5 March 2020

Draft 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) on the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 5 June 2020) 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: 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 authorisation[2]. 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.

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)[3].

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

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, 2019) in the range of 1,000 - 10,000 t/y. All tonnage appears to be in the scope of authorisation.

[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/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf
[3] Commission Implementing Decision (EU) 2018/636 at https://www.echa.europa.eu/documents/10162/8c434af5-cfbe-c87e-aa51-65893e385d1f

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 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).

The use of plastisol and of organic peroxide formulations 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).

Furthermore, according to registration data and substance in article notification, the substance is used in articles (e.g. 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. There are indications on the potential for using the substances in the same type of applications (e.g. plasticiser in polymers).

2.5. Conclusion

Verbal descriptions and scores			Total score	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + 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 1,000 – 10,000 t/y. Score: 12	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 and may be used by consumers. Refined score: 12	31	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, it is proposed to prioritise dicyclohexyl phthalate for inclusion in Annex XIV.

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 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 10th 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 dicyclohexyl 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.

[4] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf
[5] 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

3.3. 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 dicyclohexyl 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/10162/13640/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[7] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/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 dicyclohexyl 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 dicyclohexyl phthalate[8].

[8] As of 15 September 2019

4. References

Annex XV SVHC report (2016): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Dicyclohexyl phthalate (DCHP). Submitted by Sweden in cooperation with Denmark, March 2016.

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

ECHA (2019): Dicyclohexyl phthalate (DCHP). ECHA's dissemination website on registered substances. Accessed on 15 September 2019.

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

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.

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 characterised[9] 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 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 registrations but could be derived from information on uses available in registration dossiers and comments received in the consultation on the SVHC identification (RCOM, 2016).

[9] 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