COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

***Disclaimer**: Comments provided during the consultation are made available as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern. RCOM has not been agreed by the Member State Committee nor has the document been modified as result of the MSC discussions.*

Substance name: Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17]
CAS number: -
EC number: -

These substances are proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: PBT (Article 57d) vPvB (Article 57e)

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5474 2021/04/21	KÖMMERLING CHEMISCHE FABRIK GMBH, Company, Germany	 *Confidential attachment removed*	Thank you for the information submitted. Comments regarding use, exposure, alternatives, socio-economic impacts and risks, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance. As regards the initiative to submit the substance to the SVHC identification process in accordance with REACH Art. 59, please

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			note that the European Commission requested ECHA to prepare an Annex XV dossier for MCCP.
5533 2021/04/23	Altair Chimica S.p.A., Company, Italy	*Attachment*: 5533_Altair Chimica - Comments to SVHC proposal-23042021.pdf Attachment as a separate pdf file	Please refer to our responses to your comments in the Table 'Specific comments on the justification'.
5535 2021/04/23	Federchimica, Industry or trade association, Italy	We believe that, at a minimum, the SVHC proposal should consider a chlorination level cut-off and not add those substances which are biodegradable to the Candidate List. Based on the currently available data, this cut-off could be established at less of 50% Cl by weight, though additional study data will be forthcoming shortly that might warrant further consideration of the range of products in the 50-52% Cl range. Such a chlorination level cut-off is consistent not only with the database but also with prior and proposed actions on chlorinated paraffins under the Stockholm Convention. In the second place, it will be important to analyze every single use and to distinguish the uses with a relevant environmental impact from the other ones. Federchimica believes that more information have to be collected to decide on MCCP. We are awareness that the European producers are	Regarding your comment to set a chlorination level cut-off to the SVHC entry, such as e.g. less of 50% Cl by weight, ECHA does not agree with your proposal. ECHA has clearly demonstrated in the Annex XV report that based on the available information MCCP contain lower than 50% chlorinated congener groups with PBT and/or vPvB properties at a concentration ≥ 0.1 % (w/w) (please refer to the explanatory text above Table 52 in the Annex XV report). That is why 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). As regards your request to 'not add those substances which are biodegradable to the Candidate List' we assume that this is based on the outcomes of some of the OECD TG 301/302 type screening studies discussed in section '3.1.2.1.2 Screening tests' of the Annex XV report. ECHA has clearly explained why

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		performing other tests and so we think that it is important to wait the results of these to apply for a correct weight of evidence assessment. For more information refers to answer issued by MCCP REACH Consortium and PVC4Cables.	these screening studies cannot be considered appropriate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents. 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 the particular studies, it is not possible to draw conclusions on the persistence of the constituents of the substances tested, respectively MCCP. Furthermore, a reliable higher tier simulation study in sediments, modelling data and monitoring data further demonstrate that some congener groups of MCCP have P/vP properties. As 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 'persistence' (P) and 'very persistent' (vP) criteria of REACH Annex XIII (degradation half-life in sediment > 180 days). Regarding your comment on the need to analyse every single use and to distinguish the uses with a relevant environmental impact from the other ones, please note that the SVHC identification of substances is based on the hazard properties of the substances (not risk based). Regarding your comment on the need to collect more information on MCCP, ECHA is of the opinion that

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			enough information has been collected under the substance evaluation process in order to conclude on the PBT/vPvB properties of a considerable number of congener groups of MCCP (see Table 52 of the Annex XV report) so that regulatory action can be taken for MCCP. We acknowledge that for some of the congener groups of MCCP information is insufficient to conclude on their PBT/vPvB properties, however overall sufficient information is available to draw conclusions on the PBT/vPvB properties and to justify and launch regulatory action on MCCP. To our understanding and based on the comments received on MCCP, the 'other tests' you are referring to and that are ongoing is an OECD TG 314B study on MCCP at 52% Cl wt. (as referred to in the comments received from the MCCP REACH consortium). Concerning this new OECD TG 314B study, ECHA is of the opinion that the outcome of this study will not change the P conclusion for MCCP for the following reasons: according to REACH guidance Chapter R.7b, OECD TG 314B studies cannot be used on their own for PBT/vPvB assessment and may only be considered as a part of a weight-of-evidence approach. In particular, the half-lives determined from those tests are not suitable for comparison with the REACH Annex XIII criteria for persistence. These studies indeed do not employ relevant environmental conditions for assessing the persistence of the substance in the compartments relevant for the PBT/vPvB assessment, i.e.: natural surface water, sediment or soil. For the

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			PBT/vPvB assessment it has to be demonstrated that the substance will indeed not persist in any of the environmental compartments (in our case MCCP have been demonstrated to be persistent in the sediment compartment). Therefore, not only exposure to natural water from STP effluents but also other possibilities of exposure (including indirect exposure and redistribution between environmental compartments) need to be taken into account for the PBT/vPvB assessment. Furthermore, REACH guidance Chapter R.7b further mentions/recommends that the OECD TG 314 study does not give a direct measurement of degradation but rather removal of the test substance including both degradation and adsorption as characterised by a STP and it should not be used as a replacement for simulation tests for degradation in environmental compartments such as surface water, sediment or soil (i.e. OECD TG 309, 308 or 307 type studies).
5536 2021/04/23	MCCP REACH Consortium of the Chlorinated Paraffins Industry Association, Industry or trade association, United States of America	*Attachment*: 5536_MCCP REACH - SVHC Comments - Final 23-April-2021.pdf Attachment as a separate pdf file <u>Introduction</u> These are the comments of the MCCP REACH Consortium1 (the "Consortium") in response to	<u>Introduction</u>

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		the European Chemicals Agency's (ECHA) Annex XV Proposal for Identification of Substances of Very High Concern (SVHC or "Candidate List") on Medium-Chain Chlorinated Paraffin (MCCP), Alkanes, C14-17, chloro (EC 287-477-0) (the "SVHC proposal"). This SVHC proposal is the culmination of many years of testing and evaluation on MCCP by industry, government and academia. Whilst the Consortium appreciates the extensive work done by ECHA on this SVHC proposal at the behest of the European Commission (EC), and the opportunity to contribute, we urge EC, ECHA and the Member State Committee (MSC) to reconsider a number of aspects of this SVHC proposal prior to its finalisation and adoption. MCCP is a single substance as registered under REACH. Given that it is a complex substance with no identifiable individual constituents (i.e. a UVCB substance), it is defined by its manufacturing process including starting materials (C14-17 paraffins and chlorine (Cl)) and process steps (chlorination to a certain weight percent of chlorine in the overall substance). This substance has been assigned an EC number (287-477-0) and a CAS number (85535-85-9). For the purposes of the joint registration of MCCP, and since the existing EC and CAS numbers do not define the level of chlorination by weight in the substance, the	Thank you for your comment. See below our response to your comment under section '**1. The SVHC proposal lacks clear definitions the substance to be added to the Candidate List'.**

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		substance boundary composition definition includes a range of chlorination by weight from 40 to 63% Cl. In practice this means that there may be several different commercial products, varying by chlorine content only, sold under the MCCP substance registration. Conversely, MCCP is not a mixture or preparation of separately manufactured chloroalkane isomers or 'congeners.' ATTACHMENT COMMENTS ON PAGE 1, PARAGRAPH 2 The Consortium believes that ECHA is well aware of this, yet the SVHC proposal fails to clearly treat MCCP as a single substance. Further, the SVHC proposal has treated the grouping of constituents from chemical analyses (i.e congener groups) as if they are real and identifiable constituents of MCCP, which they are not.	ATTACHMENT COMMENTS ON PAGE 1, PARAGRAPH 2 The PBT/vPvB assessment must, according to Annex XIII to the REACH Regulation, take account of the PBT/vPvB properties of relevant constituents. Section R.11.4.1 of the PBT guidance sets out that constituents should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). As further explained in the guidance, this limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation. Additionally, the Judgments of the General Court in cases T-93/10, T-94/10, T-95/10 and T-96/10 confirmed the validity of this approach for PBT/vPvB constituents of a substance. Especially for very complex UVCBs it is possible that individual constituents are present in concentrations <0.1% (w/w) and that these have not been (or cannot be) characterised by chemical analysis individually. For UVCBs (such as MCCP) even the whole substance may consist of individual constituents only present in such low concentrations. The fact that all individual constituents of a UVCB-substance are present in concentration <0.1% (w/w)

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			does not exempt from the obligation to carry out the PBT/vPvB assessment. A close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be specifically addressed in the PBT/vPvB assessment. This approach, which is recommended and lined out in further detail in section R.11.4.2.2 of the PBT guidance, has been followed for the PBT assessment of MCCP (as has been already in previous PBT assessments, e.g. for SCCP (Alkanes C_{10}-C_{13}, chloro)). For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the same empirical formula (e.g. $C_{14}Cl_5$)) was used to compare to the limit of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. ECHA therefore disagrees with the claim that the approach taken to base the PBT assessment of MCCP on the respective properties of its relevant constituents (i.e. groups of congeners) rather than to assess the substance as such is inappropriate. On the contrary, the approach taken is in line with the

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		ATTACHMENT COMMENTS ON PAGE 1, PARAGRAPH 3 These substance definition concerns are not semantical as the current SVHC proposal creates considerable confusion as to the substance being reviewed and thus confusion as the appropriateness of the various data/studies being applied to the assessment. Whilst single chain-length test materials were mandate for various testing programs, including the recent ECHA substance evaluation (SEv) testing decision,[2] the reality is that MCCP under REACH is made from C14-17 normal paraffins. As such, there is only one meaningful variable on the composition of MCCP and it is chlorination by weight. This is the only parameter that is controlled by the manufacturing process. A substance evaluation of MCCP for the purposes a making an Article 57 determination should thusly be on MCCP as a whole substance with consideration given to how/if changes in chlorination level by weight impact this determination.	requirements of REACH Annex XIII to take relevant constituents of a (UVCB)substance into account and with the recommendations of the guidance on how to do this. ATTACHMENT COMMENTS ON PAGE 1, PARAGRAPH 3 ECHA agrees that, for the MCCP substances covered by this proposal, the degree of chlorination is a parameter that can be adjusted to the product chemical specifications. Also ECHA would like to clarify that the degree of chlorination has been taken into account in the assessment that was carried out. ATTACHMENT COMMENTS ON PAGE 2, PARAGRAPH 2

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		ATTACHMENT COMMENTS ON PAGE 2, PARAGRAPH 2 For some parameters there are sufficient comparable data to see how changes in chlorination level by weight impact the endpoint. In the case of the persistence (P) endpoint, there are data on a range of MCCP products at different chlorination levels by weight all run at the same lab under the similar conditions. These results clearly show that MCCP products below a certain chlorination level are readily biodegradable and/or inherently biodegradable. These data alone establish a basis for not considering all MCCP products as meeting the Article 57 criteria. Additionally, in the chlorination range (~50-52% Cl wt.) where the biodegradation results vary the Consortium has commissioned a new study to further evaluate the biodegradability of MCCP at 52% Cl (wt.).	ECHA does not agree with the following comment: 'In the case of the persistence (P) endpoint, there are data on a range of MCCP products at different chlorination levels by weight all run at the same lab under the similar conditions. These results clearly show that MCCP products below a certain chlorination level are readily biodegradable and/or inherently biodegradable'. These screening studies are discussed in the Annex XV report, and ECHA has clearly explained why these screening studies cannot be considered appropriate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents. 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 the particular studies, it is not possible to draw conclusions on the persistence of the constituents of the substances tested, respectively MCCP. Furthermore, ECHA has demonstrated in the SVHC report that the results of the OECD TG 301D for the C_{14} chlorinated n-alkane, 55.0% Cl wt. and the C_{14} chlorinated n-alkane, 60.2% Cl wt. substances indicate that these substances, and hence also their constituents, are potentially persistent (see results in Table 24). Based on the screening test results for C_{14} chlorinated n-alkane, 55.0% Cl wt., also the C_{14}

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			congener groups with 4 to 12 chlorine atoms, which are constituting the substance, screen as potentially persistent. It is worth noting that C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt. also contain C_{14} congener groups (at a relevant concentration ≥0.1% (w/w)) with 5, 6, 7 and/or 8 chlorine atoms as C_{14} chlorinated n-alkane, 55.0% Cl wt. As a conclusion, these substances (C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt.) cannot be rated as ready biodegradable (respectively rated as 'not P') as they always will contain congener groups that screen 'potentially persistent'. This information is confirmed by the outcome of the OECD TG 308 study which shows that all congener groups of MCCP with C_{14} carbon chain length and chlorine substitution numbers from 3 to 14 (i.e. $C_{14}Cl_{3-14}$) have P/vP properties. This is further supported by QSAR predictions (BIOWIN 2, 3 and 6) which indicate that C_{14-17} congener groups of MCCP with three chlorine atoms or more are potentially persistent. <u>ATTACHMENT COMMENTS ON PAGE 2, PARAGRAPH 3</u> ECHA has considered the assessment of the bioaccumulation data for MCCP in the BAT tool as commissioned by the Consortium, which suggests that the weight-of-evidence indicates that MCCP are
		<u>ATTACHMENT COMMENTS ON PAGE 2, PARAGRAPH 3</u> On other endpoints, the data are less uniform and thus harder to fully evaluate. The	

