**COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFCATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS**

**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)
**CAS number:** 68515-51-5; 68648-93-1
**EC number:** 271-094-0; 272-013-1

**The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation:** CMR (based on impurity/constituent)

*Disclaimer: Comments provided during public consultation are made available as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a Substance of Very High Concern. RCOM has not been agreed by the Member State Committee nor has the document been modified as result of the MSC discussions.*

## PART I: Comments and responses to comments on the SVHC proposal and its justification

### General comments on the SVHC proposal

| Number / Date | Submitted by (name, submitter type, country) | Comment | Response |
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| 4481<br>2015/04/16 | Finland,<br>Member State | The Finnish CA supports the proposal to identify 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0) and 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), as Substances of Very High Concern (SVHC) according to 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). The substances are proposed to be identified as SVHC only where they contain ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).<br><br>The Finnish CA notes that a Risk Management Option Analysis (RMO) Conclusion Document on substance EC 271-094-0 has been published on the ECHA website. The RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment. The Finnish CA considers that after inclusion of the substance in the Candidate List (for eventual inclusion in the Annex XIV) it | Thank you for your support. |

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| | | still needs to be further considered which risk management measures would be the most appropriate. | |
| 4482<br>2015/04/16 | Health and Environment Alliance (HEAL), International NGO, Belgium | HEAL supports the nomination of this substance to the Candidate List | Thank you for your support. |
| 4487<br>2015/04/16 | Finland,<br>Member State | The Finnish CA supports the proposal to identify 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0) and 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), as Substances of Very High Concern (SVHC) according to 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). The substances are proposed to be identified as SVHC only where they contain ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).<br><br>The Finnish CA notes that a Risk Management Option Analysis (RMO) Conclusion Document on substance EC 271-094-0 has been published on the ECHA website. The RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment. The Finnish CA considers that after inclusion of the substance in the Candidate List (for eventual inclusion in the Annex XIV) it still needs to be further considered which risk management measures would be the most appropriate. | See comment 4481 (identical). |

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| 4488<br>2015/04/16 | Netherlands, Member State | The issue of impurities in substances that have a harmonised CMR classification has been discussed during RIME-1 in Brussels. A view widely shared between ECHA and many MS is, that candidate listing of such substances is not an automatism or necessarily preferred. If the impurity content can be reduced by the registrant(s), candidate listing may not be needed. Several issues were discussed that are relevant in this context:<br><br>If the concentration of the impurity can be lowered to be below the generic concentration limit (GCL) or specific concentration limit (SCL), the substance will effectively no longer be an SVHC. The next issues should be considered:<br>- Can the impurity be lowered by the registrant(s) before deciding on the need to regulate it?<br>- Is the impurity a true contamination or is it part of the functional characteristics?<br>- How potent is the impurity and is exposure to the impurity relevant?<br>- Is candidate listing needed for recognition of the CMR properties of the contamination?<br><br>Inclusion of substances on the candidate list based on the presence of constituent/impurity/additive with a harmonised classification for CMR 1A/1B seems to have limited regulatory benefits especially for reproductive toxicants present as impurity (at concentrations below ~10%). Inclusion may be more relevant for reprotoxic constituents (concentration above 10%) and for a carcinogenic and mutagenic constituent/impurity/additive. | Thank you for your comments.<br><br>The threshold value 0.3% for dihexyl phthalate is the actual determining factor for establishing if a substance falls under the scope of the proposed entry.<br>Because the convention for differentiating between (main) constituents and impurities is not relevant for determining if a substance is covered by the entry, determining the status of dihexyl phthalate as impurity or as constituent, providing a specific technical function to the substance, is not necessary.<br><br>Since dihexyl phthalate is inevitably formed during synthesis, and the substance with ≥ 0.3 % dihexyl phthalate shall be classified as Repr. 1B (CLP Art. 10 and table 3.7.2), the substance fulfills the SVHC-identification criteria.<br><br>Based on comments from the registrant in the public consultation, there are no indications that the registrant has any intention of trying to lower the concentration of dihexyl phthalate.<br><br>Potency and exposure are in this case not relevant criteria for SVHC-identification. |

