

10 November 2016

Background document for dihexyl phthalate (DnHP)

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 dihexyl phthalate on the authorisation list or in the registration dossiers (as of the last day of the public consultation, i.e. 18 February 2016) have been taken into consideration when finalising the recommendation and are reflected in the present document.

The background document also describes how ECHA has taken into account the MSC opinion.

Contents

1. Identity of the substance	2
2. Background information for prioritisation	2
2.1. Intrinsic properties.....	2
2.2. Volume used in the scope of authorisation.....	2
2.3. Wide-dispersiveness of uses	2
2.4. Further considerations for priority setting.....	2
2.5. Conclusion	3
3. Background information for the proposed Annex XIV entry	3
3.1. Latest application and sunset dates.....	3
3.2. Review period for certain uses.....	4
3.3. Uses or categories of uses exempted from authorisation requirement	4
3.3.1. Exemption under Article 58(2).....	4
3.3.2. Exemption of product and process oriented research and development (PPORD)	4
4. References	5
Annex I: Further information on uses.....	6

1. Identity of the substance

Chemical name: Dihexyl phthalate (DnHP)
EC Number: 201-559-5
CAS Number: 84-75-3
IUPAC Name: Dihexyl phthalate

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_20_15_en.pdf.

The prioritisation results of the substances included in the draft 7th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft7threc_substances_feb2016_en.pdf

2.1. Intrinsic properties

Dihexyl phthalate was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is 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."). The substance was therefore included in the Candidate List for authorisation on 16 December 2013, following ECHA's decision ED/121/2013.

2.2. Volume used in the scope of authorisation

There are no registrations for dihexyl phthalate under Regulation (EC) No 1907/2006 (REACH)².

2.3. Wide-dispersiveness of uses

There are no registrations for dihexyl phthalate under Regulation (EC) No 1907/2006 (REACH)².

2.4. Further considerations for priority setting

Based on structural similarities and similar physico-chemical properties it appears that the C6 phthalate dihexyl phthalate might be used as a substitute for other low/transitional molecular

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

² Number of registrations as of 18 February 2016

weight phthalates of carbon backbone³ lengths of C4-C6 already included on Annex XIV or recommended for inclusion on Annex XIV⁴. There are indications on the potential for using the substances in the same types of application (e.g. plasticiser in PVC (Annex XV report, 2013)).

2.5. Conclusion

Dihexyl phthalate (DnHP) **is recommended for inclusion in Annex XIV** on the basis of grouping considerations.

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 XIV⁵. The draft Annex XIV entries that underwent public consultation are available at:

http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at:

https://echa.europa.eu/documents/10162/13640/7th_axiv_recommendation_november2016_en.pdf.

3.1. Latest application and sunset dates

The LAD slots are set in 3-month intervals (normally 18, 21 and 24 months after inclusion in Annex XIV but more slots can be considered on a case-by-case basis). In its draft recommendation, ECHA had proposed that the LAD would be the date of inclusion of the substance in Annex XIV plus 18 months and the sunset date 18 months after the LAD. ECHA had seen 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. Dihexyl phthalate (DnHP) had been considered to be placed in the same slot with 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear in this draft recommendation. These two phthalates were 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.

During the public consultation no comments were received on the proposed transitional arrangements.

Hence, in the light of the available information, ECHA recommends the following transitional arrangements:

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

³ referring to the alcohol chain of the ester

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

⁵ 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

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for dihexyl phthalate.

During the public consultation ECHA did not receive comments requesting upfront review period for certain uses for the substance.

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of dihexyl phthalate.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1. Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of dihexyl phthalate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation ECHA did not receive any requests for exemptions for the substance.

ECHA therefore **does not recommend exemptions of uses** of dihexyl phthalate 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)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of dihexyl phthalate for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

ECHA therefore **does not recommend exempting any use** of dihexyl phthalate **for PPORD** from authorisation.

4. References

Annex XV report (2013): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Dihexyl phthalate. Submitted by the German Competent Authorities, November 2013.

<http://echa.europa.eu/documents/10162/9a8b4fa6-c852-48bd-b561-c727b8d197ff>

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.

<https://echa.europa.eu/documents/10162/8fd5a74b-6807-42b6-ae1f-d1d7f04f40f8>

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

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>

Annex I: Further information on uses

Dihexyl phthalate has not been registered under REACH⁶.

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 molecular weight (LMW) 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 other⁷ plasticisers for speciality and higher-end markets (Vinylplus, 2014).

Potential alternatives to LMW phthalates include, depending on the functionality needed, chemicals like citrates, adipates, phosphates, trimellitates (Annex XV report, 2013). Potential alternatives 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).

The tonnage of low molecular weight phthalates marketed in the EU is currently 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)).

⁶ as of 18 February 2016

⁷ the nature of the 'other' plasticisers is not further specified on the webpage consulted