

**AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF**

Medium-chain chlorinated paraffins (MCCP)¹

AS SUBSTANCES OF VERY HIGH CONCERN

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006²**

Adopted on 15 June 2021

This agreement concerns

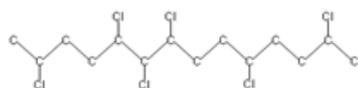
Substance name: Medium-chain chlorinated paraffins (MCCP)³

EC number: -

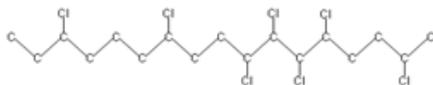
CAS number: -

Molecular formula: Approx within the range $C_xH_{(2x-y+2)}Cl_y$, where $x = 14 - 17$ and $y = 1 - 17$

Structural formula: Example structures (hydrogen atoms removed for simplicity) include:



$C_{14}H_{24}Cl_6$



$C_{17}H_{29}Cl_7$

¹Medium-chain chlorinated paraffins [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C_{14} to C_{17}]

²Regulation (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 (EEC) 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

³ Medium-chain chlorinated paraffins [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C_{14} to C_{17}]

ECHA presented a proposal in accordance with Article 59(2) and Annex XV of the REACH Regulation (2 March 2021) on identification of *Medium-chain Chlorinated Paraffins (MCCP)* as substances of very high concern due to their persistent, bioaccumulative and toxic (**PBT**) and very persistent and very bioaccumulative (**vPvB**) properties.

The Annex XV dossier was circulated to Member States on 10 March 2021 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(2) 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 24 May 2021 and discussed in the meeting on 14-17 June 2021 of the Member State Committee.

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

***Medium-chain Chlorinated Paraffins (MCCP)* are identified as substances meeting the criteria of Article 57 (d) and (e) of Regulation (EC) 1907/2006 (REACH) as substances, which are:**

- **persistent, bioaccumulative and toxic (PBT), and**
- **very persistent and very bioaccumulative (vPvB)**

both in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN

Medium-chain chlorinated paraffins (**MCCP**) are identified as substances of very high concern in accordance with Article 57(d) and (e) of Regulation (EC) 1907/2006 (REACH) because of their persistent, bioaccumulative and toxic (**PBT**) and very persistent and very bioaccumulative (**vPvB**) properties.

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used in order to conclude on the PBT/vPvB properties of MCCP at the level of the investigated congener groups (C₁₄₋₁₇Cl₁₋₍₁₄₋₁₇₎). All information (such as the results of standard tests, monitoring and modelling, information from the application of a trend analysis with respect to persistence among the MCCP congener groups of different carbon chain lengths and different levels of chlorination and (Quantitative) Structure Activity Relationship (**(Q)SAR**) results) was considered together in a weight-of-evidence approach. All studies used have been assessed as reliable (with or without restrictions), relevant and adequate for the assessment, unless otherwise stated and specified in this document.

Persistence

The assessment and the conclusions on persistence are based on the following information:

- An OECD Test Guideline (**TG**) 308 study performed on C₁₄ chlorinated n-alkane, 50% Chlorine content by weight (**Cl. wt.**) indicates that the total water-sediment **DT₅₀** (time to reach 50% disappearance/dissipation) values for the C₁₄Cl₃₋₁₄ congener groups of MCCP (equivalent to 35.32–72.98% Cl wt.) are greater than 120 days at 12°C (under aerobic conditions). The fact that there was no significant measurable degradation over 120 days suggests that it is unlikely that ≥50% mineralisation or primary degradation would occur over a subsequent 60-day period. Therefore, based on this study, it can be reasonably assumed that the C₁₄Cl₃₋₁₄ groups of congeners are very persistent in sediment (degradation half-lives >180 days). The outcome of this higher tier study is given a high weight as it provides information directly comparable with the **P** (persistent) and **vP** (very persistent) criteria set out in Annex XIII, points 1.1.1 (d) and 1.2.1 (b) of the REACH Regulation;
- Based on modelling data, almost all of the congener groups of MCCP (C₁₄₋₁₇ congener groups with three or more chlorine substituents at the carbon chain) are predicted to be not readily biodegradable and hence potentially persistent. No experimental degradation data for specific