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		Consortium has attempted to address this disparate data on the bioaccumulation (B) endpoint by commissioning a series of independent reviews on the B endpoint, including the recently completed Bioaccumulation Assessment Tool (BAT) review of MCCP. These reviews were discussed in the Consortium's 15 December 2020 submission to ECHA during the call for evidence and comments (CfE) on MCCP, though we see no mention of them in the SVHC proposal.	not bioaccumulative. We disagree with this conclusion as explained below. In Annex X of the Annex XV report we list all the experimental and modelling data used in our weight-of-evidence (WoE) assessment in order to conclude on the bioaccumulation potential of the congener groups of MCCP. In contrast to our assessment, the BAT tool does not reach a conclusion on the basis of the B/vB properties of relevant constituents (i.e. congener groups) of MCCP as required in accordance with REACH Annex XIII but considers MCCP as a whole, with two representative structures. ***Laboratory Fish data*** **Thompson et al., 2000:** This study is described in Section 3.4.2.1 of the Annex XV report. ECHA assigns this study 'medium weight' in our WoE assessment, on a scale low-medium-high and considers it to be reliable with restrictions. According to the BAT spreadsheet, the results are considered unreliable, reliability 0%. In section 3.4.2.1, we acknowledge that there are some uncertainties with the study results but we explain why we consider that it can be used in a WoE assessment. **Unpublished, 2010h:** This study is also described in Section 3.4.2.1 of the Annex XV report. ECHA considers the study is reliable with restrictions and use the kinetic BCF of around 11530 with high weight

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			in the WoE. The results of this study are considered to be enough evidence in itself to conclude the $C_{14}Cl_{3-6}$ congener groups of MCCP as B/vB. According to the BAT spreadsheet, the results are considered unreliable, reliability 0%. We understand that this is because measurements were based on total radioactivity. We discuss this in Section 3.4.2.1 and recalculate the BCF to account for 21% metabolism. We consider the study is reliable with restrictions and use the kinetic BCF of around 11530 with high weight in the WoE. The results of this study are considered to be enough evidence in itself to conclude the $C_{14}Cl_{3-6}$ congener groups of MCCP as B/vB. **Unpublished 2019e:** This study is described in section 3.4.2.2 of Annex XV report. We assign this study 'high weight' in our WoE assessment and consider it to be reliable without restrictions. The results of this study are considered to be enough evidence in itself to conclude the $C_{14}Cl_{5-11}$ congener groups of MCCP as B/vB. This study is assigned a reliability of 88.41% in the BAT tool. ECHA agrees that this study is reliable. Only the BMF result for the total test material was used in the BAT tool. However, as explained in the Annex XV report we derived the kinetic, growth corrected and lipid normalised biomagnification factors (BMF_{kgL}) for

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			individual MCCP congener groups. The corresponding fish BCFs were calculated for the different MCCP congener groups using the 15 models within the OECD TG 305 BCF estimation tool. The BAT tool concludes 'not B' for the total test material since the BMF derived from this OECD TG 305 laboratory study is ≤1. This is an incorrect conclusion. As explained in ECHA Guidance R.11, even if a BMF from an OECD TG 305 dietary bioaccumulation study is found to be <1, it cannot be considered as a good discriminator for concluding substances not to be (very) bioaccumulative according to the BCF criteria of Annex XIII. It is recommended to estimate the BCF from the dietary study data, as well as considering the depuration rate and using a benchmarking approach to compare the dietary BMF obtained with those substances known to be B or vB. We have performed such an assessment in the Annex XV report. **Fisk et al., 1996 and Fisk et al., 2000**: These studies are described in Section 3.4.2.2 of the Annex XV report. We discuss the uncertainties with the studies and estimate the growth-corrected depuration rate constants and show that they are comparable with those derived from the other fish dietary study Unpublished 2019e. The BAT tool consider these fish dietary bioaccumulation studies to be 0% reliability "critical

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			failure". We disagree with this assessment. They are considered as reliable with restrictions and are assigned a medium weight in the WoE assessment. We also include Fisk et al, 1998b in our assessment. ***Laboratory invertebrate data*** **Castro et al. 2019:** In the BAT tool, this study is assigned 77.62% reliability. ECHA agrees that this study is reliable. We discuss the study in detail in Section 3.4.2.3 of the Annex XV report. As explained in Annex X, the study is assigned a medium weight and is used as supporting information in the weight of evidence approach. We agree with the BAT Tool assessment that the BCF from this study indicates vB. We also used the Renberg et al., 1986 invertebrate study on *Mytilus edulis* and the Thompson et al., 2001 study on Earthworms (*Eisenia fetida*) in our bioaccumulation assessment. These are not included in the BAT tool. ***Field data*** **Houde et al., 2008:** In this study, MCCP levels were measured in biota collected in Lake Ontario and northern Lake Michigan. It is considered in the BAT tool as reliability 61.64% and many different lines of evidence are taken from this study and assessed, for each of the different predator-prey relationships.

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			This data is discussed in section 3.4.4.1 of the Annex XV report. We noted some uncertainties with the BMF and BAF results since the water concentrations relate to samples collected in 2004 whereas the biota samples were taken between 1999 and 2004. As indicated in ECHA Guidance R.11, as dietary and trophic biomagnification (in the field) represent different processes than bioconcentration in aquatic organisms, BMF and/or TMF values <1 cannot be directly used to disregard a valid assessment based on reliable BCF data indicating that a substance meets the numerical B/vB criteria in Annex XIII to the REACH Regulation. It was not possible to conclude based on the available (limited) field bioaccumulation studies for MCCP as they are equivocal: trophic magnification factors below and above 1 have been derived. In this regard the ECHA Guidance for PBT assessment (Chapter R11) further states that "an indication of biomagnification potential can on its own right be considered to conclude that a substance meets the B or vB criteria but absence of such biomagnification potential cannot be used to conclude that these criteria are not fulfilled". Even if there was consistent evidence from the biomagnification studies for lack of biomagnification potential this would not be sufficient to outweigh the fact that a substance or its relevant constituents would meet the B or vB criteria based on BCF alone. The inclusion of so many lines of evidence from this study (15 BAF/BMF values and 14 TMF values) in the

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			BAT tool provides too much emphasis on the results of this study and gives an unrealistic assessment of the bioaccumulation potential. As indicated in ECHA Guidance R.11, biomagnification will vary between predatory/prey relationships, so a low BMF in one does not mean that it will be low in other predatory/prey relationships. This is well illustrated by the data from Du et al., 2020 which is also discussed in section 3.4.4.1 of the Annex XV report but is not included in the BAT Tool. Lipid normalised BMF values for MCCP congeners based on mean lipid weight concentrations found in the muscle and in the liver of the red-backed rat snake and black-spotted frog were mainly >1. We consider the Du et al., 2020 data to be reliable with restrictions and use it in the weight of evidence assessment for bioaccumulation but assign it a low weight. **Estimated data** As described in Section 3.4.1.2 and Annex X of the Annex XV report, ECHA ran BCF predictions using the BCF Baseline model of CATALOGIC for the MCCP congener groups. We assigned the predictions a low weight. The BAT Tool includes 3 estimates of BAF, 2 BMF estimates and 2 BCF estimates. Since version 2.0 of the BAT Tool is not yet publicly available, we cannot check or comment on the reliability of these estimates. However, the predictions were run for two representative C_{14} structures ($C_{14}H_{25}Cl_5$ and $C_{14}H_{24}$

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			Cl_6) and not for the full range of MCCP congener groups as included in our assessment. **Fugacity ratios** The BAT Tool includes a calculation of the fugacity ratios for each line of evidence. As explained in the BAT report: "*The fugacity ratio WOE approach seeks to address the question "Does the chemical biomagnify in the environment?" This is a different problem formulation that the more general question "Does the chemical bioaccumulate in the environment*?". PBT/vPvB assessment under REACH is concerned with bioaccumulation, considering both contributing phenomena, i.e. bioconcentration as well as biomagnification. In addition, ECHA Guidance R.11 states that the fugacity approach in bioaccumulation assessment under REACH cannot be recommended at this stage due to a number of uncertainties.
		ATTACHMENT COMMENTS ON PAGE 2, PARAGRAPH 4 At a minimum, the SVHC proposal should consider a chlorination level cut-off and not add MCCP at chlorination levels which are biodegradable to the Candidate List. Based on the currently available data, this cut-off could be established at 50% Cl by weight, though additional study data will be forthcoming shortly that might warrant further consideration of the range of products in the 50-52% Cl range. Such	ATTACHMENT COMMENTS ON PAGE 2, PARAGRAPH 4 Regarding your comment to set a chlorination level cut-off to the SVHC entry, such as e.g. 50% Cl by weight, ECHA does not agree with your proposal. ECHA has clearly demonstrated in the Annex XV report that based on the available information available, MCCP contain lower than 50% chlorinated congener groups with PBT and/or vPvB properties at a concentration ≥ 0.1 % (w/w) (please refer to the explanatory text above Table 52 in the Annex XV report). That is why it is concluded that MCCP meet the criteria for a PBT and/or vPvB substance in

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		a chlorination level cut-off is consistent not only with the database but also with prior and proposed actions on chlorinated paraffins under the Stockholm Convention. The following specific concerns with the SVHC proposal are addressed further: 1. There is not a clear definition regarding the substance to be added to the Candidate List. 2. Congener groups are not tangible, identifiable constituents and thus cannot be used to determine PBT constituents. 3. The 0.1%3 substance concentration trigger under REACH has been misapplied to congener groups, which are theoretical groups of constituents. 4. Misuse of the REACH precautionary principle. 5. The proposal fails to consider the MCCP composition given in registration dossiers. 6. A proper weight of evidence approach was not done on the MCCP PBT assessment.	accordance with Annex XIII of the REACH Regulation, and thereby they fulfil the criteria set out in REACH Articles 57(d) and/or (e). To our understanding and based on the comments received on MCCP, the 'other study' you are referring to and that is ongoing is an OECD TG 314B study on MCCP at 52% Cl wt. Concerning this new OECD TG 314B study, ECHA is of the opinion that the outcome of this study will not change the P conclusion for MCCP for the following reasons: according to REACH guidance Chapter R.7b, OECD TG 314B studies cannot be used on their own for PBT/vPvB assessment and may only be considered as a part of a weight-of-evidence approach. In particular, the half-lives determined from those tests are not suitable for comparison with the REACH Annex XIII criteria for persistence. These studies indeed do not employ relevant environmental conditions for assessing the persistence of the substance in the compartments relevant for the PBT/vPvB assessment, i.e.: natural surface water, sediment or soil. For the PBT/vPvB assessment it has to be demonstrated that the substance will indeed not persist in any of the environmental compartments (in our case MCCP have been demonstrated to be persistent in the sediment compartment). Therefore, not only exposure to natural water from STP effluents but also other possibilities of exposure (including indirect exposure and redistribution between environmental compartments) need to be taken into account for the

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		ATTACHMENT COMMENTS ON PAGE 3 **1. The SVHC proposal lacks clear definitions the substance to be added to the Candidate List** MCCP, as registered under REACH, is a complex reaction product of chlorine gas and a C14-17 paraffin feedstock. The chlorination process involves random substitution of chlorine (Cl) for hydrogen (H) along the carbon chain of the paraffin feedstock. The chlorination process does not impact carbon to carbon bonds, only carbon to hydrogen bonds, thus the carbon-chain lengths of the chlorinated paraffin are the same as the starting feedstock. The chlorination	PBT/vPvB assessment. Furthermore, REACH guidance Chapter R.7b further mentions/recommends that OECD TG 314 study does not give a direct measurement of degradation but rather removal of the test substance including both degradation and adsorption as characterised by a STP and it should not be used as a replacement for simulation tests for degradation in environmental compartments such as surface water, sediment or soil (i.e. OECD TG 309, 308 or 307 type studies). Responses to comments on specific concerns with the SVHC proposal: ATTACHMENT COMMENTS ON PAGE 3 **1. The SVHC proposal lacks clear definitions the substance to be added to the Candidate List** Thank you for the comment highlighting the need for clarification of the scope of the proposed SVHC entry. The proposed entry does not address one individual substance, on the contrary all UVCB substances that correspond to the description "*UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17*" are concerned by the entry. Such approach is frequent in the Candidate List which includes several entries covering groups of substances, also including UVCB substances.

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		process is done to achieve an established level of chlorine content by weight. For registered MCCP substances under REACH, the range is 40-63% Cl by weight though the most common products based on a recent survey are between approximately 45% and 52% Cl by weight. Information can be found in the Consortium's CfE comments and registration dossiers on the tonnages of MCCP products by chlorine weight content. As ECHA is aware, the manufacturing details for UVCB substances are fundamental to the substance identification (ID) under REACH thus we think it is important to note these details here for the purposes of discussing what is (and what is not) MCCP. Article 57, *Substances to be included in Annex XIV*, is specific to substances. Whilst there may not be a legal requirement that only registered substances be included on the Candidate List, the Consortium does not believe that the current SVHC proposal is on a substance as defined under REACH. REACH defines a substance to mean "a chemical element and its compounds in the natural state or obtained by any manufacturing process" In the case of UVCB substances like MCCP we believe that it must be defined by its manufacturing process, which includes the definition of the starting feedstock. ECHA too appears to understand this requirement as it required additional	The substance registered under REACH and identified using the identifiers: EC number 287-477-0, EC name Alkanes, C14-17, chloro and CAS number 85535-85-9 meets the above description and therefore it is considered to be among the substances that fall within the scope of the proposed entry. This is the reason why information on this specific substance is reported in the Annex XV dossier. In light of the remarks provided asking for a clearer specification of the scope of the proposed entry, an explanatory text will be included in the Annex XV dossier. With regard to the comment on the choice of not specifying the manufacturing process of the substances covered by the proposed entry: the group of substances covered by the proposed entry may be manufactured following different processes. Independently from the manufacturing process used, the hazardous properties described in the Annex XV dossier are correlated to the composition of these substances. As explained above the proposed entry does not cover an individual substance that is characterised by a specific name/manufacturing process.

