Dicyclohexyl phthalate (DCHP)

Substance information provided to support the first draft recommendation of substances for inclusion in Annex 14 of UK REACH

Periodically, HSE is required to recommend priority SVHCs from the UK Candidate List which should be subject to authorisation and to submit this recommendation to the Appropriate Authorities. This document provides background information on the prioritisation of this substance, as well as on the determination of its draft entry in the Authorisation List (Annex 14 of UK REACH).

Relevant information provided during the consultation on the inclusion of dicyclohexyl phthatate on the Authorisation List will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

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1. Identity of the substance

Identity of the substance in the UK Candidate List[1]:

Name: Dicyclohexyl phthalate (DCHP)
EC Number: 201-545-9
CAS Number: 84-61-7

2. Background information for prioritisation

The criteria that HSE should use to prioritise substances for inclusion in the Authorisation List are outlined in Article 58(3) of UK REACH. This states that priority shall normally be given to substances with:

(a) PBT or vPvB properties[2]; or
(b) wide dispersive use; or
(c) high volumes.

An additional consideration under Article 58(3) is that the number of substances included in Annex 14 *"shall also take account of the Agency's capacity to handle applications in the time provided for".*

The criteria used by HSE are set out in more detail in the document titled "Approach to recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH UK REACH: Authorisation list (Annex **14**) (hse.gov.uk)

DCHP was prioritised by ECHA and included in its 10th recommendation, which was submitted to the European Commission in April 2021. The information that ECHA used for its prioritisation exercise, which was finalised in March 2020 included information from UK based companies. For this reason, HSE has used the results from ECHA's prioritisation exercise to inform its first draft recommendation. As HSE receives more registrations, it will reconsider the value of using EU information for this purpose.

2.1 Intrinsic properties

DCHP is identified as a Substance of Very High Concern (SVHC) according to Article 57(c) of UK REACH as it is classified in the GB Mandatory Classification and Labelling (MCL) list[3] as toxic for reproduction, category 1B, H360D ("May damage the unborn child.").

On the basis of Commission Implementing Decision (EU) 2018/636, DCHP is also identified as a SVHC in accordance with Article 57(f) owing to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to human

[1] The UK Candidate List can be consulted here: https://www.hse.gov.uk/reach/candidate-list.xlsx
[2] Persistent Bioaccumulative and Toxic (PBT) or very Persistent very Bioaccumulative (vPvB)
[3] The GB Mandatory Classification and Labelling list can be consulted here: https://www.hse.gov.uk/chemical-classification/assets/docs/mcl-list.xlsx

health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57.

DCHP was included in the EU Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018. It was included in the UK Candidate List on 1 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 10th recommendation for inclusion of substances in Annex XIV of the EU REACH Regulation (ECHA, 2021), the amount of DCHP manufactured and/or imported into the European Union (EU) on 5th June 2020 was in the range of 100 – 1,000 tonnes per year. According to ECHA, all the EU registered tonnage appears to be in the scope of authorisation.

2.3. Wide-dispersiveness of uses

Uses of DCHP in the scope of authorisation and identified in EU registrations include uses at industrial sites (e.g. formulation and use of plastisol used as sealant or in textile printing, formulation and use as co-plasticiser in PVC, rubber and plastic compounds, formulation and use of organic peroxides containing DCHP as phlegmatizer and dispersion agent) and by professional workers (e.g. use of plastisol, use of organic peroxide formulation containing DCHP).

EU registrations also refer to the use of DCHP in plastisol and organic peroxide formulations supplied to consumers. These uses are within the scope of the generic restriction (UK REACH Annex 17, entry 30) on the supply to the general public of substances classified as toxic to reproduction, category 1B as substances, as constituents of other substances or in mixtures at concentrations of 0.3% or more. However, DCHP is also identified as a SVHC under Article 57(f) due to endocrine disrupting properties. According to Article 56(6)(a), this lowers the concentration threshold for a requirement for authorisation to use mixtures containing DCHP from 0.3% to 0.1%. HSE does not know if consumer uses of mixtures containing DCHP in the concentration range between 0.1% and 0.3% are taking place (which would be in the scope of authorisation).

According to ECHA, DCHP may also be present in articles in volumes above 10 tonnes per year (e.g. plastic, rubber and textile articles).

2.4. Further considerations for priority setting

In recommending DCHP 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. plasticiser in polymers). HSE has no information that would support or refute this claim.

2.5. Conclusion

Based on the information available to ECHA, DCHP obtained a score of 28 out of a

possible total score of 45 in the EU prioritisation exercise.[4]

A score of 7 out of 15 was assigned due to its hazard classification as toxic for reproduction, category 1B meeting the criteria of Article 57(c) and its identification as an SVHC according to Article 57(f) due to its endocrine disrupting properties.

A score of 9 out of 15 was assigned due to the volume that is in the scope of authorisation which has been estimated as 100 - 1,000 tonnes per year.

A score of 12 out of 15 was assigned due to the wide dispersiveness of uses and taking account of the presence of this substance in articles in volumes >10 tonnes per year.

This score of 28, strengthened by grouping considerations (several other phthalates are already listed on Annex 14), gave DCHP priority among the substances on the EU Candidate List and resulted in ECHA recommending it for inclusion in the EU Authorisation List.

