

18 November 2015

Draft background document for 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear

Document developed in the context of ECHA's seventh 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, dihexyl ester, branched and linear on the authorisation list or in the registration dossiers (as of the last day of the public consultation, i.e. 18 February 2016) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

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1. Identity of the substance

Chemical name: 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear

EC Number: 271-093-5

CAS Number: 68515-50-4

IUPAC Name: 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear

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 authorisation¹. Results of the prioritisation of all substances included in the Candidate List by June 2014 and not yet included or recommended in Annex XIV of the REACH Regulation is available at http://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf.

2.1. Intrinsic properties

1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) owing to the adopted opinion² by the Committee for Risk Assessment (RAC) which has agreed that the substance meets the criteria for classification as toxic for reproduction category 1B according to Regulation (EC) No 1272/2008 (CLP)³.

The substance was therefore included in the Candidate List for authorisation on 16 June 2014, following ECHA's decision ED/49/2014.

The substance is now classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B (H360FD: "May damage fertility. May damage the unborn child.").

2.2. Volume used in the scope of authorisation

There are no registrations for 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear under Regulation (EC) No 1907/2006 (REACH)⁴.

¹ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

² Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of 1,2-benzenedicarboxylic acid, dihexylester, branched and linear EC number: 271-093-5 CAS number: 68515-50-4 CLH-O-0000002695-67-03/F Adopted 7 June 2013

<http://echa.europa.eu/documents/10162/18d3ed6d-91c5-48d0-844a-8383ab5723b3>

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

⁴ Number of registrations as of 1 June 2015

2.3. Wide-dispersiveness of uses

There are no registrations for 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear under Regulation (EC) No 1907/2006 (REACH).

2.4. Further considerations for priority setting

Based on structural similarities and similar physico-chemical properties it appears that the C6 phthalate 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear might be used as a substitute for other low/transitional molecular weight phthalates of carbon backbone lengths of C4-C6 already included on Annex XIV or recommended for inclusion on Annex XIV⁵. There are indications on the potential for using the substances in the same types of application (e.g. sealant, plasticiser in polymers (Annex XV report, 2014)).

2.5. Conclusions and justification

On the basis of grouping considerations 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear is proposed to be prioritised 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 XIV⁶. The draft Annex XIV entries for substances included in this draft recommendation are available at http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_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 **18 months**

Sunset date (SSD): 18 months after LAD

There is a priori no reason to deviate from the three LAD slots of 18, 21 and 24 months after inclusion in Annex XIV that are normally assigned in a recommendation. 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear has been considered to be placed in the same slot with Dihexyl phthalate (DnHP) in this draft recommendation. These two phthalates are assigned to the 1st LAD slot. Neither of them has been registered, indicating that they are either currently not used in the EU, or if so (i.e. in tonnages below <1 t/y) the number of different uses can be assumed to be low. Consequently, the time needed to prepare an application for authorisation is assumed to be lower when compared with other substances in this recommendation round.

⁵ e.g. DEHP (EC 204-211-0), DBP (EC 201-557-4), BBP (EC 201-622-7)

⁶ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear.

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, dihexyl ester, branched and linear 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 include in Annex XIV any exemption from authorisation for the use of 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear for PPORD.

4. Further information on uses

1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear has not been registered under REACH⁷.

Based on information available, it seems that it could be used for similar purposes and in similar applications (mainly as plasticiser in PVC) as other low/transitionnal molecular weight phthalates already included in Annex XIV (DEHP, DBP, BBP) or recommended for inclusion in Annex XIV.

However, nowadays the trend in the EU plasticiser sector seems rather to reflect regulatory changes: with the inclusion of many LMW phthalates in the Candidate List the phthalate producers in Europe are moving to non-classified high molecular weight phthalates. Development seems focused on these substances with a shift from low to high (C8 and above) molecular weight products. There is also a focus on development of other⁸ plasticisers for speciality and higher-end markets (Vinylplus, 2014).

Potential alternatives to LMW phthalates are reported for a broad range of applications. Some are further detailed in the restriction proposal for bis(2-ethylhexyl)phthalate (DEHP, CAS No 117-81-7), benzyl butyl phthalate (BBP, CAS No 85-68-7), dibutyl phthalate (DBP, CAS No 84-74-2), and diisobutyl phthalate (DIBP, CAS No 84-69-5) (ECHA 2009, 2012). Comments provided during the SVHC public consultation (RCOM, 2014) also pointed out the existence of potential alternatives to the use of PVC, or to the uses of phthalates in PVC, in applications such as cables, flooring and coated textiles.

The tonnage of low molecular weight phthalates currently marketed in the EU is estimated at about 50,000 t/y (5% of the total European plasticisers market, estimated to be close to one million tonnes per year) (Plasticisers, 2015)).

⁷ as of 1 June 2015

⁸ the nature of these 'other' plasticisers is not specified

5. References

Annex XV report (2014): 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, dihexyl ester, branched and linear. Submitted by the Swedish Chemicals Agency, March 2014.

<http://echa.europa.eu/documents/10162/7c5c54dc-e0bb-4d8b-b759-437044f82af8>

ECHA (2009): Data on manufacture, import, export, uses and releases of bis(2-ethylhexyl)phthalate (DEHP) as well as information on potential alternatives to its use. The technical work on this report has been led by COWI A/S, supported by IOM and Entec UK Ltd under framework contract ECHA/2008/2.

http://echa.europa.eu/doc/consultations/recommendations/tech_reports/tech_rep_d_ehp.pdf

ECHA (2012): Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC). Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates, ECHA/RAC/RES-O-0000001412-86-07/S1, ECHA/SEAC/RES-O-0000001412-86-10/S2.

<http://echa.europa.eu/documents/10162/3bc5088a-a231-498e-86e6-8451884c6a4f>

Plasticiser (2015): Plasticiser and flexible PVC Information Center Website. Accessed 22 September 2015.

http://www.plasticisers.org/en_GB/plasticisers/Orthophtalates

RCOM (2014): "Responses to comments" document. Document compiled the Swedish Chemicals Agency from the commenting period 03/03/2014 - 17/04/2014 on the proposal to identify 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear as a Substance of Very High Concern.

<http://echa.europa.eu/candidate-list-table/-/substance-rev/2361/term>

Vinylplus (2015): Voluntary sustainable development programme of the European PVC industry Website. Accessed 22 September 2015.

<http://www.vinylplus.eu/progress/annual-progress/2013-2>