C₁₅, C₁₆ or C₁₇ chloroalkane substances and their congener groups is available while they are expected to be less water soluble and more adsorptive than the C₁₄ substances. Based on the predicted and observed trends in physico-chemical properties of structures of the different MCCP congeners, which are in line with the general scientific knowledge on the expected partitioning behaviour and environmental fate of hydrophobic aliphatic chloroalkanes, it can be reasonably estimated that the C₁₅₋₁₇ congeners with the same or higher chlorine contents than the congeners of C₁₄ chlorinated n-alkane, 50% Cl. wt. (which contains C₁₄Cl₃₋₁₄ congeners that all are P/vP) will be equally or more adsorptive to sediment, have lower water solubilities and partition stronger to octanol. They therefore will at least be equally if not more persistent in sediments;

- Several ready biodegradation screening studies under conditions of enhanced bioavailability have been performed with commercial MCCP product types. Based on the results of the screening tests, it seems that the overall level of degradation appears to decline with increasing levels of chlorination and that the substances tested contain potentially persistent congeners. However, these screening studies are not considered appropriate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents, as without further supplementary information enabling the possibility for the dossier submitter to verify the claims made with regard to the composition of the test substance, i.e. the identity of the individual congener groups and their concentration in the substance as well as on the degree of degradation of the individual congener groups in a test, it is not possible to draw conclusions on the persistence of the constituents of MCCP. Therefore, the outcomes of the screening tests for MCCP have been assigned low weight in the Weight of Evidence (**WoE**);

- Hydrolysis of MCCP is expected to be negligible in the environment. Photodegradation in air for MCCP congeners is unlikely to be a significant degradation pathway in the environment (estimated atmospheric half-lives in the range of 0.6–7.1 days for some of the MCCP congener groups). As a conclusion, abiotic degradation of MCCP and MCCP congeners is not considered to be a significant degradation pathway in the environment;

- Monitoring data support findings from experimental and predicted data on biodegradation and abiotic degradation of MCCP congeners and MCCP. The available monitoring data, particularly from sediment core studies, suggest some dechlorination of chlorinated paraffins with high chlorine contents in sediment over time, but they also suggest that degradation in the environment may be slow and provide indirect evidence that MCCP with chlorine contents of ~ 55% by weight can persist in sediments for more than a decade. The detection and/or quantification of MCCP in marine sediments from the Arctic, in locations far away from point sources, point towards persistence of MCCP in marine sediments under aerobic conditions.

As an overall conclusion, based on the above information used in a weight-of-evidence-approach, it is concluded that the C₁₄Cl₃₋₁₄ congener groups of MCCP (equivalent to 35.32–72.98% Cl wt.) meet the P criterion and the vP criterion in accordance with Annex XIII, points 1.1.1 and 1.2.1, of the REACH Regulation on the basis of their P and vP properties in sediment (degradation half-lives > 180 days).

Based on the predicted and observed trends in physico-chemical properties it further can be reasonably estimated that also the C₁₅₋₁₇ congener groups of MCCP with the same or higher chlorine contents than the congeners present in C₁₄ chlorinated n-alkane, 50% Cl. wt. (which contains C₁₄Cl₃₋₁₄ congener groups that all are P/vP) will at least be equally if not more persistent in sediment than the congeners of C₁₄ chlorinated n-alkane, 50% Cl. wt. Consequently, it is concluded that also the C₁₅Cl₃₋₁₅, C₁₆Cl₃₋₁₆ and C₁₇Cl₃₋₁₇ congener groups of MCCP meet the P and vP criteria of REACH Annex XIII (degradation half-life in sediment > 180 days).

Finally, since MCCP always will contain congener groups with P/vP properties at a concentration ≥ 0.1 % (w/w), it is concluded that MCCP meet both the P and vP criteria of REACH Annex XIII (degradation half-life in sediment > 180 days).

Monitoring data on MCCP support the above conclusions as they point towards persistence of MCCP in sediments.