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		information4 on the manufacturing process and substance identity as a part of the MCCP Substance Evaluation (SEv) and has issued extensive guidance on the need for detailed manufacturing process information for the registration of UVCBs under REACH. The current text describes MCCP as: "UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17." and "MCCP are UVCB substances. MCCP contain linear chloroalkanes with carbon chain lengths predominantly within the range of C14-17 with chlorination levels that can differ depending on the application. The number of congeners in MCCP is large." In both of these descriptions, it appears that ECHA is attempting to cover a range of possible substances – "substances" is in fact pluralised in both cases. However, in Section 1.1 and Table 2 the text very clearly describes MCCP as being EC number 287-477-0, EC name Alkanes, C14-17, chloro and CAS number 85535-85-9, which is a specific substance. Given how UVCB substances are registered under REACH, we believe the current SVHC proposal will create far too much confusion and ambiguity as to	This is the reason why the description used for setting the boundaries of the proposed SVHC entry is based on the chemical nature of these substances.

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		what substance is to be added to the Candidate List. This confusion will likely create considerable implementation and enforcement issues, particularly with substances and articles imported from outside of Europe. ECHA should not attempt to include a substance on the Candidate List that is not clearly defined. We believe that a range of possible constituents or congener groups is not a sufficient basis for defining a substance under REACH. In the case of a proposed SVHC listing on a UVCB substance, the listing must be clear and precise pursuant to the principle of legal certainty in order to avoid confusion, ensure that application of the legal rule is predictable, and prevent its misinterpretation and misapplication in practice. ATTACHMENT COMMENTS ON PAGE 4 **2. Congener groups are not identifiable constituents and cannot be used to determine PBT constituents** The term "congener" has been defined as "a chemical substance related to another" (Merriam-Webster) and a "member of the same class or group" (Oxford). ECHA defines a congener as "individual constituents sharing the same empirical formula are congeners of each other." And that 'congeners' or 'congener group' refers to "a group of constituents sharing the	ATTACHMENT COMMENTS ON PAGE 4 **2. Congener groups are not identifiable constituents and cannot be used to determine PBT constituents.** The information included in the SVHC dossier defining the terminology "congener" and "congener group" is consistent. As pointed out in the comment, the proposal clarifies that a "congener group" refers to a *group of constituents sharing the same empirical formula irrespective of the position of the chlorine substituents on the carbon chain".*

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		same empirical formula irrespective of the position of the chlorine substituents on the carbon chain." These definitions are important as ECHA has largely based this SVHC proposal on an assessment of 'congeners' or 'congener groups'5. However, the SVHC proposal does not clearly acknowledge that an individual congener (i.e. an individual chemical constituent) in MCCP is not identifiable nor that a congener group contains hundreds or thousands of individual chemical constituents with the same molecular weight. The concept of the congener group for chlorinated paraffins (CPs) came about as a way to present analytical chemistry results for CPs, which can be very challenging given the extremely high number of unique constituents6. Congener groups share a common molecular mass, which allows them to be grouped using advanced analytical chemistry techniques. However, congeners and congener groups are not uniquely identifiable constituents but rather a grouping of hundreds or thousands of individual constituents (i.e. chemicals, structural isomers). The Consortium is deeply concerned that the current SVHC proposal does not properly recognise that congeners are groups based solely on molecular weight/formula and do not	It is clear from such text that a congener group consists of a multitude of constituents and it is not limited to one constituent. Also it should be noted that the Annex XV dossier repeatedly specifies that MCCP substances contain thousands of constituents. Also it clarifies that "it is neither feasible nor justifiable to experimentally determine key properties for every constituent separately". ECHA uses the concept of congener group because the individual constituents are not analytically accessible but as well as it would be practically impossible to assess all constituents individually. Therefore the in practice feasible approach of congener groups, defined by the carbon chain length (number of carbons of the chain) and the number of chlorine substituents per carbon chain, is used to group together the structural isomers sharing the same empirical formula. This is in line with the PBT guidance Chapter R.11 (ECHA, 2017b) where it is mentioned that 'a close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents". …. In conclusion ECHA does not agree with the comment provided.

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		represent unique constituents. For example, the SVHC proposal states under "Definitions" (page 8) that congener groups are "individual constituents sharing the same empirical formula." This same definition then goes on to describe congeners or 'congener group' as "a group of constituents sharing the same empirical formula irrespective of the position of the chlorine substituents on the carbon chain." The SVHC proposal must be revised to clearly and consistently present that congeners or congener groups are groups of chemical constituents, not individual constituents. ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 2 Recent advancements in analytical chemistry that have led to the reporting of congener groups in CP analysis are impressive. However, to date we have very limited information about what these congener groups represent and certainly not sufficient information by which to evaluate (or even if they can be evaluated) against the Annex XIII criteria for PBT and vPvB substances. For example, congener groups do not tell us anything about the position of the chlorine atoms on the CP carbon chain or the relative amounts of each individual chemical in the congener group. Additionally, depending on the chemical analysis method there is likely some overlap in the reporting of congener	ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 2 We acknowledge that a 'congener group' does not describe an individual constituent but a grouping of many, potentially hundreds or thousands of individual constituents (i.e. structural isomers), however with a specific carbon chain length and number of chlorine substituents. This grouping approach for MCCP substances is scientifically reasonable and technically correct because the current analytical methods can only identify constituents of MCCP with reasonable effort at the level of congener groups but not at the level of the individual structural isomer. This technical limitation, besides practical impossibility, entails that there is also no data available that would allow PBT assessment of MCCP at the level of individual

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		group results with isomers from one congener group being reported under a different congener group. This is not unexpected in a substance that has tens of thousands of individual isomers but only a handful of congener groups. For example, Figure 1 shows the graphical results of a GCxGC-ECD analysis of congener groups conducted by Vrije Universiteit Amsterdam of the same test material that was used in several studies under the Substance Evaluation (SEv) decision. This figure is a 2-dimensional representation of a 3-dimensional result where the brighter areas are the regions with the most responses (i.e. detector responses caused by individual chemicals). This figure shows that whilst it is possible to make some reasonable separations between the congener groups, they are really clusters of hundreds or even thousands of individual chemical responses on a detector. They simply are not individual constituents and should not be treated as such. It is important to note that the substance synthesised for the SEv studies - C14 (n-tetradecane) chlorinated to 50% Cl by weight is itself a UVCB substance which contains thousands of isomers. Whilst it will contain isomers that are present in commercial MCCP, the isomer distribution in this chlorinated tetradecane test material is unique to it.	structural isomers. That is why the PBT assessment was performed at the level of congener groups for which analytical and experimental data are available. It is important to note that when information on the composition of the testing materials was missing, the dossier submitter considered a Gaussian distribution to estimate for a given carbon chain length the composition (i.e. compositional profile) of the chlorinated congener groups. The distribution was expected to be centred between the congeners having a chlorine content just above and below the average degree of chlorination of the substance.

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		ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 3 There is no practical means of manufacturing individual congener groups or testing these groups against the Annex XIII criteria. None of the test data in the registration dossier or literature were developed on specific congener groups. Rather these studies are on various CP test materials that were analysed for congener groups. In some cases, these CP test materials do not even meet the definition of MCCP. Attempting to treat these reported groupings of isomers into meaningful constituents of MCCP for an SVHC dossier evaluation is simply not consistent with REACH Article 57.	ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 3 ECHA is of the opinion that enough information has been collected under the substance evaluation process in order to conclude on the PBT/vPvB properties of a considerable number of congener groups of MCCP so that regulatory action can be taken for MCCP. We acknowledge that for some of the MCCP congener groups information is insufficient to conclude on their PBT/vPvB properties, however overall sufficient information is available to draw conclusions on the PBT/vPvB properties and to justify and launch regulatory action on MCCP. We do not agree with the statement 'attempting to treat these reported groupings of isomers into meaningful constituents of MCCP for an SVHC dossier evaluation is simply not consistent with REACH Article 57'. The PBT/vPvB assessment must, according to Annex XIII to the REACH Regulation, take account of the PBT/vPvB properties of relevant constituents. Section R.11.4.1 of the PBT guidance sets out that constituents should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). As further explained in the guidance, this limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation. Additionally, the Judgments of the General Court in cases T-93/10, T-

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			94/10, T-95/10 and T-96/10 confirmed the validity of this approach for PBT/vPvB constituents of a substance. Especially for very complex UVCBs it is possible that individual constituents are present in concentrations <0.1% (w/w) and that these have not been (or cannot be) characterised by chemical analysis individually. For UVCBs (such as MCCP) even the whole substance may consist of individual constituents only present in such low concentrations. The fact that all individual constituents of a UVCB-substance are present in concentration <0.1% (w/w) does not exempt from the obligation to carry out the PBT/vPvB assessment. A close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be specifically addressed in the PBT/vPvB assessment. This approach, which is recommended and lined out in further detail in section R.11.4.2.2 of the PBT guidance, has been followed for the PBT assessment of MCCP (as has been already in previous PBT assessments, e.g. for SCCP (Alkanes C_{10}-C_{13}, chloro)). For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the

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		ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 4 Whilst the available CP test data that have been developed utilising chemical analysis of congener groups provide some interesting insights, we still do not know if the same congener groups act similarly or differently in different chlorinated paraffin test material. Such data may be exceptionally difficult to reliably generate since different labs and different analytical techniques may not consistently generate the same congener analysis for the same CP test material. An interlaboratory evaluation on the chemical analysis of CPs showed considerable variability between different labs even using similar analytical methods.	same empirical formula (e.g. $C_{14}cl_5$)) was used to compare to the limit of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. Based on the information available, ECHA has demonstrated that MCCP contain congener groups with PBT and/or vPvB properties (see Table 1) at a concentration ≥ 0.1 % (w/w). That is why 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). ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 4 Regarding your comment 'we still do not know if the same congener groups act similarly or differently in different chlorinated paraffin test material'. This is an irrelevant question as the environmental biota as well as humans (via the environment) will not be exposed to the substance as manufactured but to particular constituents of the substance. Once released to the environment, the constituents are dispersed and independent of each other, with their own constituent specific (i.e. structure dependent) fate (degradation potential/persistency, environmental partitioning including bioaccumulation potential) and toxicity. That is why REACH Annex XIII stipulates that constituents of a substance must be

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			considered in the PBT/vPvB assessment. These constituents may further be grouped as set out in the PBT Guidance R.11 (ECHA, 2017b) where it is mentioned that 'a close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents'. Furthermore, QSAR predictions for P and B properties have been undertaken for a number of structural isomers representing the congener groups (i.e. at the constituent level). These predictions show that several congener groups contain constituents with the property/ties of concern (e.g. P and/or B), thus enabling an overall P and/or B conclusion for each congener group (see Annex II of the Annex XV report and also above in this document response under heading ATTACHMENT COMMENTS ON PAGE 5, PARAGRAPH 2). We acknowledge that there are a number of challenges in the analysis of chlorinated paraffins (CP). It is worth noting that, in the substance evaluation report for MCCP (EA, 2019), reference is made to recent inter-laboratory studies where a technique that makes use of APCI-TOF showed for instance good results among the techniques considered (van Mourik *et al.*, 2018).

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			This is the same technique that was used for the analyses of samples in the three studies[1] performed in response to the initial Substance Evaluation decision by the same contract laboratory on behalf of the Registrants. The results of these studies were used for the PBT assessment of MCCP. Furthermore, studies from Yuan *et al.* (2020) for determining the CP composition from the congener group level to actual isomeric discrimination by using MS spectrometry and nuclear magnetic resonance spectroscopy (NMR) are also reported in the literature. It seems that novel techniques are currently available that can provide useful data on the composition of chlorinated paraffins at the congener group level (including chlorinated paraffins having a low chlorination level). <u>References:</u> EA (2019). Substance evaluation conclusion and evaluation report for Medium-chain chlorinated paraffins /Alkanes, C14-17, chloro EC No 287-477-0, Environment Agency, December 2019 available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-

[1] Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308); Bioaccumulation in Fish: Aqueous and Dietary Exposure (OECD TG 305); and Partition Coefficient (1-Octanol/Water): Slow-Stirring Method (OECD TG 123).

