5 September 2018

Draft background document for 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene[1] ("Dechlorane Plus"™)

Document developed in the context of ECHA's ninth 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 public 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.

1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus"™) is a group entry covering for example the product with the trade name "Dechlorane Plus". Only for the purpose of easier reading, **Dechlorane Plus** is used throughout this document when referring to 1,6,7,8,9,14,15,16,17,17,18,18-dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus"™).

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of Dechlorane Plus on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

[1] Covering any of its individual anti- and syn-isomers or any combination thereof

1. Identity of the substance

Identity of the substance as provided in the Candidate List[2]:

Name: 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus"™)
EC Number: -
CAS Number: -

The supporting documentation for the identification of the substance as SVHC contains a non-exhaustive list of substances that are covered by this group entry[3].

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[4]. Results of the prioritisation of all substances included in the Candidate List by January 2018 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

2.1. Intrinsic properties

1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus"™) was identified as a Substance of Very High Concern (SVHC) according to Article 57(e) as it meets the criteria of a vPvB substance and was therefore included in the Candidate List for authorisation on 15 January 2018, following ECHA's decision ED/01/2018.

2.2. Volume used in the scope of authorisation

The amount of Dechlorane Plus manufactured and/or imported into the EU is according to registration data (ECHA, 2018) in the tonnage band of 100 - 1,000 t/y. All tonnage appears to be in the scope of authorisation. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 100 - 1,000 t/y.

2.3. Wide-dispersiveness of uses

According to the registration information, Dechlorane Plus is used at industrial sites as a flame retardant in adhesives/sealants and polymers (ECHA, 2018).

Furthermore, the substance is used in articles in volumes >10 t/y, e.g. computers, electronics, vehicle textiles (Annex XV SVHC report, 2017).

More detailed information on uses is provided in Annex I.

[2] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[3] https://echa.europa.eu/documents/10162/9aa77dde-f0fc-4422-2c00-55b620e57552
[4] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.4. Further considerations for priority setting

According to the information in the Annex XV SVHC report, Dechlorane Plus is a potential substitute for DecaBDE which is restricted (entry no. 67 of REACH Annex XVII) and listed as POP under the Stockholm Convention.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Dechlorane Plus is identified as vPvB meeting the criteria of Article 57 (e) Score: 13	The amount of Dechlorane Plus used in the scope of authorisation is in the range of 100 - 1,000 t/y Score: 9	Dechlorane Plus is used at industrial sites. Initial score: 5 Furthermore, the substance is used in articles in volumes >10 t/y. Refined score: 7	29

Conclusion

On the basis of the prioritisation criteria, Dechlorane Plus receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise Dechlorane Plus 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 public consultation. ECHA will apply the Annex XIV entries approach[5] and the criteria described in the implementation document[6]. 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.

[5] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

[6] Practical implementation document can be accessed at https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

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 9th 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 Dechlorane Plus.

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.

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 Dechlorane Plus 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[7]. 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[8], there is no need to propose an additional specific exemption.

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 Dechlorane Plus 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 Dechlorane Plus[9].

[7] 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/b80fccc0-c055-7cd7-4743-8d3c26956b15, or in section C.2 in https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

[8] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

[9] As of 1 February 2018.

4. References

Annex XV SVHC report (2017): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octa-deca-7,15-diene ("Dechlorane Plus"). Submitted by United Kingdom, August 2017.

https://echa.europa.eu/documents/10162/2b729df8-a54f-1485-f77b-185457d96fbd

ECHA (2018): 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octa-deca-7,15-diene ("Dechlorane Plus"). ECHA's dissemination website on registered substances. Accessed on 18 February 2018.

https://echa.europa.eu/registration-dossier/-/registered-dossier/11906/3/1/7

RCOM (2017): "*Responses to comments*" document. Document compiled by the United Kingdom from the commenting period 05/09/2017 - 20/10/2017 on the proposal to identify 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo [12.2.1.1^{6,9}.0^{2,13}.0^{5,10}] octa-deca-7,15-diene ("Dechlorane Plus") as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/abca40a2-428f-603d-59f7-140218822afd

Annex I: Further information on uses

1. Main (sector of) uses and market trend

Dechlorane Plus is used as a non-plasticizing, chlorinated flame retardant in polymers and sealants/adhesives (ECHA, 2018). The Annex XV SVHC report (2017) states that the substance is an additive chlorinated flame retardant, introduced in the 1960s as a substitute to Dechlorane ("Mirex").

The world market of Dechlorane Plus is presumed to be mature (Annex XV SVHC report, 2017). Currently, there is one active registration. Monitoring information shows that Dechlorane Plus is found both, in remote areas (e.g. arctic) and in high concentrations in house dust, WWTP effluent and similar (Annex XV SVHC report, 2017), indicating the use of the substance in articles with potential for releases.

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 public consultation, to allocate Dechlorane Plus to a specific LAD slot in the final recommendation.

The substance is manufactured/imported by a limited number of registrants. The Annex XV SVHC report (2017) suggests that the supply chain might be relatively short, with direct supply by the current registrant to formulators and industrial users. No more 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[10] by the following actors: formulators, user at industrial sites, articles assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, SLs).

The substance seems to be formulated in adhesives, sealants, polymer preparations and compounds, and semiconductors (relevant Product Categories: PC1, PC32 and PC33).

Sectors relying on the substance for some of their uses include formulation of preparations and/or re-packaging, plastics products, computer, electronic and optical products, electrical equipment (relevant Sectors of Use: SU10, SU12 and SU16).

The substance ends up in diverse article types such as vehicles, machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators, fabrics, textiles and apparel, and plastic articles (relevant Article Categories: AC1, AC2, AC3, AC5 and AC13). There are indications, that Dechlorane Plus is also used in aircraft components (e.g. adhesives, syntactic foams and potting compounds).

Some of the categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from information on uses available in registration dossiers, the Annex XV SVHC report (2017) and the RCOM (2017).

[10] 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