Bioaccumulation

The assessment and conclusions on bioaccumulation are based on the following information. The results of the studies having been given a high weight in the WoE are considered to provide sufficient evidence to conclude the congener groups present in the MCCP test material used in these studies as meeting the bioaccumulation (**B**) criterion of Annex XIII of REACH and/or the very bioaccumulative (**vB**) criterion. The results of the other experimental studies and the QSAR predictions are used as supplementary supporting information to conclude in the WoE approach applied.

- An OECD TG 305 study (dietary exposure) performed on C₁₄ chlorinated n-alkane, 50% Cl. wt. indicates a high bioaccumulation potential with lipid-normalised kinetic fish bioconcentration factor (**BCF**) values > 5000 for C₁₄Cl₅₋₁₁ (based on the less conservative scenario with k₉=0, see further information in Table 40 of the Support Document). This study is given a high weight and its results are used to conclude that the C₁₄Cl₅₋₁₁ congener groups have B/vB properties;

- An OECD TG 305 study (aqueous exposure) performed on C₁₄ chlorinated n-alkane, 45% Cl wt. (which contains C₁₄Cl₃₋₆ congener groups) indicates a high bioaccumulation potential with a lipid-normalised and growth-corrected kinetic fish BCF value of ca. 11 530 L/kg. This study is given a high weight and its results are used to conclude that the C₁₄Cl₃₋₆ congener groups have B/vB properties;
- An OECD TG 305 study (aqueous exposure) performed on C₁₅ chlorinated n-alkane, 51% Cl wt. (which contains C₁₅Cl₅₋₈ congener groups) indicates a bioaccumulation potential with a growth-corrected kinetic fish aquatic BCF of around 1 833 – 2 072 L/kg. The growth corrected depuration half-lives are between 28 to 36 days. The results of this study are used as part of the weight-of-evidence to conclude that the C₁₅Cl₅₋₈ congener groups have B and/or vB properties;
- Toxicokinetic data on mammals using radiolabelled MCCP indicate that absorption following oral exposure is significant. MCCP have been demonstrated to have relatively long elimination or depuration half-lives in fish and mammals (growth corrected depuration half-lives in the range of 29–80 days in rainbow trout and half-life up to 8 weeks in abdominal fat of rats). These long elimination half-lives mean that significant concentrations of the substance may remain within an organism for several months, possibly years, after cessation of emission. Based on the outcome of dietary accumulation studies equivalent to OECD TG 305, experimental depuration rate constants for MCCP congeners were used in order to predict BCF values based on the work by Brooke and Crookes, which suggests that a depuration rate constant around 0.178 day⁻¹ or less, and around 0.085 day⁻¹ or less, would indicate a BCF above 2 000 and 5 000 L/kg, respectively. All of the tested substances would therefore be expected to have a BCF above 5 000 L/kg as growth-corrected depuration rate constants between 0.009–0.024 day⁻¹ were found for C₁₄H₂₆Cl₄, C₁₄H₂₅Cl₅, C₁₄H₂₄Cl₆, C₁₄H_{23.3}Cl_{6.7} (with C₁₄Cl₅₋₈), C₁₆H₃₁Cl₃ (with C₁₆Cl₂₋₅) and C₁₆H₂₁Cl₁₃ (with C₁₆Cl₁₂₋₁₅) congener groups. The results of these studies are used as part of the weight-of-evidence to conclude that the C₁₄Cl₄₋₈ and C₁₆Cl₂₋₅ congener groups have B/vB properties. For the remaining groups of congeners (C₁₆H₂₁Cl₁₃ with C₁₆Cl₁₂₋₁₅ as chlorination range) present in the tested substances, it is not possible to conclude on their potential for bioaccumulation since insufficient data is available;
- A bioaccumulation study (aqueous and dietary exposure) on *Daphnia magna* indicates a high bioaccumulation potential with lipid-normalised steady-state BCF of 10 000 000 L/kg lipid and steady-state wet weight BCF of ca. 50 119 L/kg ww for a C₁₃-C₁₈ 45% Cl wt. product (Cereclor S45; which contains C₁₄Cl₄₋₉, C₁₅Cl₃₋₉, C₁₆Cl₂₋₈ and C₁₇Cl₂₋₉ congener groups (including congeners found in *Daphnia* upon exposure even if not detected in the original substance tested)). The outcome of this study is used as part of the weight-of-evidence to conclude that the C₁₄Cl₄₋₉, C₁₅Cl₃₋₉, C₁₆Cl₂₋₈ and C₁₇Cl₅₋₉ congener groups have B and/or vB properties. For the