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			plan/corap-table/-/dislist/details/0b0236e1807e3841 ECHA (2017b). Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 3.0. June 2017. Korytár P, Parera J, Leonards PE, Santos FJ, de Boer J, Brinkman UA (2005). Characterization of polychlorinated n-alkanes using comprehensive two-dimensional gas chromatography-electron-capture negative ionisation time-of-flight mass spectrometry. Journal of Chromatography A, 1086, 71–82. https://doi.org/10.1016/j.chroma.2005.05.003 van Mourik LM, van der Veen I, Crum S, de Boer J (2018). Developments and interlaboratory study of the analysis of short-chain chlorinated paraffins. Trends in Analytical Chemistry, 102, 32 - 40. Xia D, Gao L, Zhu S, Zheng M (2014). Separation and screening of short-chain chlorinated paraffins in environmental samples using comprehensive two-dimensional gas chromatography with micro electron capture detection. Analytical and Bioanalytical Chemistry, 406, 7561–7570. https://doi.org/10.1007/s00216-014-8209-6 Yuan B, Lysak DH, Soong R, Haddad A, Hisatsune A, Moser A, Golotvin S, Aryropoulos D, Simpson AJ, Muir CG (2020). Chlorines are not evenly substituted in

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		ATTACHMENT COMMENTS ON PAGE 6, PARAGRAPH 1 **Figure 1: Graphical Presentation of GCxGC-ECD results of Chlorinated Tetradecane (50% Cl)** The Consortium also notes that ECHA has in several places made assumptions about the presence of congener groups and the relative amounts of these congener groups in studies where there were no chemical analyses for congener groups. For example, in Section 3.1.2.1.2 (pages 31-47) of the SVHC proposal there are numerous comments about the expected congener groups present in various test materials used in the Closed Bottle Test (CBT) though congener group data were only developed on the 2018 CBT studies, not on those conducted 2010 and 2014. Such an assessment gives more apparent weight to	chlorinated paraffins: A predicted NMR pattern matching framework for isomeric discrimination in complex contaminant mixtures. Environmental Science and Technology Letters, 7, 496–503. Available at: https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.0c00244 ATTACHMENT COMMENTS ON PAGE 6, PARAGRAPH 1 The average degree of chlorination of the testing materials is reported in the studies. However, further information on the composition of the testing materials is missing in many study reports. In these cases, we considered a Gaussian distribution to estimate for a given carbon chain length the composition (i.e. compositional profile) of the chlorinated congener groups. The distribution was expected to be centred between the congeners having a chlorine content just above and below the average degree of chlorination of the substance. The chemical analyses of commercial chlorinated paraffins in the literature have confirmed that the composition of chlorinated congeners with a given carbon chain length is following a Gaussian distribution. For a given carbon chain length, the numerical range of chlorine atoms around the peak of the Gaussian distribution was limited to 4 in order to ensure that all the constituents considered are present in proportions well above 0.1% (w/w). Therefore, we consider this is a robust approach.

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		congener groups when the key metric in these studies is measured oxygen consumption and the resulting biodegradation of the overall test substance.	See below Figure 1 as an example of Gaussian distribution for a C_{10} chlorinated n-alkane, 60.09% Cl wt. (average value). For this chlorinated paraffin, the peak of the Gaussian distribution corresponds to the average chlorination level (60.09% Cl wt). Based on this average chlorination level and using a Gaussian distribution, the 4 predominant congener groups present in C_{10} chlorinated n-alkane, 60.09% Cl wt. are $C_{10}Cl_5$, $C_{10}Cl_6$, $C_{10}Cl_7$ and $C_{10}Cl_8$ (all centred around the average chlorination level).

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			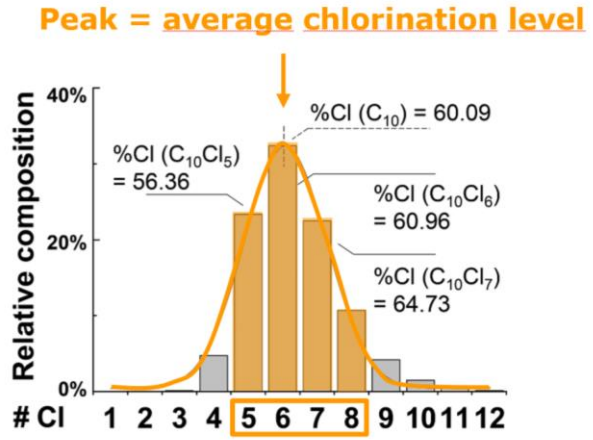 **Figure 1.** Schematic Gaussian distribution of $C_{10}Cl_m$ in the C_{10} 60.09% Cl reference standard. The curve is the Gaussian peak, the center of which is 60.09%Cl. The columns represent one possible relative composition of each $C_{10}Cl_m$ calculated from the eq 4 setting σ_i of 0.05. *Source: Yuan et al., 2017a* Reference: Yuan B, Bogdal C, Berger U, MacLeod M, Gebbink WA, Alsberg T, de Wit CA (2017a). Quantifying short-chain chlorinated paraffin congener groups. Environmental Science & Technology, 51, 10633-10641. Available at: https://pubs.acs.org/doi/pdf/10.1021/acs.est.7b02269

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			Thank you for reporting that congener groups data were developed on the 2018 CBT studies. This information has been added to the support document. Please note that for the 2018 CBT studies (Unpublished 2018a-d), from the information presented in the final study reports, it was not possible to verify the test results from the isomer-specific analyses. No data have been presented in the study report that would allow to confirm the claims with regard to removal of the substance and partitioning between dissolved fraction and particles. Also, no details were presented for extraction recoveries or method development for suspended solid extraction, liquid-liquid extraction, or acknowledgement of adherence to test vessels and processing glassware. Due to the absence of all the above information on the test results from the isomer-specific analyses, the results based on oxygen consumption are therefore considered to be the most reliable. ATTACHMENT COMMENTS ON PAGE 6, PARAGRAPHS 1 AND 2 We do not agree with your statement that 'the SVHC proposal has not clearly established that all MCCP products meet the Annex XIII criteria given that several CBT studies show these chemicals to be readily or inherently biodegradable'. These screening studies are discussed in the Annex XV report, and ECHA has clearly explained why the screening studies
		ATTACHMENT COMMENTS ON PAGE 6, PARAGRAPHS 1 AND 2 As discussed further in these comments, the Consortium believes that SVHC proposal has not clearly established that all MCCP products meet the Annex XIII criteria given that several CBT studies show these chemicals to be readily	

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		or inherently biodegradable. ECHA, essentially, appears to state that since a (OECD308) test on a different UVCB substance (i.e. tetradecane chlorinated to 50% w/w) shows little degradation, the results of OECD 301 screening tests on the registered substance can be ignored. On page 47 (paragraph 1), ECHA states "That is why screening tests without further supplementary information on 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, are considered not sufficient to draw conclusions on the persistence of MCCP as a substance and in particular on the persistence of its different congener groups and individual constituents."	cannot be considered appropriate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents. 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 the particular studies, it is not possible to draw conclusions on the persistence of the constituents of the substances tested, respectively MCCP. Furthermore, we demonstrated in the SVHC report that the results of the OECD TG 301D for the C_{14} chlorinated n-alkane, 55.0% Cl wt. and the C_{14} chlorinated n-alkane, 60.2% Cl wt. substances indicate that these substances and hence also their constituents are potentially persistent (see results in Table 24). Based on the screening test results for C_{14} chlorinated n-alkane, 55.0% Cl wt., also the C_{14} congener groups with 4 to 12 chlorine atoms, which are constituting the substance, screen as potentially persistent. It is worth noting that C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt. also contain C_{14} congener groups (at a relevant concentration ≥0.1% (w/w)) with 5, 6, 7 and/or 8 chlorine atoms as C_{14} chlorinated n-alkane, 55.0% Cl wt. As a conclusion, these substances (C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14}

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			chlorinated n-alkane, 50% Cl wt.) cannot be rated as ready biodegradable (respectively rated as 'not P') as they always will contain congener groups that screen 'potentially persistent'. The persistence of the $C_{14}Cl_{4-12}$ congener groups of MCCP (which screen as 'potentially P' based on the OECD TG 301D studies) is confirmed by a reliable higher tier OECD TG 308 simulation study in sediments, modelling data and monitoring data which further indicate that MCCP and their $C_{14}Cl_{3-14}$ congener groups have P/vP properties. Furthermore, based on the predicted and observed trends in physico-chemical properties of structures representing 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 C_{15-17} congeners with the same or higher chlorine contents than the congeners of C_{14} chlorinated n-alkane, 50% Cl. wt. (which contains $C_{14}Cl_{3-14}$ 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. Hence, MCCP always will contain congener groups with P/vP properties at a concentration ≥ 0.1 % (w/w). It therefore can be concluded that MCCP always meet both the 'persistence' (P) and 'very persistent' (vP) criteria of REACH Annex XIII (degradation half-life in sediment > 180 days).

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			The results of the OECD 301 screening tests were not excluded from the weight-of-evidence assessment for persistence. They were used but a low weight has been assigned to this information considering that it is not possible to draw conclusions from these studies on the ready biodegradability of a specific congener group present in the test substance. <u>ATTACHMENT COMMENTS ON PAGE 7, PARAGRAPH 2</u> We assume that by 2d-GC-GC results you are referring to test results for the 2018 CBT studies (Unpublished 2018a-d). As already explained above, from the information presented in the final study reports, it was not possible to verify the test results from the isomer-specific analyses. The results based on oxygen consumption are therefore considered to be the most reliable.
		<u>ATTACHMENT COMMENTS ON PAGE 7, PARAGRAPH 2</u> It appears that there is some confusion on what the 2d-GC-GC results are showing. The contribution of congener groups to biodegradation is known. The levels of congener groups at the beginning and end of the OECD 301 test can be seen and compared and indeed show the drop in levels of degradation with chlorination level. We also state again that as UVCB substances, a complete knowledge of composition (at the structural isomer level) cannot be known for this or any UVCB substance.	
		<u>ATTACHMENT COMMENTS ON PAGE 7, PARAGRAPHS 3, 4 AND 5</u> **3. 0.1% Substance trigger under REACH has been misapplied to congener groups**	<u>ATTACHMENT COMMENTS ON PAGE 7, PARAGRAPHS 3, 4 AND 5</u> **3. The 0.1% substance concentration trigger under REACH has been misapplied**

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		At numerous places throughout the SVHC proposal it is noted that there are congeners or congener groups that are present "at a relevant concentration ≥0.1% (w/w)." This approach to congener groups inappropriately elevates congener groups to the status of substance for the purposes of evaluation against the criteria in Annex XIII. The 0.1% (0,1%) threshold under REACH is established for substances in: • Article 7 – reporting/notification criteria for a substance in articles • Article 14 – criteria for determining if a CSR is need for a preparation that contains a PBT substance • Article 31 – criteria for determining if an SDS is need for a preparation that contains a PBT substance • Article 33 – reporting/notification criteria for a substance in articles • Article 56 – triggering criteria for preparations that contain substances that meet Article 57 (d), (e), or (f) At no point in REACH does the 0.1% threshold come up for constituents in UVCB substances, this is especially true for constituents which are not unique chemicals and in the case of congener groups cannot even be individually synthesised or manufactured.	**to congener groups, which are theoretical groups of constituents** The PBT/vPvB assessment must, according to Annex XIII to the REACH Regulation, take account of the PBT/vPvB properties of relevant constituents. Section R.11.4.1 of the PBT guidance sets out that constituents should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). As further explained in the guidance, this limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation. Additionally, the Judgments of the General Court in cases T-93/10, T-94/10, T-95/10 and T-96/10 confirmed the validity of this approach for PBT/vPvB constituents of a substance. Especially for very complex UVCBs it is possible that individual constituents are present in concentrations <0.1% (w/w) and that these have not been (or cannot be) characterised by chemical analysis individually. For UVCBs (such as MCCP) even the whole substance may consist of individual constituents only present in such low concentrations. The fact that all individual constituents of a UVCB-substance are present in concentration <0.1% (w/w) does not exempt from the obligation to carry out the PBT/vPvB assessment. A close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon

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		UVCB substances must not be presumed to be and/or evaluated as if they are mixtures or preparations, this is especially true in the circumstance with MCCP where individual chemicals cannot be identified. As discussed previously, congener groups are not individual constituents of MCCP. The SVHC proposal must be reconsidered and/or revised to reflect this reality.	number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be specifically addressed in the PBT/vPvB assessment. This approach, which is recommended and lined out in further detail in section R.11.4.2.2 of the PBT guidance, has been followed for the PBT assessment of MCCP (as has been already in previous PBT assessments, e.g. for SCCP (Alkanes C_{10}-C_{13}, chloro)). For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the same empirical formula (e.g. $C_{14}cl_5$)) was used to compare to the limit of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. ECHA therefore disagrees with the claim that the approach taken to base the PBT assessment of MCCP on the respective properties of its relevant constituents (i.e. groups of congeners) rather than to assess the substance as such is inappropriate. On the contrary, the approach taken is in line with the requirements of REACH Annex XIII to take relevant constituents of a (UVCB)substance into account and with the recommendations of the guidance on how to do this.

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		ATTACHMENT COMMENTS ON PAGE 7, PARAGRAPH 6 AND ON PAGE 8, PARAGRAPH 1 **4. SVHC Proposal misuses the REACH precautionary principle** There are four specific places in the PBT assessment where the REACH precautionary principle is invoked as a rationale for extrapolating results from one test material or ECHA interpretation of a test material to all of MCCP. The PBT assessment is a hazard assessment, not a risk assessment, and therefore the precautionary principle is not relevant, and cannot be invoked, to support inclusion of a substance on the Candidate List. The precautionary principle is relevant in certain risk assessments, not hazard assessments, and should not be used in this manner. It therefore follows that ECHA is legally required to ensure there is sufficient information on the hazards of the substance to support inclusion of the substance on the Candidate List. If there is no such evidence, or if there is insufficient evidence, then the substance cannot be included in the Candidate List. Here, in this case, the evidence seems to be that there is no such evidence, or there is insufficient evidence	ATTACHMENT COMMENTS ON PAGE 7, PARAGRAPH 6 AND ON PAGE 8, PARAGRAPH 1 **4. SVHC Proposal misuses the REACH precautionary principle** The text referring to the precautionary principle was deleted in order to avoid unnecessary discussions. The reference to that principle is not needed to explain why all congener groups can be considered to contribute equivalently to the observed toxicity.

