

12 April 2023

## 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<sup>1</sup> as well as the MSC opinion<sup>2</sup> were taken into consideration when finalising the recommendation and are reflected in the present final background document. For diisohexyl phthalate no comments were received in the consultation.

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<sup>1</sup> As of the last day of the consultation, i.e. 2 May 2022.

<sup>2</sup> Opinion of the Member State Committee on the draft eleventh recommendation of the priority substances to be included in Annex XIV, adopted on 8 February 2023.

## 1. Identity of the substance

Identity of the substance as provided in the Candidate List<sup>3</sup>:

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 (ECHA, 2020). 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 are available in ECHA (2022a).

The prioritisation results of the substances included in the draft 11<sup>th</sup> recommendation have been updated as necessary after the consultation. The updated results are available in ECHA (2023).

### 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 (ECHA, 2022b).

### 2.3. Wide-dispersiveness of uses

There are no registrations for diisohexyl phthalate under Regulation (EC) No 1907/2006 (ECHA, 2022b).

### 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 (ECHA, 2019)).

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<sup>3</sup> For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

## 2.5. Conclusion

**Diisohexyl phthalate is recommended 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 recommends the following transitional arrangements for diisohexyl phthalate:

Latest application date (LAD):            Date of inclusion in Annex XIV plus **18 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 recommended 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. Groups of substances are considered together.

The substance has not been registered, indicating that it is 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 consultation no comments were received that challenged the proposed transitional arrangements.

### 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 diisohexyl phthalate.

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

ECHA therefore **does not recommend to include in Annex XIV any review periods for uses of diisohexyl 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 uses of diisohexyl phthalate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH

Regulation.

During the consultation ECHA did not receive comments requesting exemptions for uses of diisohexyl phthalate.

ECHA therefore **does not 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.

### **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 diisohexyl phthalate for PPORD.

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

No PPORD notifications had been submitted by the end of the consultation.

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

## 4. References

ECHA (2019): [Registry of SVHC intentions until outcome - ECHA \(europa.eu\)](#), filter by substance diisohexyl phthalate (EC 276-090-2).

- Annex XV report. Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Substance name: Substance Name: Diisohexyl phthalate, EC Number: 276-090-2, CAS Number: 71850-09-4.
- Comments on an Annex XV Dossier for identification of a substance as SVHC and responses to these comments. Substance name: Diisohexyl phthalate, EC Number: 276-090-2, CAS Number: 71850-09-4.

ECHA (2020): Agreed and applied approaches. 5 March 2020.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance diisohexyl phthalate (EC 276-090-2)

- Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.
- Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.
- Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2021): [Assessment of regulatory needs list](#), filter by substance diisohexyl phthalate (EC 276-090-2) and authority 'ECHA'.

- Assessment of regulatory needs. Group Name: Ortho-phthalates

ECHA (2022a): ECHA's 11th draft recommendation. 2 February 2022.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance diisohexyl phthalate (EC 276-090-2)

- Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2021 and not yet recommended for inclusion in Annex XIV.
- Draft 11th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation).

ECHA (2022b): Diisohexyl phthalate. ECHA's dissemination website on registered substances. Accessed on 2 May 2022.

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

ECHA (2023): ECHA's final 11<sup>th</sup> recommendation. 12 April 2023.

[Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#), filter by substance diisohexyl phthalate (EC 276-090-2)

- Updated priority assessment results of the substances included in the draft 11th recommendation for inclusion in Annex XIV. 12 April 2023.
- Recommendation of the European Chemicals Agency of 12 April 2023 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation).

## Annex I: Further information on uses

### 1. Basis for grouping considerations

Diisohexyl phthalate has not been registered under REACH (ECHA, 2022b). 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 (ECHA, 2019; ECHA, 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 appears to have currently no uses in the scope of authorisation.