# Annex XV report

# PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance Name:** **1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters;**

**1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters**

with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)

**EC Numbers: 271-094-0, 272-013-1**

**CAS Numbers: 68515-51-5, 68648-93-1**

**Submitted by: Swedish Chemicals Agency**

**Date: 2015-02-02**

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# PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance Name:** 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters[1];

1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters[2]

**EC Numbers:** 271-094-0, 272-013-1

**CAS numbers:** 68515-51-5, 68648-93-1

- The substances are proposed to be identified as substances meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to their classification in the hazard class reproductive toxicity category 1B[3].

**Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation**

*1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0); 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)*, with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5), meet the criteria of article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to their classification as Repr. 1B (H360FD: May damage fertility. May damage the unborn child). This is due to that dihexyl phthalate is covered by Index number 607-702-00-1 in part 3 of Annex VI to the CLP Regulation, and that no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing dihexyl phthalate.

Therefore, this classification of *the substances* with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) shows that they meet the criteria for classification in the hazard class:

- reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

**Registration dossiers submitted for the substances?**
Yes, for EC No. 271-094-0.
No, for EC No. 272-013-1.

[1] The substance is proposed to be identified as SVHC only where it contains ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).
[2] The substance is proposed to be identified as SVHC only where it contains ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).
[3] Classification in accordance with section 3 of Annex I to Regulation (EC) No 1272/2008.

# PART I

# Justification

## 1. Identity of the substance and physical and chemical properties

### 1.1. Name and other identifiers of the substance

**Table 1: Substance identity**

| | | |
|---|---|---|
| **EC number:** | 271-094-0 | 272-013-1 |
| **EC name:** | 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters | 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters |
| **CAS number (in the EC inventory):** | 68515-51-5 | 68648-93-1 |
| **CAS number:**<br>**Deleted CAS numbers:** | - | - |
| **CAS name:** | 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters | 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters |
| **IUPAC name:** | Di-$C_{6-10}$ alkyl phthalate | Di-$C_{6-10\ (\text{even numbered})}$ alkyl phthalate |
| **Index number in Annex VI of the CLP Regulation** | - | - |
| **Molecular formula:** | Unspecified | Unspecified |
| **Molecular weight range:** | Unspecified | Unspecified |
| **Synonyms:** | Di(C6-C10)alkyl phthalate<br>Phthalic acid, di(C6-C10)-alkyl esters<br>Linear610Phthalate<br>Esterification of phthalic anhydride and C6-10-alcohol | Esterification of phthalic anhydride and hexanol, octanol and decanol |

The EC inventory entry for "1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters" (EC number 271-094-0; CAS number 68515-51-5) has normally been considered for the purpose of EINECS as covering both the substance presenting even carbon numbers (i.e. C6, C8 and C10) and the substance presenting both the odd and even numbers (i.e. C6, C7, C8, C9, C10). This essentially comes from the conventions followed by the CAS

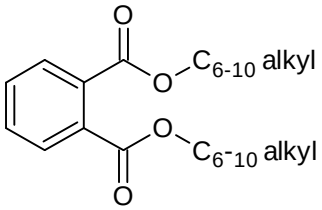
Registry which do not make this further distinction on the presence or absence of odd numbers in alkyl descriptors such as "C6-10".

The EC inventory entry for "1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters" (EC number 272-013-1; CAS number 68648-93-1) on the other hand makes this distinction by defining the alkyl groups by their chemical name (i.e. hexyl, octyl and decyl) instead of the carbon range. This EC entry therefore covers the substance with even carbon numbers, i.e. the substance "1,2-benzenedicarboxylic acid, di-C6-10 (even numbered)-alkyl esters" also known as "di-$C_{6\text{-}10\ (\text{even numbered})}$ alkyl phthalate".

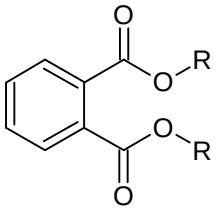
Both the substance with even carbon numbers and the substance with even and odd carbon numbers are within the scope of this proposal.

It should be noted that both EC inventory entries describe dialkyl phthalates presenting linear alkyl structures.

