

AGREEMENT OF THE MEMBER STATE COMMITTEE ON THE IDENTIFICATION OF

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" TM) [covering any of its individual anti- and synisomers or any combination thereof] AS A SUBSTANCE OF VERY HIGH CONCERN According to Articles 57 and 59 of Regulation (EC) 1907/2006¹

Adopted on 30 November 2017

This agreement concerns

Substance names: 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" TM) [covering any of its individual anti- and syn-isomers or any combination thereof]

EC numbers: 236-948-9; -; -

CAS numbers: 13560-89-9; 135821-74-8; 135821-03-3

Molecular formula: C₁₈H₁₂Cl₁₂



anti- (or exo) Dechlorane Plus [2]

syn- (or endo) Dechlorane Plus [3]

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

United Kingdom presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (28 August 2017, submission number SPS-013527-17) on identification of 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"TM) [covering any of its individual anti- and syn-isomers or any combination thereof] as a substance of very high concern due to its very persistent and very bioaccumulative properties.

The Annex XV dossier was circulated to Member States on 5 September 2017 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 20 November 2017 and agreed in the written procedure of the Member State Committee with closing date of 30 November 2017.

Agreement of the Member State Committee in accordance with Article 59(8):

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"TM) [covering any of its individual anti- and syn-isomers or any combination thereof] is identified as a substance of very high concern because it meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative (vPvB), in accordance with the criteria and provisions set out in Annex XIII of REACH Regulation.

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Persistence

Based on the weight of evidence of the data available, it is concluded that Dechlorane Plus meets the criteria for vP in Annex XIII of REACH. This is based on:

• modelling of degradation potential and microbial metabolic pathways which suggests that biodegradation is likely to be very slow; and

• a low probability that it will degrade any faster than structural analogues that are considered to be very persistent under the Stockholm Convention.

This conclusion is also supported by the very low water solubility (suggesting limited bioavailability to micro-organisms once bound to solid matrices), monitoring data indicating that the substance can persist in sediments (a major sink) for many years, lack of evidence of biotransformation in fish (supporting the premise that the molecule is metabolically recalcitrant) and widespread occurrence in remote regions.

Bioaccumulation

Using a weight of evidence assessment of the data available, Dechlorane Plus meets the vB criteria in Annex XIII of REACH. This is based on:

- the long-depuration half-life determined in fish feeding studies which is indicative of a BCF above 5 000 L/kg, by comparison with other substances (supported by a long depuration half-life in mammalian liver);
- numerous studies that show that the substance is widely dispersed in freshwater, marine and terrestrial food chains, including top predators; and
- evidence that the substance can exceed levels in biota that are of concern based on critical body burden considerations related to baseline narcosis.

This conclusion is supported by the detection of the substance in human blood, placenta and breast milk.

Toxicity

Based on the available ecotoxicity and mammalian data, Dechlorane Plus does not currently meet the T criterion. Long-term toxicity studies using relevant life stages of fish (via diet), sediment or soil organisms, and/or birds could be performed to clarify whether adverse effects can occur via these exposure routes. However, as the substance meets both the vP and vB criteria, these are not scientifically necessary for environmental risk management purposes.

Other concerns

The substances 1,3- and 1,5-Dechlorane Plus monoadduct (DPMA) have been detected in the environment, sometimes at higher concentrations than Dechlorane Plus in the same samples. DPMA might be under-reported because destructive sample preparation methods may degrade it. Dechlorane Plus is the only likely source of these two substances, although there is no information on reaction rates or amounts that can be formed under relevant environmental conditions. Based on predictive models, DPMA screens as being potentially PBT and vPvB on the basis of QSAR (although some of the predictions are uncertain). No information is available on its mammalian toxicity, but due to structural similarities to aldrin or heptachlor it might be epoxidised in the environment to form a substance that could be neurotoxic and/or cause hepatotoxicity. Experimental data would be needed to confirm these properties. However, as a degradation product of Dechlorane Plus, any concerns about DPMA would be alleviated by the identification of Dechlorane Plus as a substance of very high concern.

Conclusion

In conclusion, Dechlorane Plus meets the criteria for a vPvB substance according to Article 57 (e) of REACH Regulation based on a weight-of-evidence determination, by comparing all relevant and available information listed in Annex XIII of REACH Regulation with the criteria set out in the same Annex.

Reference:

Support Document (Member State Committee, 30 November 2017)