remaining groups of congeners (C₁₇Cl₂₋₄) present in the test substance, it is not possible to conclude on their potential for bioaccumulation since insufficient data is available;

- A bioaccumulation study (aqueous and dietary exposure) on *Mytilus edulis* indicates a high bioaccumulation potential with lipid-normalised BAF value of 7 031 L/kg (steady-state value) and 7 204 L/kg (statistically determined) with confidence limits of 4 694–9 723 L/kg for C₁₆H_{30.7}Cl_{3.3} (34.1% Cl wt.; which contains C₁₆Cl₂₋₅). The results of this study are used as part of the weight-of-evidence to conclude that the C₁₆Cl₂₋₅ congener groups have B/vB properties;

- As part of an earthworm toxicity study, uptake of C₁₅ chlorinated n-alkane, 51% Cl wt. by earthworms (*Eisenia fetida*) from soil was measured. Based on this study, earthworm-soil accumulation factors (BAFs) of 2.4 for adults and 2.3 for juveniles were determined for C₁₅ chlorinated n-alkane, 51% Cl wt. (which contains C₁₅ Cl₅₋₈ congener groups). The outcome of this study suggests that these group of congeners have B properties in earthworms. The results of this study are used as part of the weight-of-evidence to conclude that the C₁₅ Cl₅₋₈ congener groups have B and/or vB properties;

- A biomagnification study indicates a high bioaccumulation potential with lipid normalised BMFs >1 in the muscles and livers of a snake-frog predator-prey relationship for the congener groups C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₁₁, C₁₆Cl₃₋₁₀ and C₁₇Cl₅₋₁₀. The results of this study are used as part of the weight-of-evidence to conclude that the C₁₄Cl₃₋₁₁, C₁₅Cl₃₋₉, C₁₆Cl₃₋₈ and C₁₇Cl₅₋₈ congener groups have B and/or vB properties. For other group of congeners (C₁₅Cl₁₀₋₁₁, C₁₆Cl₉₋₁₀ and C₁₇Cl₉₋₁₀), it is not possible to conclude on their potential for bioaccumulation since insufficient data is available;

- Modelling data are used as supporting information to the experimental data in the bioaccumulation assessment. The BCF Baseline model of CATALOGIC yields BCF predictions for C₁₄Cl₂₋₁₁, C₁₅Cl₃₋₁₀ and C₁₆Cl₅₋₁₀ congener groups which are over the threshold of log BCF 3.3 (BCF ~ 2000 L/kg) and/or log BCF 3.69 (BCF ~ 5000 L/kg) and therefore indicating bioaccumulation potential. Furthermore, all groups of congeners of MCCP meet the screening criterion set out in the PBT Guidance (REACH Chapter R.11; ECHA, 2017b) for aquatic organisms as being potentially B and/or vB) with a range of log Kow > 4.5.

- The available (limited) field bioaccumulation studies for MCCP are equivocal: trophic magnification factors below and above 1 have been derived.

- Monitoring data support findings from experimental and predicted data on bioaccumulation of MCCP congeners and MCCP. MCCP have been detected in human blood and milk samples which indicates that MCCP are absorbed to some extent in humans. Detection of MCCP in umbilical cord blood and placenta indicates that MCCP can be transferred to the foetus. Furthermore, monitoring data demonstrate widespread contamination of wildlife by MCCP at all trophic levels (including predatory species). MCCP have also been detected in samples from

remote regions, including the Arctic. These data provide supporting evidence that MCCP are taken up by organisms in the environment.

