2 March 2017

Draft background document for 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)

Document developed in the context of ECHA's eighth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of 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) on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 2 June 2017) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

Contents

1. Identity 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
IUPAC name:	Di-$C_{6\text{-}10}$ alkyl phthalate	Di-$C_{6\text{-}10\ (\text{even numbered})}$ alkyl phthalate

The substances are identified as SVHC only if they contain ≥ 0.3 % (wt/wt) of dihexyl phthalate (EC No. 201-559-5).

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[1]. Results of the prioritisation of all substances included in the Candidate List by December 2015 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_en.pdf.

2.1. Intrinsic properties

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) were identified 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). This is due to the fact 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 the classification of substances (or mixtures) containing dihexyl phthalate.

The substances were included in the Candidate List for authorisation on 15 June 2015, following ECHA's decision ED/39/2015.

2.2. Volume used in the scope of authorisation

The amount of 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-

[1] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

559-5) manufactured and/or imported in the EU is, according to registration data, in the range of 100 - <1,000 t/y (ECHA, 2016). All tonnage appears to be in the scope of authorisation.

Additional information on uses is provided in Annex I.

2.3. Wide-dispersiveness of uses

All the information presented below refers to the registered substance 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC 271-094-0). Since 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters (EC 272-013-1) is not registered no information is available for that substance.

Registered uses of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) include uses at industrial sites (e.g. polymer processing - production of PVC compounds, formulation and use in coatings) and uses by professional workers (e.g. use in adhesives, use in artist supply (PC 9a: Coatings and paints, thinners, paint removers, PC 9b: Fillers, putties, plasters, modelling clay, PC 9c: Finger paints, PC 18: Ink and toners) (ECHA, 2016).

The substance is also registered for consumer uses, e.g. lubricants and adhesives (PC 24: Lubricants, greases, release products; PC 32: Polymer preparations and compounds), building materials (PC 32: Polymer preparations and compounds), artist supply (PC 9a: Coatings and paints, thinners, paint removers, PC 9b: Fillers, putties, plasters, modelling clay, PC 9c: Finger paints, PC 18: Ink and toners)). However, the supply of CMR substances to the general public is restricted pursuant to entries 28-30 of REACH Annex XVII, except for the use in artists' paint or the uses in mixtures in concentration lower than 0.3%. Restriction for this substance applies from 1 January 2015. Therefore consumer uses in the EU, if still existing, should be limited to those uses. Uses below the 0.3% concentration limit are exempted from authorisation. It could be assumed that the use in artists' paint in concentrations higher than 0.3% represents only a relatively low tonnage (<10t/y) but this has not been confirmed.

Furthermore, according to registration data the substance is used in articles (e.g. rubber and plastic articles, coated articles).

Additional information on uses is provided in Annex I.

2.4. Further considerations for priority setting

Potential grouping with other phthalates already recommended based on structural similarities and similar uses (e.g. uses in adhesives).

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
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) is classified as toxic for reproduction 1B meeting the criteria of Article 57(c) Score: 1	The amount of the substance used in the scope of authorisation is in the range of 100 - <1,000 t/y. Score: 9	The substance is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is reported to be used by consumers (artists' paint)[2] in tonnage likely to be low (<10t/y?) and is used in articles Refined score: 12-15	22 - 25	Potential grouping with other phthalates already recommended

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, 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) receives priority among the substances in the Candidate List (see link to the prioritisation results above).

Therefore, it is proposed to prioritise 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) for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[3] and as further specified in the practical implementation document[4]. The draft Annex XIV entries for all the substances included in this draft recommendation are available at https://echa.europa.eu/documents/10162/13640/8th_recom_draft_axiv_entries_en.pdf.

[2] Use derogated from the restriction of the supply of CMR substances to the general public (entries 28-30 of REACH Annex XVII)

[3] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

[4] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_implementation_en.pdf

3.1. Latest application and sunset dates

ECHA proposes to recommend the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **24 months**
Sunset date:	18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain.

Applying the criteria described in the implementation document[3] the time required for the preparation of application(s) for authorisation for 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) is assumed to be relatively longer than for the other substances prioritised for this recommendation.

Therefore the substance is assigned to the 3rd slot (LAD 24 months after inclusion in Annex XIV).

Additional information on the uses/supply chain is provided in Annex I.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for 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).

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of 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) on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of 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) for PPORD.

4. References

Annex XV report (2015): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 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). Submitted by Sweden, February 2015.

https://echa.europa.eu/documents/10162/a29d1d03-af35-4c82-9775-0723ab337b3f

ECHA (2016): 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC 271-094-0). ECHA's dissemination website on registered substances. Accessed on 25 October 2016.

https://echa.europa.eu/search-for-chemicals

ANNEX I: Further information on uses

1. Manufacture, import and export (current situation and trends)

The total tonnage for use in the EU is in the range 100-1000 t/y (ECHA, 2016). There is no information available on exported volumes (as such or in mixtures or articles) or on imported volumes in articles.

In the Nordic countries a general trend towards a decrease of the quantities used has been observed over the last 10 years (Annex XV report, 2015).

2. Main (sector of) uses and relative share of the total tonnage

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, 2016).

No information is available however on the relative share of the total tonnage per product types or per sector of end use.

3. Structure of the supply chain

Based on registration information (ECHA, 2016), the following can be assumed:

The substance is manufactured by a limited number of registrants (one active registrant reported on the dissemination website). The substance is formulated and further used at industrial sites, by professional workers and by consumers.

No information is available on the number of industrial use sites.

The substance seems to be formulated in diverse products (product categories reported in registrations: 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 (PC1[5], PC9a, PC9b, PC9c, PC18, PC24, PC32, PC33)

Sectors relying on the substance for some of their uses include the plastic, rubber, textile manufacturers, general and electric/electronic equipment manufacturers, the building and construction sector (SU11, SU12, SU16, SU17, SU19[6]).

The substance ends up in diverse article types such as rubber, plastic and textile articles, vehicles, machinery, appliances and electric/electronic articles (AC1, AC2, AC5, AC10, AC13).

No additional specific information on the structure or complexity of supply chain is available.

[5] PC1 not reported as part of the use descriptors but use in 'adhesives' indicated in the use name
[6] SU19 not reported as part of the use descriptors but use in 'building material' indicated in the use name