Justification for the selection of a candidate CoRAP substance

**Substance Name (Public Name):** bis(2-ethylhexyl) adipate

**Chemical Group:**

**EC Number:** 203-090-1

**CAS Number:** 103-23-1

**Submitted by:** Finnish Safety and Chemicals Agency (Tukes), Finland

**Published:** 20/03/2013

**NOTE**

This document has been prepared by the evaluating Member State given in the CoRAP update.
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1 IDENTIFY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

<table>
<thead>
<tr>
<th>Public Name:</th>
<th>bis(2-ethylhexyl) adipate</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC number:</td>
<td>203-090-1</td>
</tr>
<tr>
<td>EC name:</td>
<td>bis(2-ethylhexyl) adipate</td>
</tr>
<tr>
<td>CAS number (in the EC inventory):</td>
<td>103-23-1</td>
</tr>
<tr>
<td>CAS number:</td>
<td>103-23-1</td>
</tr>
<tr>
<td>CAS name:</td>
<td>Hexanedioic acid, bis(2-ethylhexyl) ester</td>
</tr>
<tr>
<td>IUPAC name:</td>
<td>bis(2-ethylhexyl) adipate</td>
</tr>
<tr>
<td>Index number in Annex VI of the CLP Regulation</td>
<td>-</td>
</tr>
<tr>
<td>Molecular formula:</td>
<td>C22H42O4</td>
</tr>
<tr>
<td>Molecular weight or molecular weight range:</td>
<td>370.5665 [g/mol]</td>
</tr>
</tbody>
</table>

Synonyms:

- Di-octyl-adipat
- Sicol 250
- Flexol A 26
- Di(2-ethylhexyl) adipate
- Vestinol OA
- Effomoll DOA
- Octyl adipate
- Dioctyl adipate
- Plastomoll DOA
- Adipic acid, bis(2-ethylhexyl) ester (6CI, 7CI, 8CI)
- Truflex DOA
- Monoplex DOA
- DOA
- Bisoflex DOA
- Bis(2-ethylhexyl) adipate
- Adipol 2EH
- Witamol 320
- Effomoll DA
- Lankroflex DOA
- Diethylhexyl adipate
- Ergoplast AdDO
- Wickenol 158
- Kodaflex DOA
- Hexanedioic acid, bis(2-ethylhexyl) ester (9CI)
- Jayflex DOA 2
- Reomol DOA
- Sansocizer DOA
<table>
<thead>
<tr>
<th>Type of substance</th>
<th>Mono-constituent</th>
<th>Multi-constituent</th>
<th>UVCB</th>
</tr>
</thead>
</table>

**Structural formula:**

![Structural formula image]
2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP
Not classified.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP
None proposed.

2.3 Self classification
According to the registration data not classified.

Notified classifications from the C&L Inventory according to CLP criteria:
Acute Tox. 4; H302: Harmful if swallowed.
Acute Tox. 4; H312: Harmful in contact with skin.
Acute Tox. 4; H332: Harmful if inhaled.
Skin Irrit. 2; H315: Causes skin irritation.
Eye Irrit. 2; H319: Causes serious eye irritation.
Repr. 2; H361: Suspected of damaging fertility or the unborn child.
Carc. 2; H351: Suspected of causing cancer.
Aquatic Acute 1; H400: Very toxic to aquatic life.
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)

Di(2-ethylhexyl) adipate (DEHA) is a commonly used plasticizer in lubricants, glue, scotch-tape, and sealants (Remберger et al. 2005). DEHA is an EPA High Production Volume chemical, indicating an annual production volume or importation volume above 1 million pounds in the U.S. (HPVIS). Because DEHA is identified as potential alternative for phthalates, its use e.g, in plastics will probably increase in the EU after four phthalates (BBP, DEPH, DBP, DIBP) become subject to authorisation in 2015.

DEHA has been suspected of having effects on the male reproductive system because it shares similarities in chemical structure and metabolism with DEHP. DEHA did produce some effects on development and reproduction in reproductive toxicity studies (e.g. Miyata et al., 2006, Dalgaard et al., 2002, 2003).

In our view, at this point the registration data needs more evaluation and it is not clear whether there is enough information to adequately assess the toxicity for reproduction. The need of harmonized classification for reproductive toxicity will also be evaluated.

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 aggregated tonnage of DEHA is expected to increase after four phthalates (BBP, DEPH, DBP, DIBP) become subject to authorisation in 2015.

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)
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) | |

Please provide further details

3.6 Potential follow-up and link to risk management

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

Depending on outcome of evaluation the classification for reproductive toxicity might be needed.

References:


Dalgaard M, Hass U, Lam HR, Vinggaard AM, Sorensen IK, Jarfelt K, Ladefoged O. 2002. Di(2-ethylhexyl) adipate (DEHA) is foetotoxic but not anti-androgenic as di(2-ethylhexyl)phthalate (DEHP). Reproductive Toxicology 16:408.