Based on the weight of evidence of the data available, it can be concluded that the C₁₄Cl_{3–11} congener groups of MCCP (equivalent to 35.3–67.6% Cl wt.) have B/vB properties, C₁₅Cl_{3–9} congener groups of MCCP (equivalent to 33.8–61.15% Cl wt.) have B and/or vB properties, C₁₆Cl_{2–9} congener groups of MCCP (equivalent to 24.1–59.55% Cl wt.) have B and/or vB properties and C₁₇Cl_{5–9} congener groups of MCCP (equivalent to 43–58% Cl wt.) have B properties in accordance with REACH Annex XIII. For other congener groups of MCCP, it is not possible to conclude on their potential for bioaccumulation due to the lack of appropriate data.

Based on the information available, as MCCP contain congener groups with B and/or vB properties at a concentration ≥ 0.1 % (w/w), it is concluded that MCCP meet the B and vB criterion in accordance with Annex XIII, points 1.1.2 and 1.2.2, of the REACH Regulation.

Monitoring data on MCCP support the above conclusion as they point towards bioaccumulation of MCCP in biota.

Toxicity

Only limited experimental information is available on the aquatic toxicity of individual MCCP congeners. The majority of the ecotoxicity data is available for the commercial C_{14–17}, 52% Cl wt. substance.

48h EC₅₀ results from acute *Daphnia magna* studies fall in the range $< 6.5 - 2200$ µg/L. The most reliable result is 48h EC₅₀ 5.9 µg/L for the C_{14–17}, 52% Cl wt. substance. According to the PBT guidance (REACH Chapter R.11, ECHA, 2017b), a short-term aquatic toxicity result in fish, daphnia, or algae with EC₅₀ or LC₅₀ < 0.01 mg/L (≈ 10 µg/L) is sufficient to meet the toxic (T) criterion. Based on this guidance, the T criterion is met.

For the chronic toxicity of MCCP to *Daphnia magna*, 21d NOEC (reproduction) values range from $\sim 4 - 15.6$ µg/L. The most reliable result is 21d NOEC 8.7 µg/L for the C_{14–17}, 52% Cl wt. substance which meets the T criterion in accordance with Annex XIII, point 1.1.3 (a), of the REACH Regulation.

For a UVCB substance like MCCP, observed toxicity may represent toxicity of one or more of its constituents. As the testing material of the acute and chronic toxicity studies available for MCCP contained several groups of congeners of MCCP and no testing and analysis was performed at the level of the congener groups, it is not possible to identify whether the congener groups present in the tested substance contributed differently to the observed toxicity.

However, the congener groups expected to be present in the test material for both these tests are C₁₄ congener groups having 4, 5, 6 and 7 chlorine atoms; C₁₅₋₁₆ congener groups having 5, 6, 7 and 8 chlorine atoms and C₁₇ congener groups having 6, 7, 8 and 9 chlorine atoms. These same congener groups have been detected in *Daphnia magna* in a bioaccumulation test reported in Section 3.4.2.3. This indicates that these congener groups are bioavailable to *Daphnia magna* and taken up by this organism. Since these congener groups are structurally very similar (they differ only in carbon chain length and number of chlorine substituents), they can be expected to exert toxic effects by the same mode(s) of action. It is therefore reasonable to assume that all congener groups present in the C₁₄₋₁₇, 52% Cl wt. test substance contributed equivalently to the observed toxicity.

It is therefore concluded that MCCP and all the following congener groups of MCCP meet the toxicity criterion (T) in accordance with Annex XIII, point 1.1.3 (a), of the REACH Regulation: C₁₄ congeners having 4, 5, 6 and 7 chlorine atoms; C₁₅ congeners having 5, 6, 7 and 8 chlorine atoms; C₁₆ congeners having 5, 6, 7 and 8 chlorine atoms and C₁₇ congeners having 6, 7, 8 and 9 chlorine atoms.

