2 February 2022

Draft background document for diisohexyl phthalate

Document developed in the context of ECHA's eleventh 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 the 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 consultation on the inclusion of diisohexyl phthalate in the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 2 May 2022) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: diisohexyl phthalate
EC Number: 276-090-2
CAS Number: 71850-09-4

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[2]. Results of the prioritisation of all substances included in the Candidate List by July 2021 and not yet recommended or included in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/17232/prior_results_cl_subst_february_2022_en.pdf.

2.1. Intrinsic properties

Diisohexyl 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 (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") and was therefore included in the Candidate List for authorisation on 16 January 2020, following ECHA's decision ECHA/01/2020.

2.2. Volume used in the scope of authorisation

There are no registrations for diisohexyl phthalate under Regulation (EC) No 1907/2006 (REACH)[3].

2.3. Wide-dispersiveness of uses

There are no registrations for diisohexyl phthalate under Regulation (EC) No 1907/2006 (REACH)[3].

2.4. Further considerations for priority setting

Based on structural similarities and similar physico-chemical properties it appears that diisohexyl phthalate might be used as a substitute for other low/transitional molecular weight phthalates of carbon backbone lengths of C4-C6 already included in Annex XIV or recommended for inclusion in Annex XIV. There are indications on the potential for using the substances in the same types of application (e.g. plasticiser in PVC (Annex XV SVHC report, 2019)).

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf
[3] Number of registrations as of 1 August 2021.

2.5. Conclusion

Diisohexyl phthalate is proposed to be prioritised for inclusion in Annex XIV on the basis of grouping considerations.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[4] and the criteria described in the implementation document[5]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in section 2 of Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 11th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

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

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

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[4] General approach can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_2020_en.pdf/

[5] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

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 diisohexyl phthalate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[6]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[7], there is no need to propose an additional specific exemption.

[6] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/17232/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/17232/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[7] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf

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 diisohexyl phthalate for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for diisohexyl phthalate[8].

[8] As of 1 August 2021.

4. References

Annex XV SVHC report (2019): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Diisohexyl phthalate. Submitted by Sweden, August 2019.

https://www.echa.europa.eu/documents/10162/cf92bdc0-80ac-f93e-f66d-3d60d740af51

Assessment of regulatory needs (2021): Group name: *Ortho*-phthalates. Submitted by ECHA, June 2021.

https://echa.europa.eu/documents/10162/5914e10f-18c0-7733-f044-738f8867b973

ECHA (2021): Diisohexyl phthalate. ECHA's dissemination website on registered substances. Accessed on 1 August 2021.

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

RCOM (2019): "*Responses to comments*" document. Document compiled by Sweden from the commenting period 03/09/2019-18/10/2019 on the proposal to identify diisohexyl phthalate as a Substance of Very High Concern.

https://www.echa.europa.eu/documents/10162/82a5aa16-63f0-c655-0325-125ff409ad4d

Annex I: Further information on uses

1. Basis for grouping considerations

Diisohexyl phthalate has not been registered under REACH (ECHA, 2021). 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/transitional molecular weight phthalates already included in Annex XIV (DEHP, DBP, BBP) or recommended for inclusion in Annex XIV (Annex XV SVHC report, 2019; RCOM, 2019; Assessment of regulatory needs, 2021).

2. Structure and complexity of supply chains

The following assumptions are made to allocate the substance to a specific LAD slot.

Diisohexyl phthalate is not registered and appear to have currently no uses in the scope of authorisation.