**Specific comments on the justification**

| Number / Date | Submitted by (name, submitter type, country) | Comment | Response |
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| 4469<br>2015/04/08 | Sasol Germany GmbH,<br>Company,<br>Germany | The proposed identification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS #: 68515-51-5, EC #: 271-094-0) as a Substance of Very High Concern (SVHC) is based solely on the presence of a classified minor component (dihexyl phthalate – CAS #: 84-75-3; EC #: 201-559-5). The proposal by the Swedish Chemicals Agency would not be unreasonable in the situation where no data exist for the substance in question (1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters). It is, however, not reasonable when high quality studies are available for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters that cover the endpoints in question (reproductive toxicity including fertility and developmental effects).<br><br>As documented in the 2012 registration dossier, 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters contains approximately 3% of di-n-hexyl phthalate with a maximum of less than 5%. This substance was tested in GLP OECD 414 (Prenatal Development Toxicity) and OECD 416 (Two-Generation Reproduction Toxicity) guideline studies. The detailed robust study summaries for these studies are included in the registration dossier and the results are summarized below.<br><br>A study of developmental toxicity (OECD 414) was conducted on 1,2 - Benzenedicarboxylic acid, di-C6-10-alkyl esters using Sprague-Dawley rats. In this study slight maternal effects were observed at 1000 mg/kg bw/day indicated by slightly increased body weight gain and food consumption. Foetal effects were confined to increases in the incidence of vestigial supernumerary ribs at 500 and 1000 mg/kg bw/day and to a slight increase in the incidence of retarded sternebrae at 1000 mg/kg bw/day. Both of these findings were considered to be of a minor nature. The No Observed Adverse Effect Level (NOAEL) for maternal toxicity was considered to be 500 mg/kg bw/day. The No Observed Adverse Effect Level (NOAEL) for developmental toxicity was considered to be 1000 mg/kg bw/day. This study was classified as Klimisch 1 (reliable without restrictions).<br><br>In the two-generation reproduction toxicity study (OECD 416), Sprague- | Thank you for your comments.<br><br>According to Art. 10 and Table 3.7.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation) 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% shall be classified as Repr. 1B. The substances therefore fulfil the requirement to be identified as SVHC.<br><br>• Dihexyl phthalate has an EU harmonised classification of Repro. 1 B as per Commission Regulation (EU) No 944/2013 amending the CLP Regulation (an entry in Part 3 of Annex VI to the CLP Regulation). This harmonised classification does not include any specific concentration limit (SCL).<br><br>• According to Article 10(1) CLP specific concentration limit (SCL) and generic concentration limits (GCL) 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 |

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| | | Dawley rats were exposed to 1,2 -Benzenedicarboxylic acid, di-C6-10-alkyl esters in the diet at concentrations of 1000, 3000 and 10,000 ppm. These concentrations corresponded to mean doses of 78/116, 235/346 and 809/1181 mg/kg bw/day in males/females, respectively. In this study statistically significant reproductive effects occurred at the highest treatment level (10,000 ppm). The effects observed were reduced pup survival and weights, and a marginal delay in sexual maturity. Effects on reproductive organs, liver and kidney were essentially similar in all generations and were therefore not classed as specific reproductive effects. The NOAEL for reproductive toxicity was therefore considered to be 3000 ppm (corresponding to a mean daily intake of 235 mg/kg bw/day for males and 346 mg/kg bw/day for females). It was not possible to identify a no effect level in this study, although at 1000 ppm (corresponding to a mean daily intake of 78 mg/kg bw/day for males and 116 mg/kg bw/day for females) effects were confined to increased liver and kidney weights among F1 females (LOAEL 1000 ppm). There were no obvious effects of treatment on mating performance, fertility indices or the duration of gestation. This study was classified as Klimisch 1 (reliable without restrictions).<br><br>Considering results from actual studies conducted on 1,2 -Benzenedicarboxylic acid, di-C6-10-alkyl esters, the toxicity profile observed with di-n-hexyl phthalate should not be used as a basis to justify the addition of 1,2 -Benzenedicarboxylic acid, di-C6-10-alkyl esters to the SVHC Candidate list. | classification of the substance/mixture as hazardous. Art. 10(3) provides that companies shall not set SCL for harmonised hazard classes, which means that GCL must apply, as is the case here. Accordingly, GCL of ≥ 0.3% laid down for Repro 1 B classification in Table 3.7.2, Part 3 of Annex I to the CLP Regulation applies.<br><br>• If you have new information that may lead to a change of the existing harmonised C&L of dihexyl phthalate, you may submit a proposal to modify the existing C&L entry to a MSCA (Art. 37(6) CLP), including a proposal for SCL. In addition, you may submit a proposal for a harmonised C&L of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters to ECHA pursuant to Art. 37(2) CLP. However, these 2 processes are different from the current SVHC process and not within the mandate of MSC.<br><br>The SVHC-identification process is not the forum for re-evaluating neither the harmonized classification of dihexyl phthalate, nor the harmonized rules for classification in CLP. |