In deciding which substances to include in its first recommendation HSE took account of this prioritisation score. HSE also considered information that was submitted to ECHA during the public consultation on its 10th draft recommendation and published in ECHA's Responses to Comments (RCOM) document[5]. More detail on the information that HSE took into account is provided in the initial summary document[6]. HSE is recommending that DCHP is added to the UK Authorisation List – however, this draft recommendation will be revised in line with GB specific information received in the commenting period.

3. Background information for the proposed Annex 14 entry

3.1. Latest application and sunset dates

HSE 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

HSE will make the final LAD allocation 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, HSE also considers its capacity to process

[4] To help it identify priority substances, ECHA has developed a scoring system which it uses to rank SVHCs against these criteria. A SVHC can score a maximum of 45 points, 15 for each criterion, based on its inherent properties, use profile and the tonnage that is put to uses within the scope of authorisation. This scoring system is set out in sections 5.1 – 5.5 of its guidance note "Prioritisation of substances of very high concern (SVHCs) for inclusion in the authorisation list (Annex XIV)" 2014 (amended 2020) https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930

[5] The comments submitted to ECHA in response to the inclusion of DCHP in ECHA's draft 10th recommendation can be viewed here: https://echa.europa.eu/documents/10162/ce86b534-c3cb-2364-b8c1-b8dba8597b50

[6] The initial assessment summaries are available here: https://www.hse.gov.uk/reach/authorisation-list.htm

authorisation applications. If a high workload is anticipated, a later LAD may be allocated.

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

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)

HSE proposes not to recommend exemptions for uses of DCHP 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, HSE 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 HSE on a case-by-case basis.

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

HSE proposes not to recommend including in Annex 14 any exemption from

authorisation for the use DCHP 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.

ECHA noted in its background document that no PPORD notifications had been submitted to it for DCHP by 5 June 2020. By 28 July 2021 no PPORD notifications had been received by HSE.

4. References

ECHA (2021). Background document for dicyclohexyl phthalate. Document developed in the context of ECHA's 10th recommendation for the inclusion of substances in Annex XIV. https://echa.europa.eu/documents/10162/cf47b384-d2d4-7a47-f57c-dba0c54261c3

Annex I: Further information on uses

1. *Further details on some type of applications*

According to comments received by ECHA during the consultation on the SVHC identification of dicyclohexyl phthalate (RCOM, 2016), the substance can be used in the semiconductor sector in special glues at low concentration (below 0.3%). The total amount used in the EU for this application seems to sum up to less than 100 kg per year. It is expected that the amount used, if any, for this application in Great Britain will be less.

2. *Structure and complexity of supply chains*

The following assumptions are made based on currently available information and will be used, together with any relevant information from the consultation, to allocate the substance to a specific LAD slot in the final recommendation.

ECHA states in its background document that DCHP is manufactured and/or imported into the EU by a limited number of registrants. This suggests that few or no companies manufacture or import DCHP into Great Britain. HSE has precise and up-to-date information on the number of industrial sites where the substance is currently used.

The supply chain can be characterised[7] by the following actors: formulators, users at industrial sites (including article producers), professional workers and users of articles (including article assemblers (multi-layer assembling chain)) (relevant life cycle stages include formulators, industrial sites, professional workers and service life of articles (multi-layer)).

DCHP seems to be used in the following product categories: polymer preparations and compounds, adhesives, sealants, coatings, paints, inks, toners and processing aids (relevant product categories: PC1, PC9a, PC18, PC20 and PC32).

A number of sectors rely on the substance in some of their uses including manufacturers of plastic or rubber products, textiles, leather, fur, fine chemicals, computers, electronic and optical products, electrical equipment, machinery, equipment, vehicles or other transport equipment as well as the printing sector (relevant sector of use categories: SU5, SU7, SU9, SU11, SU12, SU16 and SU17).

DCHP may be used to produce article types such as plastic or rubber articles, fabrics, textiles and apparel as well as machinery, mechanical appliances and electrical/electronic articles (relevant article categories: AC2, AC5, AC10, AC13).

Some of the categories mentioned are not explicitly reported in EU registrations but were deduced by ECHA from information on uses available in registration dossiers and comments received in the consultation on the SVHC identification (RCOM, 2016).

In the absence of UK REACH registrations for this substance, HSE assumes that the use pattern described for the EU is applicable to Great Britain.

[7] The categories listed here (life cycle stage, sector of use (SU), product categories (PC) and article categories (AC)) were developed by ECHA in Chapter R12 of its Guidance on Information Requirements and Chemical Safety Assessment. Further details of the use descriptor system are available here: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

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Declarations

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

The following documents:

- ED/61/2018: Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV (Decision of the European Chemicals Agency) dated 20 June 2018.
- COMMISSION IMPLEMENTING DECISION (EU) 2018/636 of 17 April 2018 on the identification of dicyclohexyl phthalate (DCHP) as a substance of very high concern according to Article 57(c) and (f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.
- Recommendation of the European Chemicals Agency of 14 April 2021 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation).
- Comments on ECHA's Draft 10th Recommendation for Dicyclohexyl phthalate (DCHP) (EC number: 201-545-9) and references to responses dated 14 April 2021.
- ECHA (2021). Background document for dicyclohexyl phthalate (DCHP) thdated 14 April 2021.

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For the avoidance of doubt, no part of this document has been endorsed by ECHA.

Further information

This document is available at: www.hse.gov.uk/pubns/indg000.htm.

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