**Structural formula:**




EC No. 271-094-0




EC No. 272-013-1 R= decyl, hexyl or octyl

## 1.2. Composition of the substance

**Name:** 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters[4];

1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters[5]

**Description:** The substance "1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters" should have a composition that is equivalent to the result from the diesterification reaction between 1,2-benzenedicarboxylic acid and "C6-10 alcohols". In line with the

[4] with ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).
[5] with ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).

OECD Guidance for characterising oleochemical substances for assessment purposes (Series on Testing & Assessment No. 193, 2014), the upper concentration level in C6, C7, C8, C9 and C10 within the alcohols of "C6-10 alcohols" is normally expected to be ≥10% and <80%.

Any substance having a composition equivalent to the diesterification reaction products between 1,2-benzenedicarboxylic acid and "C6-10 alcohols" is within the scope of this proposal. This proposal is therefore not limited to substances obtained by reacting 1,2-benzenedicarboxylic acid and "C6-10 alcohols" but covers also substances obtained from precursors such as phthalic anhydride instead of 1,2-benzenedicarboxylic acid.

Similarly, the substance named "1,2-benzenedicarboxylic acid, di-C6-10 (even numbered) alkyl esters" or "1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters" should have a composition that is equivalent to the result from the diesterification reaction between 1,2-benzenedicarboxylic acid and "C6-10 (even numbered) alcohols". The upper concentration level in C6, C8 and C10 within the alcohols of "C6-10 (even numbered) alcohols" is expected to be ≥10% and <80%.

Any substance having a composition equivalent to the diesterification reaction products between 1,2-benzenedicarboxylic acid and "C6-10 (even numbered) alcohols" is within the scope of this proposal. This proposal is therefore not limited to substances obtained by reacting 1,2-benzenedicarboxylic acid and "C6-10 (even numbered) alcohols" but covers also substances obtained from precursors such as phthalic anhydride instead of 1,2-benzenedicarboxylic acid.

## 1.3. Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant.

## 1.4. Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant.

## 1.5. Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (c).

# 2. Harmonised classification and labelling

*1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0); 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)* are not themselves listed in Annex VI of Regulation (EC) No 1272/2008. Potential possibilities for harmonised classification of the substances themselves or their constituents could be dealt with in other processes than SVHC-identification.

According to Article 10(1) of the CLP Regulation, specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance (or in a mixture) as an identified impurity, additive or individual constituent leads to the classification of the substance (or mixture) as hazardous.

For dihexyl phthalate (EC No. 201-559-5) no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing dihexyl phthalate.

The generic concentration limit for reprotoxic substances, Repr. 1B, is 0.3 %, as set out in Table 3.7.2 in Part 3 of Annex I to the CLP Regulation.

**Table 2: Classification of *dihexyl phthalate* (according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008)**

| Index No | International Chemical Identification | EC No. | CAS No. | Classification | | Labelling | | | Spec. Conc. Limits, M-factors | Notes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Hazard Class and Category Code(s) | Hazard statement code(s) | Pictogram, Signal Word Code(s) | Hazard statement code(s) | Suppl. Hazard statement code(s) | | |
| 607-702-00-1 | Dihexyl phthalate | 201-559-5 | 84-75-3 | Repr. 1B | H360FD | GHS08<br>Dgr | H360FD | - | - | - |

Therefore, on such basis, the classification of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters where they contain dihexyl phthalate ≥ 0.3 %* is as seen in **Table 3**.

**Table 3: Classification of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters where they contain dihexyl phthalate ≥ 0.3 %*** according to Art. 10 and Table 3.7.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number for dihexyl phthalate in Part 3 of Annex VI to CLP Regulation

| Index No | International Chemical Identification | EC No. | CAS No. | Classification | | Labelling | | | Spec. Conc. Limits, M-factors | Notes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Hazard Class and Category Code(s) | Hazard statement code(s) | Pictogram, Signal Word Code(s) | Hazard statement code(s) | Suppl. Hazard statement code(s) | | |
| | 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters with dihexyl phthalate ≥ 0.3% | 271-094-0 | 68515-51-5 | Repr. 1B | H360FD | GHS08 Dgr | H360FD | - | - | - |
| | 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with dihexyl phthalate ≥ 0.3% | 272-013-1 | 68648-93-1 | Repr. 1B | H360FD | GHS08 Dgr | H360FD | - | - | - |

H360FD = May damage fertility. May damage the unborn child.

