

1 October 2019

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-diene¹ ("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-diene¹ ("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 dossiers², as well as the MSC opinion³ were taken into consideration when finalising the recommendation and are reflected in the present document.

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

² As of the last day of the public consultation, i.e. 5 December 2018

³ Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

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1. Identity of the substance

Identity of the substance as provided in the Candidate List⁴:

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-diene¹ ("Dechlorane Plus"TM)
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 entry⁵.

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 authorisation⁶. 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 are available at

https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

The prioritisation results of the substances included in the draft 9th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft9threc_substances_October2019_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-diene¹ ("Dechlorane Plus"TM) 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 to 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.

More detailed information is provided in Annex I.

⁴ For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

⁵ <https://echa.europa.eu/documents/10162/9aa77dde-f0fc-4422-2c00-55b620e57552>

⁶ Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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), automobiles, aerospace and defence engines (ComRef, 2019).

More detailed information on uses is provided in Annex I.

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 (EC 214-604-9) which is restricted (entry no. 67 of REACH Annex XVII) and listed as POP under the Stockholm Convention.

Recently Norway has submitted a proposal to include Dechlorane Plus as POP under the Stockholm Convention. The decision to include Dechlorane Plus into Annex XIV may be impacted depending on the further developments.

2.5. Conclusion

Inherent properties (IP)	Verbal descriptions and scores		Total score (= IP + V + WDU)
	Volume (V)	Wide dispersiveness of uses (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, Dechlorane Plus 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 XIV⁷ and as further specified

⁷ General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

in the practical implementation document⁸. The draft Annex XIV entries for all the substances that underwent public consultation are available at https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf.

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for Dechlorane Plus:

Latest application date (LAD):	Date of inclusion in Annex XIV plus 21 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.

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

During the public consultation, comments were received arguing for the need to have long review periods for the uses of Dechlorane Plus in cables for automobile and aerospace applications, as these are essential for safety reasons, until alternatives would be available. However, the setting of upfront review periods requires detailed use-specific information which should be provided in applications for authorisation. Furthermore, all authorisation decisions include review periods that are set case-by-case for each use applied for (see also RCOM, 2019).

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of Dechlorane Plus.

⁸ Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

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 (categories of) uses of Dechlorane Plus on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation ECHA received some requests for exemptions for the use of Dechlorane Plus as flame retardant in aerospace and automotive industry sectors. Those were referring to other existing Community legislation, e.g. to Regulation 748/2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations.

In its opinion MSC expresses the view that there appears to be no grounds for an exemption under Article 58(2).

ECHA has carefully assessed all the requests made (see detailed assessment in Section C, in particular C.2, of the response document (RCOM, 2019)). ECHA concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of Dechlorane Plus, and therefore does not 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.

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 Dechlorane Plus for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of public consultation.

ECHA therefore does not recommend exempting any use of Dechlorane Plus for PPORD from authorisation.

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-185457d96fdb>
- ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include Dechlorane Plus in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_dechlorane_pl_us_en.rtf
- 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 5 December 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>
- RCOM (2019): "Responses to comments" document. Document compiling the responses to comments by ECHA from the commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include 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") in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).
https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_dechlorane_pl_us_en.pdf

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 relatively stable (Annex XV SVHC report, 2017). Currently, there is one active registration. Monitoring information shows that Dechlorane Plus is found in remote areas (e.g. arctic) as well as in high concentrations in house dust, WWTP effluent and similar (Annex XV SVHC report, 2017; ComRef, 2019), indicating the use of the substance in articles with potential for releases.

2. Structure and complexity of supply chains

The following assumptions were made to allocate the substance to a specific LAD slot.

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 characterised⁹ 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 plastics products, computer, electronic and optical products, electrical equipment and general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (relevant Sectors of Use: SU12, SU16 and SU17).

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), the RCOM (2017) and ComRef (2019).

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