Classification and Labelling Inventory with a classification:

Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

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 criterion for selecting the substance for future substance evaluation is concern for reproductive toxicity. Structurally related substances have been classified as reproductive toxicants (see below).

The Danish EPA has now proposed that C7-11 phthalates, branched and linear (1,2-Benzenedicarboxylic acid, di-C7-11 branched and linear alkyl esters = DHNUP [68515-42-4]) for the candidate list, because it can be used as a substitute for other phthalate plasticisers already agreed for inclusion in Annex XIV (the authorisation list), and it has a harmonised C&L of Repr. 1B. Furthermore, DHNUP was included in the list of pre-registered substances with an anticipated registration deadline by end of November 2010.

Following the registration deadline, it appears that DHNUP has not been registered. However, a number of other individual phthalates with alkylchain lengths within the same range as DHNUP (i.e. in the C7-C11 range) have been registered as shown in the table below.

EC No.	CAS No.	Name	Full
271-082-5	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	Yes
271-085-1	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	Yes
271-089-3	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	Yes
271-090-9	68515-48-0	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich	Yes
271-091-4	68515-49-1	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich	Yes
249-079-5	28553-12-0	di-''isononyl'' phthalate	Yes
222-884-9	3648-20-2	diundecyl phthalate	Yes
287-401-6	85507-79-5	diundecyl phthalate, branched and linear	Yes

It appears that none of these have been classified by the registrants, which presumably would mean that no exposure assessment (incl. exposure scenarios) and risk characterization have been developed for these phthalates. Furthermore, recent studies on Di-Isononyl Phthalate (DINP)[1] seem to document that also this phthalate is a reproductive toxicant, although with a lower potency than the already classified phthalates.

Thus, it might be beneficial to conduct a thorough review of the whole group of phthalates with alkylchain lengths within the C7-C11 range with the aim of clarifying whether these eventually should be classified as reproductive toxicants. It appears from the Commission's document for CARACAL-07 (CA/23/2011) that the Commission has requested ECHA to review and analyse information in registration dossiers for phthalates included in REACH, Annex XVII, entry 52. This comprises three of the above listed phthalates (EC Nos 271-090-9, 271-091-4, 249-079-5). Consequently, the Danish EPA would like to express a preliminary interest in reviewing some of remaining five of these phthalates under Substance Evaluation.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1,000 tpa
☒ 1,000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ > 10,000,000 tpa	☐ Confidential
Please provide further details if appropriate		

[1] Boberg J, Christiansen S, Axelstad M, Kledal TS, Vinggaard AM, Dalgaard M, Nellemann C, Hass U, Reproductive and behavioral effects of Diisononyl phthalate (DINP) in perinatally exposed rats, *Reproductive Toxicology* (2010), doi:10.1016/j.reprotox.2010.11.001

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System
The substance is used as a plasticizer.			

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)	
Depending on the outcome of the substance evaluation, it might be necessary to request further information on reproductive toxicity in order to decide on a proper classification.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)
Depending on the outcome DK may put forward a proposal for harmonized C&L. Further action could be taken such as proposal for inclusion on the candidate list.			