# 3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (c) REACH.

# 4. Human health hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (c) REACH.

# 5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (c) REACH.

# 6. Conclusions on the SVHC Properties

## 6.1. CMR assessment

*1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0); 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)*, with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5), meet the criteria of article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to their classification as Repr. 1B (H360FD: May damage fertility. May damage the unborn child). This is due to that dihexyl phthalate is covered by Index number 607-702-00-1 in part 3 of Annex VI to the CLP Regulation, and that no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing dihexyl phthalate.

Therefore, this classification of *the substances* with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) shows that they meet the criteria for classification in the hazard class:

- reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

# Part II

## 7. Manufacture, import and export

All information refers to the registered substance *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0)*. Since *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)* is not registered, no information is available for that substance. However, since the two substances are closely related, information on the substance with EC No. 271-094-0 is considered relevant also for the substance with EC No. 272-013-1.

### 7.1. Imports and exports of the substance into and from the EU

Total tonnage band is 100-1000 tonnes per annum (ECHA dissemination site 2015). There is no information available on exported volumes (as such or in mixtures or articles) or on imported volumes in articles.

### 7.2. Recent and future trends

In the SPIN database the reported quantities of *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* are in many cases excluded due to confidentiality (in Norway between the years 2007-2012, Finland 2006-2011, Denmark 2011-2012, Sweden 2005-2010). According to the last update in SPIN, which is for 2012, both Finland and Sweden have not had any reported chemical products (i.e. mixtures or pure substance) containing the substance. Quantities in Denmark decreased from 0.89 tonnes in year 2000 to 0.01 tonnes in 2009 (SPIN Database 2014).

The quantity of *the substance* in chemical products (i.e. in mixtures or as pure substance) in Sweden was quite high in the 1990's. In 1994 there were 487 tonnes reported to the Swedish Products Register. The quantity dropped to 21 tonnes in 1998 and has continued to decrease since then. In 2011 and 2012 there were no products at all reported to contain the substance (KemI-Stat 2014).

The website Chemical Book listed one global supplier for *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS number 68515-51-5)*, in Germany. The website listed no suppliers for *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (CAS number 68648-93-1)* (Chemical Book 2015).

## 8. Information on uses of the substance

All information refers to the registered substance *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0)*. Since *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)* is not registered, no information is available for that substance. However, since the two substances are closely related, information on the substance with EC No. 271-094-0 is considered relevant also for the substance with EC No. 272-013-1.

Information on uses of *the substance* are in some cases ambiguous and not clear. For example, in the registration there is sometimes what seem to be industrial uses reported under consumer uses, and different types of article manufacture are reported under formulation (ECHA dissemination site 2015). Since there are uncertainties in the information, it has been aggregated and is presented below in a less detailed manner than on dissemination site, to avoid obvious faults.

## 8.1. Overview of uses

Phthalates are well known to be used as plasticisers and lubricants, and the registered uses of *the substance* are for example in adhesives, lubricants, coatings, building material, cable compounding, polymer foils, PVC compounds and artist supply (ECHA dissemination site 2015).

There are no indications of that any of the registered uses should be exempted from the scope of authorisation requirement.

Information on tonnage per use is not available.

**Use descriptors** (ECHA dissemination site 2015)

The different processes involved in the uses of the substance include for example use in closed (batch) processes, mixing or blending in batch processes, transfer of substance between vessels, hand-mixing (personal protective equipment available) and as laboratory reagent. Other processes include calendering operations, industrial and non-industrial spraying, roller application or brushing, use of blowing agents in manufacture of foam, treatment of articles by dipping and pouring, production of preparations or articles by tabletting etc., manipulation and work-up of substances bound in materials and/or articles and other hot work operations with metals (PROC 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 11, 12, 13, 14, 15, 19, 21, 24, 25).