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		- and therefore the substance cannot be included on the Candidate List. ATTACHMENT COMMENTS ON PAGE 8, PARAGRAPHS 2, 3 AND 4 **5. The SVHC proposal fails to consider the MCCP composition given in registration dossiers** On page 21 of the proposal (first paragraph), ECHA states that "constituents outside of the C14-17 range may also be present in the composition at lower concentration levels. However, the constituents within the C14-17 range are expected to represent at least 80% of the composition." There is no reason to make this statement since full compositional details on the registered substance are given in the registration dossiers. Additionally, since the substance is registered as a UVCB substance it is registered at 100% including all constituents (UVCB guidance). The registrants agreed on a maximum 1% of constituents lying outside of the C14-17 range. In practice levels are less than 0.5% w/w. In the next paragraph the proposal states that "it is possible that chlorinated paraffins with carbon chain lengths of C18 and above may be present in other types of chlorinated paraffins than long-chain chlorinated paraffins (LCCP),	ATTACHMENT COMMENTS ON PAGE 8, PARAGRAPHS 2, 3 AND 4 **5. The proposal fails to consider the MCCP composition given in registration dossiers** The information given in Section 1.2 of the Annex XV dossier does not reflect the composition of one specific substance. This section aims at providing generic information on the compositions that may be expected for the various UVCB substances that fall within the scope of the proposed entry. In addition, the possible presence of other chain lengths than $C_{14\text{-}17}$ in the composition of these substances is reported for completeness and for enabling the reader to appreciate the variety of possible constituents present in the composition of these substances. The information given does not refer to impurities, in line with the approach followed for UVCB substances in the Guidance for identification and naming of substances under REACH and CLP.

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		such as the MCCP." We do not understand the point being made here. Substances registered under paraffin waxes and hydrocarbon waxes, chloro (CAS 63449-39-8; EINECS 264-150-0 are also UVCB substances with unique compositions. Further details of these compositions are fully available in the respective registration dossiers. The paragraph continues to state "this means that constituents having C10-13 chlorinated alkyl chains corresponding to constituents of alkanes, C10-13, chloro (short-chain chlorinated paraffins or SCCP, CAS no. 85535-84-8) may as well be present in Alkanes, C14-17, chloro." Once again, information about the composition of the registered substance, MCCP, are given in the registration dossiers. This information does not need to be inferred. As stated above, the registrants agreed on a maximum 1% of constituents lying outside of the C14-17 range (including C18 and above and C13 and below. In practice levels are less than 0.5% w/w. For the low carbon number range, this is principally C13 components, but these are always present when MCCP is tested (since it is a UVCB substance registered in accordance with the UVCB guidance. SCCP, MCCP and LCCP are all UVCB substances so to described one UVCB substance as an impurity in another is not consistent with the UVCB approach since all	

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		three substances were registered at 100% concentration (the SCCP registration is now inactive) ATTACHMENT COMMENTS ON PAGE 8, PARAGRAPH 5 **6. Proper weight of evidence approach was not done on PBT assessment** The SVHC proposal indicates that a weight-of-evidence (WoE) approach was utilised in the overall PBT assessment and in specific P and B endpoint reviews. In practice, however, the SVHC proposal has favoured certain studies and results over others without clearly establishing or employing a true WoE methodology. Specific concerns with stated WoE approach used in the SVHC proposal for the P and B endpoint reviews are discussed below. ATTACHMENT COMMENTS ON PAGE 9, PARAGRAPHS 1 AND 2 **Persistence** The apparent WoE approach for P in the SVHC proposal has been to disregard a series of well conducted guideline 301 biodegradation studies on the full range of possible chlorination levels of MCCP, and run under the same conditions, in favour of a single guideline 308 study. The apparent justification for this position is:	ATTACHMENT COMMENTS ON PAGE 8, PARAGRAPH 5 **6. A proper weight of evidence approach was not done on the MCCP PBT assessment** ATTACHMENT COMMENTS ON PAGE 9, PARAGRAPHS 1 AND 2 **Persistence** ECHA does not agree with the following statement: 'the apparent WoE approach for P in the SVHC proposal has been to disregard a series of well conducted guideline 301 biodegradation studies on the full range of possible chlorination levels of MCCP, and run under the same conditions, in favour of a single guideline 308 study'. The screening studies using chlorinated paraffins were not excluded from the weight-of-evidence for persistence. They were used in the P assessment but a low weight has been assigned to this information considering that it is not possible to draw conclusions from these studies on the ready biodegradability of a specific congener

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		"Overall, these screening studies are not considered appropriate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents. Indeed, based on the outcome of the screening tests and in absence of information on the degree of degradation of the individual congener groups in the tests, it can be reasonably assumed that the substances tested (see Table 24) contain potentially persistent congeners. For UVCB substances, there are uncertainties related to the screening tests where the contribution of the different congeners of MCCP to the overall degradation is unknown. Therefore screening tests without further supplementary information on 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, are normally not sufficient to draw conclusions on the persistence of MCCP as a substance and in particular on the persistence of its individual constituents, respectively different congener groups. That is why the outcomes of the screening tests for MCCP have been given a low weight in the weight-of-evidence assessment."	group present in the test substance. We demonstrated in the SVHC report that the results of the OECD TG 301D for the C_{14} chlorinated n-alkane, 55.0% Cl wt. and the C_{14} chlorinated n-alkane, 60.2% Cl wt. substances indicate that these substances and hence also their constituents are potentially persistent (see results in Table 24). Based on the screening test results for C_{14} chlorinated n-alkane, 55.0% Cl wt., also the C_{14} congener groups with 4 to 12 chlorine atoms, which are constituting the substance, screen as potentially persistent. It is worth noting that C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt. also containC_{14} congener groups (at a relevant concentration ≥0.1% (w/w)) with 5, 6, 7 and/or 8 chlorine atoms as present in C_{14} chlorinated n-alkane, 55.0% Cl wt. As a conclusion, these substances (C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt.) cannot be rated as ready biodegradable (respectively rated as 'not P') as they always will contain constituents (i.e. congener groups with 5-8 chlorine substituents) that belong to the congener groups that screen 'potentially persistent'. The persistence of the $C_{14}Cl_{4-12}$ congener groups of MCCP (which screen as 'potentially P' based on the OECD TG 301D studies) is confirmed by a reliable higher tier simulation study in sediments, modelling data and monitoring data which further indicate that MCCP and their $C_{14}Cl_{3-14}$ congener groups have P/vP properties.

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		ATTACHMENT COMMENTS ON PAGE 9, PARAGRAPH 3 This does not appear to be a true WoE approach to evaluating the available P data for MCCP, but an apparent policy change by ECHA that the OECD 301 guideline is not suitable for UVCB substances. Further, as previously noted in these comments, ECHA has apparently elevated the "congener" to a real constituent of MCCP when it is not. In reality, we cannot identify the individual constituents of MCCP. This means that the 301 guideline studies are as appropriate for the determination of the biodegradation rate of MCCP as the OECD 308; a test guideline which suffers from well-established8 methodological concerns for poorly soluble, highly lipophilic substances.	Furthermore, the OECD TG 308 study was not the only study considered to conclude on persistence, as the weight-of-evidence approach also includes modelling data and monitoring data available for MCCP and/or congener groups of MCCP (including results at the level of structural isomers of MCCP for modelling data). ATTACHMENT COMMENTS ON PAGE 9, PARAGRAPH 3 We do not agree with the statement 'this does not appear to be a true WoE approach to evaluating the available P data for MCCP, but an apparent policy change by ECHA that the OECD 301 guideline is not suitable for UVCB substances'. Please note that the P assessment performed by ECHA for MCCP and their congener groups is following the PBT guidance (REACH Chapter R.11, ECHA, 2017b). On page 115 of the PBT guidance under Section R.11.4.2.2 'Assessment of substances containing multiple constituents, impurities and/or additives', the following is recommended regarding the interpretation of the screening test results: 'if the test item composition does not consist of similar structures or is not well characterised, it may still contain a certain amount of constituents that are persistent although the amount of easily degradable constituents is high enough to lead to an overall degradation percentage sufficient to meet the criteria for ready biodegradation'.

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
			As demonstrated above, based on the screening test results for C_{14} chlorinated n-alkane, 55.0% Cl wt., also the C_{14} congener groups with 4 to 12 chlorine atoms, which are constituting the substance, screen as potentially persistent. Some of these congener groups (such as C_{14} congener groups having 5, 6, 7 and/or 8 chlorine atoms) that screen as potentially P are also present at relevant concentrations ≥0.1% (w/w) in C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt. As a conclusion, these substances (C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt.) cannot be rated as ready biodegradable (respectively rated as 'not P') as they always will contain constituents that belong to groups of congeners that screen 'potentially persistent'. This information is confirmed by the outcome of the OECD TG 308 study which shows that all congener groups of MCCP with C_{14} carbon chain length and chlorine substitution numbers from 3 to 14 (i.e. $C_{14}Cl_{3\text{-}14}$) have P/vP properties. This is further supportedby QSAR predictions (BIOWIN 2, 3 and 6) which indicate that $C_{14\text{-}17}$ congener groups of MCCP with three chlorine atoms or more are potentially persistent. Regarding the statement 'ECHA has apparently elevated the 'congener' to a real constituent of MCCP when it is not. In reality, we cannot identify the

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
			individual constituents of MCCP'. We acknowledge that a 'congener group' does not describe an individual constituent but a grouping of many, potentially hundreds or thousands of individual constituents (i.e. structural isomers), however with a specific carbon chain length and number of chlorine substituents. This approach is scientifically reasonable and technically correct because the current analytical methods can only identify constituents of MCCP with reasonable effort at the level of congener groups but not at the level of the individual structural isomer. This technical limitation, besides practical impossibility, entails that there is also no data available that would allow PBT assessment of MCCP at the level of individual structural isomers (/constituents). That is why the PBT assessment was performed at the level of congener groups for which analytical and experimental data are available. However, QSARs were also run in order to predict the P and B properties of congener groups $C_{14}Cl_{1\text{-}14}$, $C_{15}Cl_{1\text{-}15}$, $C_{16}Cl_{1\text{-}16}$ and $C_{17}Cl_{1\text{-}17}$. The predictions were used as supporting information to the experimental data available for the congener groups of MCCP in order to conclude on the P and/or B properties of these congener groups. Furthermore, by fractionating/grouping the constituents of MCCP to 'congener groups' having distinct carbon chain lengths and numbers of chlorine substituents the PBT assessment of MCCP is following

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			the REACH guidance Chapter R.11 (ECHA, 2017b) where it is mentioned that 'a close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be covered in the PBT/vPvB assessment'. For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the same empirical formula (e.g. $C_{14}cl_5$)) was used to compare to the limit of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. ECHA does not agree with following statement 'the OECD 308; a test guideline which suffers from well-established methodological concerns for poorly soluble, highly lipophilic substances'. In the OECD TG 308 it is reported in paragraph 5 that this test 'is applicable to slightly volatile, non-volatile, water-soluble or poorly water-soluble compounds'. Furthermore in paragraph 38 of the test guideline it is mentioned that 'for hydrophobic test substances, additional sampling points during the initial period of the study may be necessary in order to determine the rate of distribution between water and sediment

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		ATTACHMENT COMMENTS ON PAGE 9, PARAGRAPH 4 The Consortium believes a proper WoE approach to the P assessment of MCCP would consider things such as how representative the test material is to the registered substance and how comprehensively the studies cover the potential range of chlorination levels of the boundary composition of the registered substance. Under these considerations the OECD 301 studies, which includes 25 separate experiments with 11 distinct test materials, provides far more weight than the single OECD 308 study.	phases' thus suggesting that this test is also applicable to lipophilic substances as lipophilicity goes along with hydrophobicity and limited/poor water-solubility. ATTACHMENT COMMENTS ON PAGE 9, PARAGRAPH 4 Regarding your comment 'the Consortium believes a proper WoE approach to the P assessment of MCCP would consider things such as how representative the test material is to the registered substance and how comprehensively the studies cover the potential range of chlorination levels of the boundary of the registered substance. Under these considerations the OECD 301 studies, which includes 25 separate experiments with 11 distinct test materials, provides far more weight than the single OECD 308 study'. ECHA would like to point out that the OECD 308 study was not the only study considered in the WoE approach as modelling data and monitoring data were also considered. Also the available OECD 301 /302 studies have been addressed in Section 3.1.4 (Summary and discussion on degradation) of the Annex XV report and it is explained and justified (this in further detail also in section '3.1.2.1.2 Screening tests') why these studies are in general terms not suitable to draw conclusions on the potential persistency of MCCP and their constituents and therefore are of limited relevance (i.e. low weight) in the WoE-based conclusions on persistency.

