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Background document for dicyclohexyl phthalate (DCHP)

Document developed in the context of ECHA's tenth 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 dicyclohexyl phthalate (DCHP) in the Authorisation List or in the registration dossiers¹ as well as the MSC opinion² were taken into consideration when finalising the recommendation and are reflected in the present document.

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¹ As of the last day of the consultation, i.e. 5 June 2020

² Opinion of the Member State Committee on the draft tenth recommendation of the priority substances to be included in Annex XIV, adopted on 10 February 2021

1. Identity of the substance

Identity of the substance as provided in the Candidate List³:

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

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 authorisation⁴. Results of the prioritisation of all substances included in the Candidate List by July 2019 and not yet recommended or included in Annex XIV of the REACH Regulation are available at

https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf.

The prioritisation results of the substances included in the draft 10th recommendation have been updated as necessary after the consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft10threc_substances_april2021_en.pdf.

As stated above, registration information as available on the last day of consultation (5 June 2020) was considered. Therefore, the impact of the UK withdrawal from the EU (for which the transition period ended 31 December 2020) was not taken into account.

2.1. Intrinsic properties

Dicyclohexyl 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, H360D ("May damage the unborn child").

Furthermore, taking into account all available information on the intrinsic properties of dicyclohexyl phthalate and their adverse effects, it was concluded that the substance can be regarded as substance with endocrine disrupting properties for which in accordance with Article 57(f) of REACH there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Dicyclohexyl phthalate was identified as a Substance of Very High Concern (SVHC) according to Article 57(f)⁵.

Therefore, dicyclohexyl phthalate was included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

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

⁴ Document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf

⁵ Commission Implementing Decision (EU) 2018/636 at <https://www.echa.europa.eu/documents/10162/8c434af5-cf8e-c87e-aa51-65893e385d1f>

2.2. Volume used in the scope of authorisation

The amount of dicyclohexyl phthalate manufactured and/or imported into the EU is according to registration data (ECHA, 2020) in the range of 100 - 1,000 t/y. All tonnage appears to be in the scope of authorisation.

2.3. Wide-dispersiveness of uses

Registered uses of dicyclohexyl phthalate in the scope of authorisation include uses at industrial sites (e.g. formulation and use of organic peroxides with dicyclohexyl phthalate as phlegmatizer and dispersion agent, use of adhesives, formulation and use of plastisol used as sealant or in textile printing, formulation and use as co-plasticiser in PVC, rubber and plastic compounds) and by professional workers (e.g. use of organic peroxide formulations containing dicyclohexyl phthalate, use of plastisol).

The use of organic peroxide formulations and plastisol are also registered for consumer uses. However, these uses fall under the restriction on substances that are toxic for reproduction (REACH Annex XVII, entry 30) used in concentrations equal to or above 0.3 %. However, dicyclohexyl phthalate is also identified as SVHC under Art. 57(f) due to endocrine disrupting properties. Therefore, uses of the substance in mixtures at concentrations equal to or above 0.1 % require authorisation (Art. 56(6)(a)). There is uncertainty whether any consumer uses in the concentration range between 0.1 % and 0.3 % are taking place (which would be in the scope of authorisation). For the purpose of prioritisation consumer uses of DCHP have not been considered.

Furthermore, according to registration data, substance in article notification and a comment received during the consultation (ComRef, 2021), the substance is used in articles (e.g. machinery, electrical/electronic articles or vehicles, to which adhesives have been applied, as well as plastic, rubber and textile articles) in volumes above 10 t/y.

2.4. Further considerations for priority setting

Based on structural similarities dicyclohexyl phthalate might be used as a substitute for other phthalates that were already recommended for or included in Annex XIV in (some of) their uses (e.g. plasticiser in polymers).

Comments received during the consultation challenged the grouping of dicyclohexyl phthalate with other phthalates used as plasticisers arguing that the use as plasticiser is not any more reported in registration dossiers of DCHP. Furthermore, it was stated that the phthalates included in Annex XIV have different uses than DCHP and that the substance is not considered as an alternative for the substitution of four of the phthalates in Annex XIV (DEHP, BBP, DBP and DIBP). Another comment agreed with the prioritisation of DCHP (ComRef, 2021).

Although the use of dicyclohexyl phthalate as plasticiser in polymers like PVC is not anymore reported by a number of registrants, that use was reported in previous dossier versions and is still reported in some registration dossiers. This indicates that dicyclohexyl phthalate can be used in the same type of applications as those phthalates recommended for or included in Annex XIV (e.g. plasticiser in polymers).