Possible environmental release of the substance can occur for example during manufacture of the substance, formulation of preparations and materials and industrial use of processing aids in processes and products. It can also occur from wide dispersive indoor and outdoor use of processing aids in open systems, wide dispersive indoor and outdoor use resulting in inclusion into or onto a matrix, wide dispersive indoor and outdoor use in closed systems, wide dispersive indoor and outdoor use of long-life articles and materials with low release, wide dispersive indoor and outdoor use of long-life articles and materials with high or intended release (including abrasive processing) and industrial processing of articles with abrasive techniques (ERC 1, 2, 3, 4, 5, 6b, 8a, 8c, 8d, 8f, 9a, 9b, 10a, 10b, 11a, 11b, 12a).

Sector of uses reported are formulation [mixing] of preparations and/or re-packaging, manufacture of rubber products and plastics products, including compounding and conversion, manufacture of computer, electronic and optical products, electrical equipment and general manufacturing, e.g. machinery, equipment, vehicles and other transport equipment (SU 10, 11, 12, 16, 17).

The substance is included in the product categories coatings, paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners, lubricants, greases, release products, polymer preparations and compounds, and semiconductors (PC 9a, 9b, 9c, 18, 24, 32, 33).

The substance is also included in the article categories vehicles, machinery, mechanical

appliances, electrical/electronic articles, fabrics, textiles and apparel, rubber articles and plastic articles (AC 1, 2, 5, 10, 13).

Not all use descriptors are relevant for all life cycle stages. It also varies whether consumers or professionals are the users of the products and articles. The substance is not only used at industrial sites, but also by professional workers and by consumers, when incorporated in mixtures and articles.

**Uses in the different life cycle stages**

The information on dissemination site regarding uses per life cycle stage is sometimes ambiguous and hard to follow. For example, use descriptors referring to industrial processes are reported under consumer uses, and the use "Artist supply" has been reported under every life cycle stage except manufacture (ECHA dissemination site 2015). The dossier submitter guesses that the registrant has tried to be transparent about that the artist supply products are e.g. formulated at industrial sites, rather than that finger paint is used at industrial sites.

An attempt to match the reported uses to the different life cycle stages has been done, see **Table 4**.

**Table 4: Uses per life cycle stage**

| Life cycle stage | Use |
|---|---|
| **Manufacture** | Manufacture of substance |
| **Formulation** | Industrial formulation and use of adhesives<br><br>Not reported in registration: formulation of different product categories, such as coatings and artist supply (coatings, paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners) |
| **Uses at industrial sites** | Industrial formulation and use of adhesives<br><br>Polymer processing – production of PVC compounds: The substance is used in polymer preparations and compounds. It is used for manufacture of plastics products, including compounding and conversion.<br><br>Use in coatings<br><br>Polymer foils (unclear if it refers to production of such)<br>Cable application (unclear if it refers to production of such, or use of cables at industrial sites, etc.)<br>Cable compounding (unclear if it refers to production of such) |
| **Uses by professional workers** | Artist supply: The substance is included in coatings, paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners, rubber and plastic articles. |

| | |
|---|---|
| | Professional use of adhesives<br><br>Professional use of articles obtained by calendering etc. |
| **Consumer uses** | Building material and other consumer uses: The substance is used in polymer preparations and compounds and in plastic articles.<br><br>Consumer use of lubricants and adhesives: The substance is used in lubricants, greases, release products, polymer preparations and compounds and is included in vehicles, machinery, mechanical appliances, electrical/electronic articles, fabrics, textiles and apparel and plastic articles.<br><br>Artist supply: The substance is included in coatings, paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners, rubber and plastic articles. |
| **Article service life** | Building material and other consumer uses: The substance is used in polymer preparations and compounds and in plastic articles.<br><br>Consumer use of lubricants and adhesives: The substance is used in lubricants, greases, release products, polymer preparations and compounds and is included in vehicles, machinery, mechanical appliances, electrical/electronic articles, fabrics, textiles and apparel and plastic articles.<br><br>Cable compounding: The substances is used in polymer preparations and compounds and in semiconductors.<br><br>Polymer foils (not reported under article service life in the registration)<br><br>Professional use of articles obtained by calendering etc.<br><br>Artist supply: The substance is included in coatings, paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners, rubber and plastic articles. |

A specific use was found in a US safety data sheet for a polyurethane product, containing 15-40 % (wt/wt) of *the substance (CAS No. 68515-51-5)*, intended for adhesives and sealants for windshields (MSDS 2014).