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		Based on these 301 data it can be concluded that:	We agree that the representativeness of the testing material to the registered substance is important including that the studies cover the potential range of chlorination levels, however the weight given to a study in a weight-of-evidence approach should be based on its reliability, relevance and adequacy for the assessment. The screening studies have been given a low weight in the WoE because ECHA has clearly explained why the screening studies cannot be considered appropriate or adequate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents. 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 the particular studies, it is not possible to draw conclusions on the persistence of the constituents of the substances tested, respectively MCCP. We do not agree that 'MCCP at 45% Cl is readily biodegradable', 'MCCP products in the range of 45-51% Cl are either readily or inherently biodegradable and therefore not persistent', 'chemical analysis of long-term CBT shows that the vast majority of all MCCP test material, regardless of chlorination level, are removed'. Please see above responses to your comments, as we already addressed these points.

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		1) MCCP at 45% Cl is readily biodegradable and therefore not persistent, 2) MCCP products in the range of 45-51% Cl are either readily or inherently biodegradable and therefore not persistent, and 3) Chemical analysis of longer-term closed bottle tests shows that the vast majority of all MCCP test materials, regardless of chlorination level, are removed (i.e. biodegraded into a metabolite). <u>ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPH 2</u> In order to further investigate the biodegradation of MCCP a new simulation study (OECD 314B guideline) is now being conducted on MCCP at 52% Cl wt. The results of the pilot study (provided in the CfE comments) using this test method showed extensive biodegradation (>90% in 24 hr). The Consortium believes that this new study will provide a critical data point on this range of chlorination level, which is the most common in the EU. The new study is expected to be completed by Q3 2021. <u>ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPH 3</u> It should be further noted that to the extent environmental monitoring data are used in a P WoE assessment, the mere detection of a	<u>ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPH 2</u> Please refer to our above response regarding the new simulation study (OECD 314 B). <u>ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPH 3</u> We do not agree with the following statement 'the mere detection of a chemical should not be the only consideration but rather whether levels in the environment exceed PNECs after years'. It is important to note that the PBT assessment is hazard based and not risk based. According to the PBT guidance (REACH Chapter R.11, ECHA, 2017b, see Section R.11.1 Introduction), 'the properties of the PBT/vPvB substances lead to an increased uncertainty

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		chemical should not be the only consideration but rather whether levels in the environment exceed PNECs after years (decades in the case of MCCP) of ongoing manufacture and use. In the case of MCCP, the environmental monitoring data in Europe, including the sediment compartment, demonstrate that levels are below the PNECs after more than 70 years of manufacture and use. These data are discussed in more detail in the registration dossier and SEv report. Under a WoE evaluation, the Consortium believe that these monitoring data indicate that MCCP is not building up in the EU environment and therefore support a 'not P' conclusion.	in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies. For PBT and vPvB substances a "safe" concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way (cf. PEC/PNEC ratio). Indeed according to the PBT guidance: 'experience with PBT/vPvB substances has shown that they can give rise to specific concerns that may arise due to their potential to accumulate in parts of the environment and that the effects of such accumulation are unpredictable in the long-term'. 'These specific concerns occur particularly with substances that can be shown both to persist for long periods and to bioaccumulate in biota and which can give rise to toxic effects after a longer time and over a greater spatial scale than substances without these properties. These effects may be difficult to detect at an early stage because of long-term exposures at normally low concentration levels and long life-cycles of species at the top of the food chain (REACH Chapter R.11, ECHA, 2017b)'. As MCCP have been demonstrated to have PBT/vPvB properties all the above statements from the PBT guidance are applicable to these substances. We do not agree with the following statement 'under a WoE evaluation, the Consortium believe that these monitoring data indicate that MCCP is not building up

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			in the EU environment and therefore support a 'not P' conclusion'. ECHA does not agree with this statement although the available monitoring data, particularly from sediment core studies, seem to 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. In addition, MCCP have been detected in various media in the Arctic, including in air from Svalbard, 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. According to the PBT guidance (REACH Chapter R.11, ECHA, 2017b) 'if monitoring data as a part of a Weight-of-Evidence analysis show that a substance is present in remote areas (i.e. long distance from populated areas and known point sources, e.g. arctic sea or Alpine lakes), it may be possible to conclude a substance as P or vP'. All this information points towards the conclusion that MCCP are persistent substances in the environment.

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			Due to a lack of temporal trend analysis of monitoring data at the EU level, we acknowledge that the monitoring data indicating an increase in concentrations of MCCP during the last decades were observed outside the EU (but in some cases in Europe, respectively the European Economic Area) such as: Switzerland (sediment and soil), Norway (biota), the Arctic (air), the Tibetan Plateau (air), China (biota) and the Antarctic (air). It is important to note that we have demonstrated that MCCP have PBT/vPvB properties and a potential for long-range environmental transport. This means that an increase in environmental concentrations at the worldwide level would have an impact at the EU level and EU emissions at the global level as the substance can be long-range transported. Furthermore, we have indication that the manufacture volume of CP has been continuously and rapidly growing during the past decades. As reported in the Annex XV report, Stiehl *et al.* (2008) further suggest that with the ban of pentabromodiphenyl ethers, the use and manufacture of CP as a flame retardant could increase even more. The global rise of CP manufacture volumes comes primarily from China (van Mourik, 2016). In recent years, manufacture of CP has decreased in Europe and North America, but has increased significantly in Asia (e.g. India, China, Taiwan and Japan) (EFSA, 2020). In addition, we have indication that in the Antarctic air, an increasing trend was observed in the ratio of MCCP to SCCP suggesting that the use of MCCP as substitute to SCCP

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		ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPHS 4 AND 5 **Bioaccumulation** In the Consortium's December 2020 CfE submission, we included a new independent WoE assessment of MCCP using the Bioaccumulation Assessment Tool (BAT) version 2.0, yet there is no mention of the SVHC proposal. The BAT provides a systematic approach to evaluating B results and thus we believe it would have provided an excellence comparison to the B evaluation provided in the SVHC proposal. Related to the B assessment, the Consortium also believe that individual communications with researchers central to the assessment (e.g. communication with M. Castro et al. regarding various studies) should be included in	had increased (Jiang *et al.,* 2021). Due to the PBT/vPvB and the potential for long-range transport properties of MCCP, the increasing trend of the concentrations of MCCP in the overall environment gives reason for concern. ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPHS 4 AND 5 WoE approach for the B assessment using the BAT tool: Please see our response above. Communication with researchers on studies used for the B assessment: The information received in our communications with study authors was already included in the Annex XV report and provides a sufficient basis to review and comment on the studies. Regarding the work on bioaccumulation in *Daphnia magna* (Castro et al., 2019 and Castro, 2020), the following information was requested from the lead author M. Castro and the relevant page where it is reported in the Annex XV report is indicated: Congener pattern distribution of the Cereclor S45 test material and the detection in Daphnia: Congeners detected are listed on page 109.

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		the assessment document. It is impossible to review and comment upon these aspects of the SVHC proposal.	The concentration of algae (when added) of 4 µC/mL is approximately $3x10^5$ algae cells/mL: page 105. Number of daphnids sampled (after the 48-hour uptake, 10 daphnids/replicate and after the 24-hour depuration, 25 daphnids/ replicate): page 105. The range of concentrations of Cereclor S45 in Daphnia after 48-hour uptake via water only: page 106. Standard deviation of the water concentration (1.18 µg/L with a standard deviation of 0.41 µg/L): page 107. Mortality in the control and treatment groups (<10%): page 106. Checking our re-calculation of BAF and BCF results from dry to wet weight, based on a 90% water content as reported in Table S4 of the supplementary information: Table 43, page 106-107. Regarding the biomagnification study (Du *et al.,* 2020) in a snake-frog prey-predator relationship, the following information was requested from one of the study author Y. Zhou and the relevant page where it is reported in the Annex XV report is indicated:

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			The date of sampling collection (the snake samples were collected in October 2011 and the frog samples were collected on 25th September, 4th October and 22nd October 2011): page 118. The recovery rate of MCCP (a recovery of 85±15% (mean±RSD) was observed for MCCP): page 119. BMF values for the different congener groups of MCCP in the muscle and in the liver: Table 45 on pages 120-121. <u>ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPH 6</u> **7. Conclusions** Please refer to our previous responses to your comments in the conclusions section.
		<u>ATTACHMENT COMMENTS ON PAGE 10, PARAGRAPH 6</u> **7. Conclusions** There is an overall inherent contradiction in ECHA's approach to the MCCP SVHC proposal in that it simultaneously attempts to treat MCCP as both a substance and also a mixture of different congeners. Given that congeners are themselves UVCB groupings of constituents, we believe that the only appropriate path is to consider MCCP as the substance that it is. On this approach, MCCP below a certain chlorination level by weight does not meet the	

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		SVHC criteria in accordance with ECHA's guidance of 11.4.2.2 and thus should not be added to the Candidate List. The Consortium believes that there is clear basis for limiting the SVHC listing on MCCP to just those commercial products above a certain chlorination level. This practice has been established under the Stockholm Convention with the listing of Short-Chain Chlorinated Paraffins (SCCP) only above 48% Cl by weight. A similar proposal has been made by the United Kingdom for MCCP, though the Consortium believes that the POP's proposed chlorination level of 45% Cl is too low based on the existing evidence and should be 50% Cl based on existing data or perhaps even 52% Cl pending the results of the new OECD 314B study on that chlorination level. Listing all MCCP, regardless of chlorination level by weight, based on "congeners" is simply inconsistent with the whole substance data already available. <u>ATTACHMENT COMMENTS ON PAGE 11, PARAGRAPHS 2, 3, 4 AND 5</u> Though socioeconomic and risk considerations are not the focus of the SVHC proposal, the Consortium feels it is important to emphasise the following given the very real impact that an SVHC listing has on a substance: • • MCCP is being manufactured and used in a responsible manner in the EU that	<u>ATTACHMENT COMMENTS ON PAGE 11, PARAGRAPHS 2, 3, 4 AND 5</u> Thank you for the information submitted. Comments regarding alternatives, socio-economic impacts and risks, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance.

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		minimises releases and is not, according to the SEV, creating unacceptable risks to human health and the environment. These results are confirmed by environmental and human monitoring studies, including an extensive review recently conducted by EFSA. This may not be the case for MCCP (or broader chain length CPs) that are manufactured and used outside of Europe. This is relevant since the elimination of responsible use of MCCP in Europe will likely provide an incentive to import articles that contain MCCP or other CPs. The Consortium does not believe that this concern can be addressed by the attempt to add a range of chloroalkane constituents to the Candidate List. The reality is that this approach will primarily impact European manufacturers and users and may not be fully understood (or perhaps even openly disregarded) by foreign manufacturers. • MCCP registrants take the responsible use of MCCP very seriously by communicating with downstream users about the importance of not discharging or releasing MCCP into the environment and treating wastes appropriately. The Consortium is working closely with the registrants and downstream users to ensure that these no discharge/no release practices are being followed.	

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		• A new lifecycle assessment of MCCP use in PVC cable insulation is being completed by the CEFIC Chloroalkanes Product Group and will be available for review by ECHA and member states shortly. This assessment found that MCCP has a lower environmental impact than the alternatives for use in PVC cables in all impact categories that were available.	
5542 2021/04/23	INOVYN, Company, Liechtenstein		**Background** Thank you for submitting information during the call for evidence on MCCP in December 2020. Please note that the PBT assessment performed by ECHA concluded at the level of the congener groups of MCCP in accordance with REACH Annex XIII. For this work, ECHA re-assessed all the studies in the substance evaluation report (EA, 2019). The PBT assessment performed by ECHA is in line with the REACH Guidances and the provisions of REACH Annex XIII. Please refer to our responses to comment #5536, as these responses address your comments made for the call for evidence. **1.1. Substance Identity** The proposed entry does not address one individual substance, on the contrary all UVCB substances that correspond to the description "*UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17*" are concerned by the entry.

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			The substance registered under REACH and identified using the identifiers: EC number 287-477-0, EC name Alkanes, C14-17, chloro and CAS number 85535-85-9 meets the above description and therefore it is considered to be among the substances that fall within the scope of the proposed entry. The information given in Section 1.2 of the Annex XV dossier does not reflect the composition of one specific substance. This section aims at providing generic information on the compositions that may be expected for the various UVCB substances that fall within the scope of the proposed entry. In addition, the possible presence of other chain lengths than $C_{14\text{-}17}$ in the composition of these substances is reported for completeness and for enabling the reader to appreciate the variety of possible constituents present in the composition of these substances. **Biodegradation Screening tests:** Regarding your comment 'even though congener groups may share the same empirical formula, it is not possible that one single constituent of MCCP can be present at above 0.1% w/w. Since exact degradation will depend upon precise molecular (as opposed to empirical) formula, it cannot be concluded

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			that all members of a congener group will have the same biodegradation property'. We acknowledge that a 'congener group' does not describe an individual constituent but a grouping of many, potentially hundreds or thousands of individual constituents (i.e. structural isomers), however with a specific carbon chain length and number of chlorine substituents. We also acknowledge that the current analytical methods can only identify congener groups of MCCP and that identification at the level of the individual constituent (i.e. structural isomer) is not technically feasible or at least very challenging. Due to the analytical challenges and the practical impossibility to carry out assessment on thousands of structural isomers the PBT assessment was performed at the level of congener groups for which experimental data are available. The PBT assessment of MCCP is following the REACH guidance Chapter R.11 (ECHA, 2017b) where it is mentioned that 'for very complex UVCBs it is possible that individual constituents are present in concentrations <0.1% (w/w) and that these have not been characterised by chemical analysis individually. For UVCBs even the whole substance may consist of individual constituents only present in such low concentrations. The fact that all individual constituents of a UVCB-substance are present in concentration <0.1% (w/w) does not exempt the registrant from the obligation to carry out the PBT/vPvB assessment. A close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same

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			carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be covered in the PBT/vPvB assessment'. For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the same empirical formula (e.g. $C_{14}cl_5$)) was used to compare to the limit of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. Although the PBT assessment was performed at the level of congener groups for which experimental data are available, QSAR predictions confirm that several congener groups contain constituents with the property of concern (or under assessment,) thus enabling an overall conclusion on the P or B properties of the congener group(s) assessed. For the purpose of modelling, several isomeric structures (constituents) were enumerated per congener group (see Annex II of the SVHC support document and other responses to your comments below). The predictions for the individual structural isomers were used as supporting information (low weight in WoE) to the experimental data available for the congener groups of MCCP in order to conclude WoE based on the P and B properties of each group of congener.