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| 4470<br>2015/04/10 | BOMcheck shared industry database, Industry or trade association, United Kingdom | Please separate this into two new entries in the new REACH Candidate List. It will be much easier for suppliers to respond to customers if there is one separate entry in the REACH Candidate List for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters and another separate entry for 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters | Thank you for your comment. The reason why the proposal for SVHC identification combines the two EC entries for<br><br>"1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters" (EC number 271-094-0; CAS number 68515-51-5) and "1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters" (EC number 272-013-1; CAS number 68648-93-1) is that these two entries are closely related to each other. As specified in the Annex XV report,<br><br>EC entry 271-094-0 has normally been considered for the purpose of EINECS as covering both<br>o the substance presenting even carbon numbers (i.e. C6, C8 and C10) and<br>o the substance presenting both the odd and even numbers (i.e. C6, C7, C8, C9, C10).<br><br>EC entry 272-013-1 covers the substance presenting even carbon numbers (i.e. C6, C8 and C10).<br><br>Therefore entry 271-094-0 covers also the same substance described by EC entry 272-013-1. These entries, therefore, have been combined considering that creating two separate entries may create overlapping entries and confusion in relation to the substance identity. |

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| 4472<br>2015/04/14 | Belgium,<br>Member State | p.5:<br>Belgium supports the proposal to identify 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters with ≥ 0.3% of dihexyl phthalate; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate as SVHC based on article 57(c) of the REACH Regulation due to the classification of dihexyl phthalate as Toxic for Reproduction at concentration ≥ 0.3% | Thank you for your support. |
| 4475<br>2015/04/15 | CHEM Trust,<br>National NGO,<br>United Kingdom | General comment:<br>CHEM Trust supports the inclusion of 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters;<br>1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate in the REACH candidate list according to article 57 c). | Thank you for your support. |
| 4477<br>2015/04/15 | Germany,<br>Member State | The German CA supports the identification of 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS-Nr. 68515-51-5) and 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (CAS-Nr. 68648-93-1) with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) as SVHC. Nevertheless we have some comments regarding the identity.<br><br>For 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters a table describing the substance identity in more detail is given in the report (Annex I). In this table some constituents are classified as impurities. According to the guidance document for identification and naming of substances constituents of UVCB substances are not designated as impurities. We know that this information was taken from the registration dossier, but we suggest to presenting the identity in the correct way in the report.<br><br>For 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters no detailed information about the substance identity is given in the report. Even though the substance is an UVCB at least groups of substances present in 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters should be identified – comparable to the information provided for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters.<br><br>Next to this the information on the substance identity of 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters should also be available in the IUCLID file section 1.2. Furthermore information on physico-chemical properties for the substance are missing in the IUCLID file.<br>In addition there is no IUCLID file available for 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters. | Thank you for your support and your comments.<br><br>A lot of effort was put into describing the substances‘s identities in the correct way in the dossier. Substance identification is found in sections 1.1 and 1.2 in the dossier, and covers both substances. Substance composition has been described with text only to make sure all variations are covered. Description of the substances as multi or UVCB has been left out, as recommended by ECHA.<br><br>Annex I shows the data from the registrant and should not be modified.<br><br>Information on physico-chemical properties is not relevant for the SVHC-identification in this case.<br><br>The EC numbers specifying the entry proposed are closely related. As long as the scope of the proposal in |

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| | | | terms of SID is clearly defined in the Annex XV report and there is no contradicting information with the information reported in IUCLID, we consider that there should not be any ambiguity on the identity of the substance(s) proposed to be identified as SVHC. For this specific case, the scope of the proposal is clear. Duplicating the information from the Annex XV report creating a separate IUCLID dossier for "1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters" would not appear to provide an added value. |
| 4478<br>2015/04/15 | Norway,<br>Member State | The Norwegian CA supports that 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) should be identified as a substance of very high concern and should be included in the Candidate List. This is important since dihexyl phthalate is a SVHC in the Candidate List and has a harmonised classification for reproductive toxicity category 1B in accordance with Annex VI CLP. | Thank you for your support. |
| 4485<br>2015/04/16 | ChemSec,<br>International NGO,<br>Sweden | ChemSec supports the identification of the substance as a Substance of Very High Concern and the placement on the REACH candidate list. | Thank you for your support. |

**PART II: Comments and responses to comments on uses, exposures, alternatives and risks**

**No specific comments on use, exposure, alternatives and risks**