## 8.2. Imports and exports of articles into and from the EU

No information available.

# 9. Release and exposure from uses

## 9.1. Introduction

The available information on uses of *the substance* (chapter 8) indicates potential release and potential human exposure during the whole life cycle of the substance. Industrial and professional workers can be exposed during several scenarios where the substance is manufactured and also when it is used in mixtures and articles. Consumers can be exposed during use of mixtures, such as lubricants and adhesives, and during use of articles, such as rubber and plastic articles, containing the substance. Information on how well *the substance* is "bound" in an article´s matrix, from which release potentially could occur, has not been gathered.

Exposure of humans via the environment could potentially occur as a result of emissions from industrial and professional processes, and from diffuse releases from consumer and professional use of articles.

It is reasonable to assume that if materials containing *the substance* are recycled, *the substance* could occur in new products where it was not intended. This could result in additional exposure of humans, including of workers at recycling facilities and waste management sites.

If waste containing *the substance* is incinerated no major releases of *the substance* are expected. Landfills could leak *the substance* to the environment, resulting in indirect human exposure via the environment.

## 9.2. Formulation

See 9.1.

## 9.3. Industrial uses

See 9.1.

## 9.4. Professional uses

See 9.1.

## 9.5. Consumer uses

See 9.1.

## 9.6. Releases from use of articles

See 9.1.

## 9.7. Releases from the waste stage

See 9.1.

## 9.8. Summary of releases

The available information on uses of *the substance* (chapter 8) indicates potential

release and potential human exposure during the whole life cycle of the substance. Both consumers and workers at professional and industrial settings could be exposed during use of mixtures and articles containing the substance.

If materials containing *the substance* are recycled, the substance could occur in new products where it was not intended. This could result in additional exposure of humans, including of workers at recycling facilities and waste management sites.

If waste containing *the substance* is incinerated no major releases of the substance are expected. Landfills could leak the substance to the environment, resulting in indirect human exposure via the environment.

# 10. Current knowledge on alternatives

## 10.1. Introduction

The most obvious alternative to *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* and to *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters,* which are only proposed to be included in the candidate list if they contain ≥ 0.3% (wt/wt) of dihexyl phthalate, is *the substances* themselves when they contain less than 0.3 % (wt/wt) of dihexyl phthalate.

## 10.2. Literature review

Potential alternatives to several phthalates have been reported in SVHC-identification reports for other phthalates. There is for example valuable information in the SVHC-reports for the "high-medium weight" phthalates 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) (DK Annex XV dossier 2011) and 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP) (ECHA Annex XV dossier 2011). Also, the SVHC-dossier for dihexyl phthalate (DE Annex XV dossier 2013) could be of interest.

The Swedish Chemicals Agency has recently published a report from a government assignment on ortho phthalates. The report contains a survey of alternatives to ortho phthalates, which could be relevant as alternatives to *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* and to *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters*. The report lists several non-phthalate alternatives and some alternative flexible polymer materials. The report will soon be available in English (KEMI 2014).

In the report "Phthalate Strategy", the Danish EPA writes "In 2010 the Danish EPA prepared a report about plasticisers that can be used as alternatives to the phthalates DEHP, DBP and BBP (Danish EPA 2010). As these phthalates are used for many diverse purposes, we assume that alternatives to these three phthalates can substitute most uses of phthalates." (Miljøstyrelsen, 2013). Since the registered uses for *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* are common phthalate uses, and there is no indication of any speciality use, it is likely that there are alternatives that can substitute for *the substance*.

## 10.3. Information from consultation

No consultation has been done.

## 10.4. Conclusions on alternatives

The most obvious alternative to *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* and to *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters,* which are only proposed to be included in the candidate list if they contain ≥ 0.3% (wt/wt) of dihexyl phthalate, is *the substance* themselves when they contain less than 0.3 % (wt/wt) of dihexyl phthalate.

Alternatives to phthalates have been assessed in several earlier reports, where alternative substances and alternative materials have been presented. It is likely that there are alternatives to *the substance* since there are no indications of any speciality uses of it.