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			Your comments in the second paragraph of the "Biodegradation Screening tests" section starting with "**Page 84** of the SVHC proposal…" concerns among other issues the selection of structures for the QSAR predictions. This selection is described in detail in Annex II of the Annex XV report as follows: A software (UVCB G Graph v. 1.8.0) was used to enumerate the structures for the QSAR predictions so that the process was rather automatic and to some degree random. A pre-selection was defined to exclude branched structures and structures with a second chlorine substitution on the same carbon. A choice was also made to have more structures for those congener groups that represent the more typical chlorination degree of commercial mixtures with 40—65% chlorination by weight. The enumeration of structures was undertaken in two steps. Firstly, the software generated all possible combinations of structures for the congeners of each carbon chain length (C_{14}-C_{17}). Secondly, a more manageable number of structures were selected per carbon chain length based on log Kow, so that twenty fractions based on difference in log Kow were defined across the congener groups per carbon chain length. From each of the twenty fractions three structures were chosen at random. The enumerated structures of this selection include structures where the chlorine substituent is bound to carbon atoms separated by unsubstituted carbon,

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			structures where the chlorine substituent is bound to carbon atoms adjacent to each other, as well as structures where the chlorine substituent is bound to the terminal carbon(s). In other words, some structures have the chlorine substituents more spaced out, whereas other have them more grouped together. Based on the above, ECHA does not agree with the following statement: "Consequently, structures for example wherein two carbon substituted chlorine atoms are separated by unsubstituted carbon may not have been included for the QSAR calculations". Many such structures were indeed included in the whole selection (for example, structure $C_{15}Cl_4$ (D) in Table 38). For transparency we have added images of the enumerated structures which have been used for the QSAR predictions to Annex II of the SVHC support document. From this Annex it can be seen that structures wherein two chlorine substituted carbon atoms are separated by unsubstituted carbon have been used in the QSAR predictions. The selection of structures for Table 38 was a means to illustrate the differences in predicted BCFs, mitigating factors (metabolism and molecular size) and log Kow for a couple of different structures (constituents) of the same congener groups $C_{15}Cl_4$ and $C_{16}Cl_9$. ECHA believes this is appropriately described in the text explaining Table 38. As can be seen, the structures included for the congener group $C_{15}Cl_4$ in Table 38 comprise structures where chlorine

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			atoms are substituted to carbon atoms separated by unsubstituted carbon ($C_{15}Cl_4$ (D)), structures where chlorine atoms are substituted to carbon atoms adjacent to each other ($C_{15}Cl_4$ (A and B)) and structures where a chlorine atom is substituted to the terminal carbon(s)($C_{15}Cl_4$ (B, C and D)). Hence, ECHA does not agree with your comment that "…the structures selected in Table 38 for C15Cl4 are all those structures wherein chlorine atoms are positioned on adjacent carbon atoms." The structures for the congener group $C_{16}Cl_9$ include those where the positioning of the chlorines is more grouped together ($C_{16}Cl_9$ (B)) as opposed to more spread across the carbon chain ($C_{16}Cl_9$ (C)). For this congener group, structures with the chlorine atoms positioned on carbon atoms separated by unsubstituted carbon is not possible due to the number of chlorine atoms (which is nine). All the enumerated structures used for the QSAR predictions for the congener groups $C_{15}Cl_4$ and $C_{16}Cl_9$ are presented in Annex II of the Support Document. ECHA believes that this illustration and Table 38 demonstrate that log Kow, bioaccumulation and metabolism may to some extent vary for different constituents of a particular congener group that can be present in MCCP. You further state in your comments that "these structures (wherein two carbon substituted chlorine atoms are separated by unsubstituted carbon) are coincidently thought to more readily biodegradable than those structures in which chlorine atoms are

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			substituted on the adjacent carbon atoms…" We also believe that the position of the chlorine atom in the structure to some extent influences physical chemical properties and environmental fate of the constituents. Hence we believe that applying a log Kow range for the second step of the enumeration of structures with the UVCB G Graph software captures differences in log Kow that are a result of differences in the positioning of the chlorine atoms in the structure. ECHA's view is that in this way the selection captured structures which can be considered both "best- and worst case" when it comes to predicting bioaccumulation, metabolism and biodegradation. Furthermore, Inovyn raise a concern about "…this grouping approach is used to tackle isomers not fitting whole product reality…". ECHA believes that the method used to enumerate structures for the QSAR predictions have resulted in a broad and diverse selection of structures that include structures with chlorine substituted to carbon atoms which have unsubstituted carbon(s) next to them, with chlorine substituted to carbon atoms adjacent to each other, as well as structures where the chlorine atom is substituted on the terminal carbon(s). Generation of the enumerated structures during chlorination of the MCCP feedstock alkanes is possible and therefore probable. There is no indication nor evidence that the commercial products would not contain these types of constituents and hence ECHA thinks that the structures used for the QSAR predictions are suitable

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			for their intended use in this PBT/vPvB assessment. Results from the QSAR predictions are used to assess and reflect potential trends in environmental fate properties for different congener groups of MCCP as well as supporting evidence in the weight-of-evidence based conclusions. Inovyn also comments that a SMILE formula for only one constituent per congener group was used for the 3.2.3 Distribution modelling, thereby ignoring the many other isomer structures present per congener group. ECHA agrees with Inovyn's comment and confirms that the modelling was run for two congener groups only ($C_{14}Cl_6$ and $C_{16}Cl_7$) using one constituent per congener group. It is mentioned in the Annex XV report that these constituents were chosen because the majority of product types have a chlorine content between 45-52 % by weight and the C_{14} chlorinated alkane dominates in the commercial products. The C_{16} congener was chosen because of its longer carbon chain length so that a comparison between two different chain lengths would be possible (EA, 2018). The main reason for undertaking the distribution modelling was to get indication of the environmental compartments to which MCCP might predominantly partition and which therefore might be of most concern regarding exposure to MCCP (namely the soil and sediment compartments). For assessment of the intrinsic hazard properties, i.e. as to whether the PBT/vPvB criteria are met, the distribution modelling results are not of particular relevance and therefore

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			they were not used in the weight-of-evidence assessment. Furthermore, the distribution modelling requires various input parameters, which are not all available for individual constituents, and this is a practical reason why only two input structures were used. We do not agree with your comment that 'the 0.1% substance concentration trigger under REACH has been misapplied to congener groups, which are theoretical groups of constituents whereas Article 57, is specific to substances'. The PBT/vPvB assessment must, according to Annex XIII to the REACH Regulation, take account of the PBT/vPvB properties of relevant constituents. Section R.11.4.1 of the PBT guidance sets out that constituents should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). As further explained in the guidance, this limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation. Additionally, the Judgments of the General Court in cases T-93/10, T-94/10, T-95/10 and T-96/10 confirmed the validity of this approach for PBT/vPvB constituents of a substance. Especially for very complex UVCBs it is possible that individual constituents are present in concentrations <0.1% (w/w) and that these have not been (or cannot be) characterised by chemical analysis individually. For UVCBs (such as MCCP) even the

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			whole substance may consist of individual constituents only present in such low concentrations. The fact that all individual constituents of a UVCB-substance are present in concentration <0.1% (w/w) does not exempt from the obligation to carry out the PBT/vPvB assessment. A close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be specifically addressed in the PBT/vPvB assessment. This approach, which is recommended and lined out in further detail in section R.11.4.2.2 of the PBT guidance, has been followed for the PBT assessment of MCCP (as has been already in previous PBT assessments, e.g. for SCCP (Alkanes C_{10}-C_{13}, chloro)). For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the same empirical formula (e.g. $C_{14}cl_5$)) was used to compare to the limit of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. ECHA therefore disagrees with the claim that the approach taken to base the PBT assessment of MCCP

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			on the respective properties of its relevant constituents (i.e. groups of congeners) rather than to assess the substance as such is inappropriate. On the contrary, the approach taken is in line with the requirements of REACH Annex XIII to take relevant constituents of a (UVCB)substance into account and with the recommendations of the guidance on how to do this. Thank you for reporting that congener groups data were developed on the 2018 CBT studies. This information has been added to the support document. Regarding your comment on the OECD TG 305 dietary study using a C_{14} chlorinated n-alkane, 50% Cl wt. (Unpublished, 2019e) which states that 'numerous results for analysis were <LOD in this study, leading to different conclusions on whether <LOD is taken as zero, 0.5LOD or at the LOD'. Please note that ECHA followed the recommendations of the Guidance document on Aspects of OECD TG 305 on Fish Bioaccumulation (OECD, 2017) where it is mentioned on page 54 (see footnote 11) that: 'In many cases chemical concentrations in fish at the end of the depuration phase in BMF studies will be very low and may fall below the limit of detection (l.o.d.). For these concentrations it will be difficult to decide on their true value, in particular when the l.o.d. is relatively high. For this reason it may be advisable to not use the time-points showing chemical concentrations in fish below the l.o.d. in data analysis. However, in some

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			cases (e.g. when depuration is fast and many of the chemical concentrations in the fish fall below the l.o.d.), it may be advisable to allocating a specific value to those values below l.o.d. (e.g., 0.5 × l.o.d.). This would then allow a sensitivity analysis to be performed for the influence of these values below l.o.d. on the outcome of the test. An example where such a consideration may be needed is where both values below and above l.o.d. are observed at the same time point'. As the depuration of MCCP congener groups was slow, we followed the recommendation of the above Guidance and we did not use the time-points showing chemical concentrations in fish below the LOD in data analysis. Regarding your comment on 'the registrants' own BAT assessment', please refer to our responses to comment #5536. **Additional Information** Thank you for the information submitted. Comments regarding alternatives, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance.

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			Regarding the proposals to set a % w/w chlorination limit, please refer to our responses to comment #5536.
5543 2021/04/23	PVC4Cables, Industry or trade association, Belgium	It will be important to analyse every single use of the MCCPs to distinguish the uses and related environmental impact. In 2019 in Europe about 140 ktonnes of PVC cables have been recycled (https://vinylplus.eu/uploads/images/progreport2020/VinylPlus%20Progress%20Report%202020_EN_sp.pdf). Additional restrictions on MCCPs would endanger this recycling activity. In addition to the impact on the Circular Economy, there would be an economic impact (loss of turnover and landfill costs) as well as a negative impact on employment at a very critical time for European economy.	Regarding your comment on the need to analyse every single use and to distinguish the uses with a relevant environmental impact from the other ones, please note that the SVHC identification of substances is based on the hazard properties of the substances (not risk based). Thank you for the information submitted. Comments regarding socio-economic impacts and impacts on the circular economy, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance.

Specific comments on the justification

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5467 2021/04/19	CHEM Trust Europe , National NGO, Germany	CHEM Trust fully supports the inclusion of Medium-chain chlorinated paraffins (MCCP) in the REACH candidate list based on REACh article 57 d) and e). The comprehensive Annex XV dossier presents a convincing a weight-of-evidence-approach and an excellent overview of how the congener groups of	Thank you for your support.

		MCCP meet the PBT and/or vPvB properties in accordance with the criteria set out in Annex XIII of the REACH Regulation	
5470 2021/04/20	Health and Environment Alliance (HEAL), International NGO, Belgium	The Health and Environment Alliance (HEAL) thanks ECHA for its proposal to identify medium-chain chlorinated paraffins (MCCP) as substances of very high concern under REACH article 57(d) and article 57(e). In our view, the supporting dossier is well-structured and fully supports this SVHC identification proposal.	Thank you for your support.
5474 2021/04/21	KÖMMERLING CHEMISCHE FABRIK GMBH, Company, Germany	*Confidential attachment removed*	See our response to your comment in Part I 'General comments on the SVHC proposal'.
5477 2021/04/22	Germany, Member State	The German CA thanks ECHA for preparing this comprehensive SVHC proposal. We support the identification of MCCPs as PBT / vPvB substances as outlined in the dossier.	Thank you for your support.
5486 2021/04/22	ANSES, National Authority, France	Despite the complexity and the high amount of data, the document is very well written and clearly demonstrates that some congeners of MCCP are PBT/vPvB. The minor comments below do not change the conclusion of the dossier. Summary of toxicokinetic data on p 13:	Thank you for your comment and your support.