Conclusion on the P, B and T properties

On the basis of all the evidence available, it is concluded that the C₁₄Cl₃₋₁₁ congener groups of MCCP (equivalent to 35.3–67.6% Cl wt.) have PBT and/or vPvB properties, C₁₅Cl₃₋₈ congener groups of MCCP (equivalent to 33.8–58.2% Cl wt.) have PBT and/or vPvB properties, C₁₆Cl₃₋₈ congener groups of MCCP (equivalent to 32.3–56.6% Cl wt.) have PBT and/or vPvB properties and C₁₇Cl₆₋₉ congener groups of MCCP (equivalent to 47.65–58% Cl wt.) have PBT properties in accordance with Annex XIII of the REACH Regulation (see **Table 1**).

Based on the information available, as MCCP contain congener groups with PBT and/or vPvB properties (see **Table 1**) at a concentration ≥ 0.1 % (w/w), it is concluded that MCCP meet the criteria for a PBT and/or vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby they fulfil the criteria set out in REACH Articles 57(d) and/or (e).

*(Note - some of the PBT and/or vPvB congener groups of MCCP listed in **Table 1** have been identified in other substances than MCCP, thus suggesting that these substances also could be considered to meet the REACH Annex XIII criteria for a PBT and/or vPvB substance if these congener groups are present in a concentration ≥ 0.1 % (w/w)).*

Table 1: Congener groups of MCCP concluded as PBT and/or vPvB in accordance with the criteria set out in Annex XIII of the REACH Regulation

Number chlorine atoms and Carbon chain length	Cl ₁	Cl ₂	Cl ₃	Cl ₄	Cl ₅	Cl ₆	Cl ₇	Cl ₈	Cl ₉	Cl ₁₀	Cl ₁₁	Cl ₁₂	Cl ₁₃	Cl ₁₄	Cl ₁₅	Cl ₁₆	Cl ₁₇
C ₁₄	-	-	vPvB	vPvB PBT	vPvB PBT	vPvB PBT	vPvB PBT	vPvB	vPvB	vPvB	vPvB	-	-	-			
C ₁₅	-	-	vPvB	vPvB	vPvB PBT	PBT	PBT	PBT	-	-	-	-	-	-	-		
C ₁₆	-	-	vPvB	vPvB	vPvB PBT	PBT	PBT	PBT	-	-	-	-	-	-	-	-	
C ₁₇	-	-	-	-	-	PBT	PBT	PBT	PBT	-	-	-	-	-	-	-	-

Note: Symbol '-' means that not enough information is available to conclude whether the congener group has PBT and/or vPvB properties. Grey cells means congener groups not considered in the PBT/vPvB assessment.

Summary of other considerations

Based on their physical-chemical properties, some congeners of MCCP are predicted to have long-range environmental transport (estimated atmospheric half-lives in the range of 0.6–7.1 days for different MCCP congeners). Indeed, MCCP have similar physical-chemical properties to legacy persistent organic pollutants (**POPs**).

Monitoring data tend to confirm this prediction as it has been found that MCCP with C₁₄₋₁₅ and Cl₄₋₉ were found in biota from the Arctic and in air from the Antarctic. MCCP have been detected in various media in the Arctic, including in air from Svalbard, in marine sediments from the Barents Sea and the Norwegian Sea, in terrestrial, avian and marine biota samples from the Norwegian Arctic, including in top predators such as Polar Bears. MCCP were also found in air samples from the Antarctic and from the Tibetan Plateau at high altitude.

The presence of MCCP at sites remote from known point sources such as the Arctic and Antarctic therefore indicates long-range environmental transport.

Furthermore, monitoring data indicate that concentrations of MCCP have increased in biota, in sediment and in air (from the Arctic, the Tibetan Plateau and the Antarctic) during the last decades. In addition, in the Antarctic air, an increasing trend was observed in the ratio of MCCP to SCCP (short-chain chlorinated paraffins) suggesting that the use of MCCP as substitute to SCCP had increased. Due to the PBT/vPvB properties of MCCP, the increasing trend of the concentrations of MCCP in the environment gives reason for concern.

In conclusion, *Medium-chain Chlorinated Paraffins (MCCP)* meet the criteria for PBT and vPvB substances according to Article 57 (d) and (e) of REACH Regulation by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

References:

Support Document (Member State Committee, 15 June 2021)