# 11. Existing EU legislation

For *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0); 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)* there are no completed or ongoing legislative processes. For some of their possible constituents/impurities there are several relevant regulations:

- Dihexyl phthalate (EC No. 201-559-5) is included in the candidate list.
- Dihexyl phthalate (EC No. 201-559-5) is harmonised classified as Repr. 1B according to Annex VI CLP.
- Dihexyl phthalate is anticipated to be listed in REACH Appendix 6, meaning that it would be restricted according to REACH Annex XVII, entry 30, and should not be placed on the market or used as substance, as constituent of other substances or in mixtures for supply to the general public.
- Di-n-octyl phthalate (EC No. 204-214-7) is included in REACH Annex XVII, entry 52, restricting its use in toys and childcare articles.

*1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0); 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1) with ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5)* should be regulated in the same way as other phthalates with similar toxic properties.

All phthalates already included in the candidate list are seen in **Table 5**.

**Table 5: Phthalates already included in the candidate list**

| **Name** | **EC No.** | **CAS No.** | **Reason for inclusion, Reach Article** | **Date of inclusion** |
|---|---|---|---|---|
| Dihexyl phthalate | 201-559-5 | 84-75-3 | 57 c) | 2013/12/16 |
| 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear | 271-093-5 | 68515-50-4 | 57 c) | 2014/06/16 |

| **Name** | **EC No.** | **CAS No.** | **Reason for inclusion, Reach Article** | **Date of inclusion** |
|---|---|---|---|---|
| 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear | 284-032-2 | 84777-06-0 | 57 c) | 2012/12/19 |
| 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich | 276-158-1 | 71888-89-6 | 57 c) | 2011/06/20 |
| 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters | 271-084-6 | 68515-42-4 | 57 c) | 2011/06/20 |
| Dipentyl phthalate (DPP) | 205-017-9 | 131-18-0 | 57 c) | 2013/06/20 |
| n-Pentyl-isopentylphthalate | - | 776297-69-9 | 57 c) | 2012/12/19 |
| Diisopentylphthalate | 210-088-4 | 605-50-5 | 57 c) | 2012/12/19 |
| Bis(2-methoxyethyl) phthalate | 204-212-6 | 117-82-8 | 57 c) | 2011/12/19 |
| Diisobutyl phthalate | 201-553-2 | 84-69-5 | 57 c) | 2010/01/13 |
| Bis (2-ethylhexyl)phthalate (DEHP) | 204-211-0 | 117-81-7 | 57 c)<br>57 f) | 2008/10/28<br>2014/12/17 |
| Benzyl butyl phthalate (BBP) | 201-622-7 | 85-68-7 | 57 c) | 2008/10/28 |
| Dibutyl phthalate (DBP) | 201-557-4 | 84-74-2 | 57 c) | 2008/10/28 |

57 c) = Toxic for reproduction
57 f) = Equivalent level of concern having probable serious effects to the environment

# 12. Previous assessments by other authorities

There are no assessments for either *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0)* or *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC No. 272-013-1)* on their own.

# 13. Executive summary of information on manufacture, use, exposure and alternatives

## 13.1. Manufacture, imports and exports

The substance *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* is registered and the total tonnage band is 100-1000 tonnes per annum. The substance *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters* is not registered, but closely related to the first substance. There is no information available on exported volumes (as such or in mixtures or articles) or on imported volumes in articles.

In 2012, both Finland and Sweden had no reported chemical products containing *the substance*. Quantities in Denmark decreased from 0.89 tonnes in year 2000 to 0.01 tonnes in 2009.

## 13.2. Uses

Information regarding uses of *the substance* are in some cases ambiguous and not clear. However, it is noticed that the use descriptors show a wide variety of processes involved and several wide dispersive uses are registered. A variety of products and articles are produced with *the substance*. The registered uses are for example in adhesives, lubricants, coatings, building material, cable compounding, polymer foils, PVC compounds and artist supply. Both consumers and professionals use products and articles containing *the substance* and it is used in all life cycle stages.

There are no indications of that any of the registered uses should be exempted from the scope of authorisation requirement.