The information provided in the comments does not allow to conclude that it is technically not feasible to use dicyclohexyl phthalate as substitute for other phthalates used as plasticisers. Furthermore, MSC in its opinion expressed the view that the grouping approach is justified.

Therefore, ECHA sees no reason to change the grouping consideration for this substance (RCOM, 2021).

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Dicyclohexyl phthalate is classified as toxic for reproduction 1B and has endocrine disrupting properties with effects to human health meeting the criteria of Article 57 (c) and (f). Score: 7	The amount of dicyclohexyl phthalate used in the scope of authorisation is in the range of 100 – 1,000 t/y. Score: 9	Dicyclohexyl phthalate is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles in volumes >10 t/y. Refined score: 12	28	Grouping with other phthalates already recommended/ included in Annex XIV

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, dicyclohexyl phthalate receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, dicyclohexyl phthalate **is recommended for inclusion in Annex XIV**.

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 XIV⁶ and as further specified in the practical implementation document⁷. The draft Annex XIV entries for all the substances that underwent consultation are available at

https://echa.europa.eu/documents/10162/13640/10th_recom_draft_axiv_entries_en.pdf.

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

https://echa.europa.eu/documents/10162/13640/10th_axiv_recommendation_april2021_en.pdf.

⁶ General approach can be accessed at

https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf

⁷ Practical implementation document can be accessed at

https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements for dicyclohexyl 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 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.

During the consultation, comments were received arguing for an LAD of 24 months due to the time needed for changes in automotive applications, or the need to await the outcome of a study that could lead to another hazard classification. A further comment supported the LAD of 18 months (ComRef, 2021). ECHA did not consider these viable reasons for prolonging the latest application date (RCOM, 2021). Furthermore, MSC is of the view that the LAD allocation proposed by ECHA is appropriate.²

ECHA made the final LAD allocation using all available relevant information including that received in the consultation.

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

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 dicyclohexyl phthalate.

During the consultation ECHA received a comment requesting an upfront review period due to lack of alternatives for all uses of the substance. However, the provided information is not considered adequate as basis for a decision on review periods.

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

During the consultation ECHA received a request for exemption which, however, did not refer to any legislation that could constitute the basis for an exemption.

In its opinion MSC expresses the view that no information was submitted that would warrant the inclusion of a specific exemption for a use or a category of uses.

ECHA therefore **does not recommend exemptions** for uses of dicyclohexyl 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 dicyclohexyl 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 have been submitted by the end of the consultation.

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

4. References

Annex XV SVHC report (2016): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Dicyclohexyl phthalate (DCHP). Submitted by Sweden in cooperation with Denmark, February 2016.

<https://www.echa.europa.eu/documents/10162/0f8a6fd1-835f-4686-8cca-bcbbdc137b73>

ComRef (2021): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include dicyclohexyl phthalate in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_comref_dchp_en.rtf

ECHA (2020): Dicyclohexyl phthalate (DCHP). ECHA's dissemination website on registered substances. Accessed on 5 June 2020.

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

RCOM (2016): "Responses to comments" document. Document compiled by Sweden from the commenting period 29/02/2016 – 14/04/2016 on the proposal to identify dicyclohexyl phthalate (DCHP) as a Substance of Very High Concern.

<https://www.echa.europa.eu/documents/10162/7c084e67-f635-4cc2-b6dd-d5f7fa2f9bf7>

RCOM (2021): "Responses to comments" document. Document compiling the responses to comments from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include dicyclohexyl phthalate in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_dchp_en.pdf

Annex I: Further information on uses

1. Further details on some type of applications

According to comments received 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/y.

Comment received during the consultation on the draft recommendation mentioned uses of the substance in a glue for electronics components manufacturing, in semiconductor packaging material or industrial adhesives used in automotive products (ComRef, 2021).

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.

Dicyclohexyl phthalate is manufactured and/or imported by a limited number of registrants. No precise and up-to-date information is available on the number of industrial sites where the substance is currently used.

The supply chain can be characterised⁸ 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: F, IS, PW, SLs (multi-layer)).

Dicyclohexyl phthalate 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 is relying 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).

Uses of dicyclohexyl phthalate in the scope of authorisation seem to be relevant for the production of a number of article types such as plastic or rubber articles, fabrics, textiles and apparel, vehicles as well as machinery, mechanical appliances and electrical/electronic articles (relevant article categories: AC1, AC2, AC5, AC10, AC13).

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers, substance in article notification and comments received in the consultation on the SVHC identification (RCOM, 2016) as well as on the draft recommendation (ComRef, 2021).

⁸ Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description:

https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf