



Diisohexyl phthalate

Information provided to support the draft recommendation of substances for inclusion in Annex 14 of UK REACH

Date: September 2023

Relevant information provided during the consultation on the inclusion of diisohexyl phthalate on the authorisation list will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Cover Note

The Health and Safety Executive (in its role as the Agency for UK REACH and referred to as the Agency hereafter) will recommend substances of very high concern (SVHCs) from the UK candidate list to be included on the authorisation list (Annex 14).

The Agency is required to submit its recommendation to the appropriate authorities after inviting comments from interested parties over a three month period. The Agency will update its recommendation, taking account of any comments received.

This document provides background information on the prioritisation of diisohexyl phthalate, as well as on the determination of its draft entry in the authorisation list (Annex 14 of UK REACH).

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1. Identity of the substance

Identity of the substance in the [UK candidate list](#)

Name: Diisohexyl phthalate

EC Number: 276-090-2

CAS Number: 71850-09-4

2. Background information for prioritisation

The criteria the Agency use to prioritise substances for inclusion in the authorisation list (Annex 14) are outlined in Article 58(3) of UK REACH. These state that priority shall normally be given to substances with:

- (a) Persistent Bioaccumulative and Toxic (PBT) or very Persistent very Bioaccumulative (vPvB) properties; or
- (b) wide dispersive use; or
- (c) high volumes.

The criteria used by the Agency are set out in more detail in the document entitled [“Approach to recommendation of priority substances for inclusion in Annex 14 \(list of substances subject to authorisation\) of UK REACH”](#).

Diisohexyl phthalate was prioritised by the European Chemicals Agency (ECHA) and included in its [11th recommendation](#), which was submitted to the European Commission in April 2023. The Agency has used the results from [ECHA’s prioritisation exercise](#) to inform the second draft recommendation.

2.1. Intrinsic properties

Diisohexyl phthalate is identified as a Substance of Very High Concern (SVHC) according to Article 57(c) of UK REACH. It is classified in the [GB Mandatory Classification and Labelling \(MCL\) list](#) as toxic for reproduction, category 1B, H360F (“May damage fertility.”).

Diisohexyl phthalate was included in the EU candidate list for authorisation on 16th January 2020, following ECHA’s decision [ED 30 2017 \(europa.eu\)](#). It was included in the UK candidate list on 1st January 2021 by virtue of Article 59(1A) of UK REACH.

2.2. Volume used in the scope of authorisation

According to ECHA’s [background document](#), developed in the context of its [11th recommendation](#) for inclusion of substances in Annex XIV of the EU REACH Regulation (ECHA, 2021), there were no registrations under EU REACH for diisohexyl phthalate. This remains the case. Therefore, if the substance is manufactured in or imported into the EU this is at less than 1 tonne per year by any individual manufacturer or importer. Furthermore, no registrations have been submitted under UK REACH for this substance to date. Information from [Downstream User Import Notifications](#) (DUINs) indicates that the substance may be imported into the UK from EU suppliers. However, as DUIN submission was a simple process and free of charge, companies may have under or over-reported substances (potentially erring on the side of caution

to be compliant). Consequently, the DUIN data are treated with caution.

2.3. Wide-dispersiveness of uses

Owing to the lack of GB and EU registrations for diisohexyl phthalate, there is no information on uses for this substance which may be in scope of authorisation. However, it is considered a potential candidate to replace other phthalates that are already recommended for or included in Annex 14 (e.g., for use as a plasticiser in polymers).

2.4. Further considerations for priority setting

In recommending diisohexyl phthalate for inclusion in the EU authorisation list, ECHA considered the possibility that this substance might be used as a replacement for other phthalates that are already recommended for or included in that list (e.g. as plasticisers in polymers). The Agency has no information that would support or refute this claim.

No comments were received for this substance during ECHA's consultation on the [11th draft recommendation](#) for inclusion of substances in Annex XIV of EU REACH.

2.5. Conclusion

Whilst diisohexyl phthalate is not registered under UK REACH, there is potential for this substance to be used in the place of other phthalates that have been added to Annex 14. As such, the Agency is recommending that diisohexyl phthalate is added to the UK REACH authorisation list to avoid regrettable substitution.

This draft recommendation may be revised depending on information received during the consultation.

3. Background information for the proposed Annex 14 entry

3.1. Latest application and sunset dates

The Agency proposes the following transitional arrangements as referred to in Article 58(1)(c):

Latest application date (LAD):	Date of inclusion in Annex 14 plus 18, 21 or 24 months
Sunset date:	18 months after LAD

The Agency will set the LAD when finalising the recommendation and will use all available relevant information, including that received in the consultation. It has been estimated that a period of 18 months is required to prepare good quality applications for authorisation. When setting the LADs, the Agency also considers its capacity to process authorisation applications. If a high workload is anticipated, a later LAD may be allocated.

3.2. Review period for certain uses

Review periods will be considered during the decision on whether to grant authorisation for specific applications submitted by manufacturers, importers or downstream users. All authorisation decisions will include specific review periods based on information provided in the application.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

The Agency proposes not to recommend exemptions for uses of diisohexyl phthalate based on Article 58(1)(e) in combination with Article 58(2) of UK REACH. According to Article 58(2) of UK REACH it is possible to exempt from the authorisation requirement uses or categories of uses 'provided that, on the basis of the existing specific 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'.

In deciding whether to recommend an exemption, the Agency considers if:

- There is existing legislation addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing 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 14; generally, the legislation in question should specifically refer to the substance to be included in Annex 14 either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing 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) has to allow more stringent requirements than the specific minimum requirements set out in the legislation in question to be imposed. 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).

Requests for exemption from authorisation under Art. 58(2) for a particular use will be assessed by the Agency on a case-by-case basis.

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

The Agency proposes not to recommend including in Annex 14 any exemption from authorisation for the use of diisohexyl phthalate for PPORD.

At the EU level, no exemptions for PPORD have been recommended for any substance. If an operator wishes to use a substance included in Annex 14 for a PPORD activity, it is possible for the operator to obtain authorisation for that use of the substance in accordance with Articles 60 to 64 of UK REACH.

DRAFT: BACKGROUND DOCUMENT FOR DIISOHEXYL PHTHALATE

ECHA noted in its background document that no PPORD notifications had been submitted to it for diisohexyl phthalate by the end of their consultation. As of July 2023, no PPORD notifications had been received by the Agency.

4. References

ECHA (2021). Background document for diisohexyl phthalate. Document developed in the context of ECHA's 11th recommendation for the inclusion of substances in Annex XIV. [Annex XIV background document \(europa.eu\)](#)

Declarations

Within this document we have provided links to the following ECHA documents and information found on ECHA's website:

The following documents:

- [ED 30 2017 \(europa.eu\)](#): Inclusion of substances of very high concern in the candidate list for eventual inclusion in Annex XIV (Decision of the European Chemicals Agency) dated 20th June 2018.
- [Recommendation of the European Chemicals Agency of 12th April 2023](#) for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation).
- [Comments on ECHA's Draft 11th Recommendation for Diisohexyl phthalate](#) and references to responses dated 5th May 2023.
- [ECHA \(2023\)](#). Background document for diisohexyl phthalate dated 12th April 2023.

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Further information

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