## 13.3. Releases from manufacture and use

The available information on uses of *the substance* indicates potential release and potential human exposure during the whole life cycle of the substance. Both consumers and workers at professional and industrial settings could be exposed during use of mixtures and articles containing *the substance*.

If materials containing *the substance* are recycled, it could occur in new products where it was not intended. This could result in additional exposure of humans, including of workers at recycling facilities and waste management sites.

If waste containing *the substance* is incinerated no major releases of *the substance* are expected. Landfills could leak the substance to the environment, resulting in indirect human exposure via the environment.

## 13.4. Current knowledge of alternatives

The most obvious alternative to *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters* and to *1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters,* which are only proposed to be included in the candidate list if they contain ≥ 0.3% (wt/wt) of dihexyl phthalate, is *the substances* themselves when they contain less than 0.3 % (wt/wt) of dihexyl phthalate.

Alternatives to phthalates have been assessed in several earlier reports, where alternative substances and alternative materials have been presented. It is likely that there are alternatives to *the substance* since there are no indications of any speciality uses of it.

# REFERENCES

## References for Part I

(CLP). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.

ECHA Dissemination site (2015). 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters. Information on registered substances, published on ECHA´s website. http://echa.europa.eu/information-on-chemicals/registered-substances. Accessed 2015-01-28.

ECHA Guidance for identification and naming of substances under REACH and CLP. Version: 1.3, February 2014 http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf.

OECD Guidance for characterising oleochemical substances for assessment purposes (Series on Testing & Assessment No. 193, 2014), http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)6&doclanguage=en

(REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.

## References for Part II

Chemical Book (2015). http://www.chemicalbook.com/ProdSupplierGWCB5938915_EN.htm. Accessed 2015-01-07.

Danish EPA (2010). Maag J, Lassen C, Brandt UK, Kjølholt J, Molander L, Hagen Mikkelsen S, 2010. Identification and assessment of alternatives to selected phthalates. Danish ministry of the environment. http://www2.mst.dk/udgiv/publications/2010/978-87-92708-00-7/pdf/978-87-92708-01-4.pdf.

DE Annex XV dossier (2013). Proposal for identification of a substance as a category 1A or 1B CMR, PBT, vPvB or a substance of equivalent level of concern. Dihexyl phthalate, CAS number 84-75-3. http://echa.europa.eu/documents/10162/9a8b4fa6-c852-48bd-b561-c727b8d197ff.

DK Annex XV dossier (2011). Proposal for identification of a substance as a category 1A or 1B CMR, PBT, vPvB or a substance of equivalent level of concern. 1,2-Benzenedicarboxylic acid, di-C7-11 -branched and linear alkyl esters, CAS

number 68515-42-4. http://echa.europa.eu/documents/10162/248dd51f-b218-455f-bb00-fbe34d500a5c.

ECHA Annex XV dossier (2011). Proposal for identification of a substance as a category 1A or 1B CMR, PBT, vPvB or a substance of equivalent level of concern. 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP), CAS number 71888-89-6. http://echa.europa.eu/documents/10162/eec0b364-e29e-48f8-970c-a4cdb78465b8.

ECHA Dissemination site (2015). 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters. Information on registered substances, published on ECHA´s website. http://echa.europa.eu/information-on-chemicals/registered-substances. Accessed 2015-01-28.

KEMI (2014). Proposal to phase out reprotoxic and endocrine-disrupting phthalates in Sweden. Report of a government assignment. Report 7/14, November 2014. http://www.kemi.se/en/Content/Publications/Reports/.

KemI-Stat (2014). Search tool for statistics produced by the Swedish Chemicals Agency, based on data in the Products Register and the Pesticide Register. http://apps.kemi.se/kemistat/start.aspx?sprak=e. Accessed 2014-07-10.

Miljøstyrelsen (2013). Phthalate strategy. Danish EPA. Environmental Project No. 1488, 2013. http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf.

MSDS (2014). Material Safety Data Sheet 3M™Windo-Weld™Super Fast Urethane PN 08608, 08609, 10/14/09. http://www.finishmaster.com/prod/assets/08609.pdf

SPIN Database (2014). Database on substances in preparations in Nordic Countries. http://195.215.202.233/DotNetNuke/default.aspx. Accessed 2014-10-07.