		"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, C14H23.3Cl6.7 (with C14Cl5-8), C16H31Cl3 (with C16Cl2-5) and C16H21Cl13 (with C16Cl12-15) congener groups." Therefore, according to this sentence, C16H21Cl13 (with C16Cl12-15) could be concluded to be vB. However according to a following sentence, no conclusion can be stated for C16H21Cl13 (with C16Cl12-15). Could you please revise or add further explanations?	Thank you for your comment on the toxicokinetic data on page 13. We agree that based on the outcome of the dietary accumulation study (Fisk *et al.,*1996) equivalent to OECD TG 305, C_{16} Cl_{12-15} congener groups of MCCP are concluded as B/vB. However, the conclusion you are referring to corresponds to the overall B conclusion for the congener groups of MCCP after applying the weight-of-evidence (WoE) approach for concluding on the bioaccumulation potential of the congener groups of MCCP (see Annex X for further information). Details of the weight-of-evidence assessment for C_{16} Cl_{12-15} congener groups of MCCP is reported on page 145 (see section 3.4.5 Summary and discussion of bioaccumulation). On page 145, it is reported that for C_{16} Cl_{12-15} congener groups of MCCP only one supporting study is available which indicates vB (Cf. dietary accumulation studies - Fisk *et al.,*1996). BCF predictions for C_{16} Cl_{12-15} congener groups indicate 'not B'. That is why based on the above information for C_{16} Cl_{12-15} congener groups of MCCP used in a weight-of-evidence-approach, we conclude that 'it is not possible to conclude on their potential for bioaccumulation since the data available is insufficient and the results inconsistent'.
		Table 1 on p 17. It is indicated that C15 Cl6, 7, 7 are only PBT whereas it is reported to be vB on p 13, probably based on depuration half life. Could you please clarify?	Based on the weight of the evidence available, the $C_{15}Cl_5$ group of congeners is concluded B/vB (see on page 137) and C_{15} Cl_{6-8} congener groups are concluded (at least) B (see on pages 138-140). The text on page 13 is referring to $C_{15}Cl_{5-8}$ congener groups (including $C_{15}Cl_5$ concluded as B/vB) and as a consequence, the overall conclusion for all these congeners is B and/or vB.

		Biodegradation –estimated data p 30-31: Could you please add when the conclusions "Potentially P" and "Potentially P, further data needed" are applied. Please note that according to the R 11, when Biowin 2 or 6 are below 0.5 and Biowin 3 below 2.25, the conclusion potentially P/vP should be applied (for instance for C17, 3-17 Cl). "Potentially" already means that additional data would be required to conclude on the P criterion. Although the R11 guidance indicates that more degradation information is generally warranted when Biowin 3 value is between 2.25 and 2.75, it is not clear in which case you apply this conclusion and an additional explanation would be valuable. Tables 12, 13, 14, 15 and 16: Could you please add on which parameter the percentage of degradation is provided, as it is well indicated in the following tables?	Regarding your comments on the section biodegradation in water – estimated data, we have changed the conclusion phrase "Potentially P, further data needed" to "Potentially P / vP, more information needed" in Table 11 for consistency. In Table 55 (Annex II) we have changed the conclusion phrase to "Potentially P/vP**,** more information needed". We have added the explanation for "Potentially P/vP, more information needed" in a footnote under Table 11 (in the same way as for Table 55) for further clarity. We believe that the difference between "Potentially P/ vP" and "Potentially P/vP, more information needed" is explained in the second paragraph of section 3.1.2.1.1 Estimated data": "The predictions have been compared against the screening criteria for persistence in accordance with the PBT guidance (Chapter R.11, ECHA, 2017b) as follows; BIOWIN 2 <0.5 and BIOWIN 3 <2.25, or BIOWIN 6 <0.5 and BIOWIN 3 <2.25: potentially persistent or very persistent. BIOWIN 2 <0.5 and BIOWIN 3 between 2.25 and 2.75, or BIOWIN 6 <0.5 and BIOWIN 3 between 2.25 and 2.75: potentially persistent or very persistent, more information needed. Congener groups, for which the screening criteria are met for at least one of its considered constituents, are concluded as screening 'potentially persistent or very persistent', or 'potentially persistent or very persistent and more information is needed'." These Tables have been amended as suggested in the support document.

5493 2021/04/22	Norway, Member State	The Norwegian Environment Agency agrees that MCCP fulfils the SVHC criteria in REACH Article 57 d) persistent, bioaccumulative and toxic (PBT) and Article 57 (e) very persistent and very bioaccumulative (vPvB). The data used in the proposal are reliable and adequate to conclude for the substance based on available laboratory studies. Further, monitoring showing widespread contamination of MCCP in the environment and organisms support the conclusion that MCCP is P/vP and B/vB. Overall, we support that MCCP should be identified as SVHC based on REACH Article 57 d) and e).	Thank you for your support.
5498 2021/04/22	Sweden, Member State	The Swedish CA agrees that medium-chain chlorinated paraffins (MCCP) meets the criteria according to Article 57(d) and Article 57(e) in REACH and is thus eligible for identification as a substance of very high concern.	Thank you for your support.
5507 2021/04/22	Netherlands, Member State	NL supports the proposal to include Medium-chain chlorinated paraffins (MCCP) in the candidate list of SVHC in accordance with Article 57(d and e) of Regulation (EC) 1907/2006 (REACH) given the PBT and vPvB properties.	Thank you for your support.
5519 2021/04/23	European Environmental Bureau, International NGO,	The EEB welcomes ECHA's proposal to identify medium-chain chlorinated paraffins (MCCP) as Substances of Very High Concern due to their PBT and vPvB properties. The dossier provides a comprehensive motivation for SVHC identification	Thank you for your support.

	Belgium	and EEB supports the proposal to identify MCCP as SVHC according to Articles 57(d) and 57(e) of the REACH Regulation. MCCPs are complex mixtures of chlorinated n-alkanes with carbon chain lengths ranging mainly between C14 - C17 and with varying degrees of chlorination, covering thousands of constituents. Persistency: Reliable simulation biodegradation studies demonstrated that a range of C14 congeners meet the P and vP criteria of REACH Annex XIII. With the presence of these C14 congeners exceeding 0.1% (w/w) in MCCP mixtures, it can be concluded that MCCP meets the P and vP criteria. Further evidence is provided confirming that also longer chain MCCP congeners will have P and vP properties. MCCP have been detected in remote areas far away from point sources, including in the Arctic and Antarctic regions. The increasing environmental concentrations of MCCP are of concern. The monitoring data support MCCPs' persistence in the environment and long-range transport potential. Bioaccumulation: Reliable Bioconcentration studies have shown that a range of C14, C15 and C16 congeners meet the B and vB criteria of Annex XIII. As MCCP contain congeners with B and vB properties exceeding 0.1 % (w/w), MCCP can be concluded to have B and vB properties. In addition, MCCP have been detected in a wide range of wildlife. MCCP were also detected in maternal blood, umbilical cord	

		blood and breast milk, indicating that MCCP exposure of the unborn child is possible. Toxicity Based on acute and chronic aquatic toxicity studies, MCCP can be concluded to contain congener groups exceeding 0.1 % (w/w) and hence meeting the T criterion of Annex XIII. Overall, ECHA reported convincingly the very persistent, very bioaccumulative and toxic properties of MCCP, meeting the criteria laid down in REACH Annex XIII. MCCP should be included in the Candidate List and further risk management measures need to be implemented. EEB recommends that other substances than MCCP containing the MCCP congeners with PBT or vPvB properties at concentrations exceeding 0.1 % (w/w) are prioritised for SVHC identification under REACH as well. Further consideration is needed on the inclusion of MCCP under the Stockholm convention on POPs to address MCCP at the global scale.	Thank you for your comment and recommendations for additional Regulatory actions. We will point out your comment to the European Commission for potential future work on other substances containing PBT and/or vPvB congener groups of MCCP and potential inclusion of MCCP to the Stockholm Convention on POPs.
5523 2021/04/23	ChemSec, International NGO, Sweden	ChemSec agrees to identify Medium Chained Chlorinated Paraffins as Substance of Very High Concern based on the PBT/vPvB properties presented in the dossier.	Thank you for your support.
5528 2021/04/23	chemsec, International NGO,	Articles 57(d) and/or (e). ChemSec agrees to identify Medium Chained Chlorinated Paraffins as Substance of Very High	Thank you for your support.

	Sweden	Concern based on the PBT/vPvB properties presented in the dossier.	
5533 2021/04/23	Altair Chimica S.p.A., Company, Italy	MCCP is a UVCB substance as registered under REACH with EC number (287-477-0) and a CAS number (85535-85-9): so that MCCP is not a mixture or preparation of separately manufactured chloroalkane isomers or 'congeners'. We believe that SVHC proposal fails to treat in some points MCCP as a single substance instead of an unknown and variable composition substance. Further, the SVHC proposal has treated the grouping of constituents from chemical analyses (i.e congener groups) as if they are real and identifiable constituents of MCCP, which they are not. The reality is that MCCP under REACH is made from C14-17 normal paraffins, the starting feedstock has a natural distribution of the carbon chain lengths from C14 to C17. As such, there is only one meaningful variable on the composition of MCCP and it is chlorination by weight. This is the only parameter that can be controlled by the manufacturing process.	ECHA would like to highlight that the proposed entry does not address one individual substance, on the contrary all UVCB substances that correspond to the description "*UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17*" are concerned by the entry. The proposed entry addresses substances and not mixtures. The substance registered under REACH and identified using the identifiers: EC number 287-477-0, EC name Alkanes, C14-17, chloro and CAS number 85535-85-9 meets the above description and therefore it is considered to be among the substances that fall within the scope of the proposed entry. ECHA agrees that, for the MCCP substances covered by this proposal, the degree of chlorination is a parameter that can be adjusted to the product chemical specifications. Also ECHA would like to clarify that the degree of chlorination has been taken into account in the assessment that was carried out. The PBT/vPvB assessment must, according to Annex XIII to the REACH Regulation, take account of the PBT/vPvB properties of relevant constituents. Section R.11.4.1 of the PBT guidance sets out that constituents should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). As further explained in the guidance, this limit of 0.1% (w/w) is

			set based on a well-established practice recognised in European Union legislation. Additionally, the Judgments of the General Court in cases T-93/10, T-94/10, T-95/10 and T-96/10 confirmed the validity of this approach for PBT/vPvB constituents of a substance. Especially for very complex UVCBs it is possible that individual constituents are present in concentrations <0.1% (w/w) and that these have not been (or cannot be) characterised by chemical analysis individually. For UVCBs (such as MCCP) even the whole substance may consist of individual constituents only present in such low concentrations. The fact that all individual constituents of a UVCB-substance are present in concentration <0.1% (w/w) does not exempt from the obligation to carry out the PBT/vPvB assessment. A close structural similarity of individual constituents within a fraction of a UVCB substance, i.e. constituents with the same carbon number, chain lengths, degree and/or site of branching or stereoisomers, triggers the need to sum up the concentrations of these constituents and to compare the total concentration with the limit of 0.1% (w/w) in order to determine whether these constituents need to be specifically addressed in the PBT/vPvB assessment. This approach, which is recommended and lined out in further detail in section R.11.4.2.2 of the PBT guidance, has been followed for the PBT assessment of MCCP (as has been already in previous PBT assessments, e.g. for SCCP (Alkanes C_{10}-C_{13}, chloro)). For MCCP, the concentration of each congener group (which corresponds to the sum of the concentrations of individual constituents sharing the same empirical formula (e.g. $C_{14}Cl_5$)) was used to compare to the limit

			of 0.1% (w/w) in order to determine whether these congener groups of MCCP need to be specifically addressed in the PBT/vPvB assessment. ECHA therefore disagrees with the claim that the approach taken to base the PBT assessment of MCCP on the respective properties of its relevant constituents (i.e. groups of congeners) rather than to assess the substance as such is inappropriate. On the contrary, the approach taken is in line with the requirements of REACH Annex XIII to take relevant constituents of a (UVCB)substance into account and with the recommendations of the guidance on how to do this.
		These results clearly show that MCCP products below a certain chlorination level are readily biodegradable and/or inherently biodegradable. These data alone establish a basis for not considering all MCCP products as meeting the Article 57 criteria. *See the corresponding embedded attachment in table 1 of Part I:* 5533_Altair Chimica - Comments to SVHC proposal-23042021.pdf	Based on the available studies on MCCP and as reported in the Annex XV report, ECHA does not agree with the following statement: 'MCCP products below a certain chlorination level are readily biodegradable and/or inherently biodegradable'. These screening studies are discussed in the Annex XV report, and ECHA has clearly explained why the screening studies cannot be considered appropriate for assessing and concluding on the persistence properties of UVCB substances such as MCCP and their constituents. 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 the particular studies, it is not possible to draw conclusions on the persistence of the constituents of the substances tested, respectively

			MCCP. Furthermore, a reliable higher tier simulation study in sediments, modelling data and monitoring data further demonstrate that some congener groups of MCCP have P/vP properties. As 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 'persistence' (P) and 'very persistent' (vP) criteria of REACH Annex XIII (degradation half-life in sediment > 180 days). Response to comments in the attachment: Thank you for the information submitted in the attachment. Comments regarding use, volumes and socio-economic impacts, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance. Regarding your proposal to limit the SVHC listing on MCCP to just those commercial products above a certain chlorination level (50% or 52% Cl by weight), please note that ECHA was mandated by the European Commission to prepare an SVHC dossier on MCCP with this proposed SVHC entry. Furthermore, ECHA does not agree with your proposal. ECHA has clearly demonstrated in the Annex XV report that based on the available information, MCCP contain lower than 50% chlorinated congener groups with PBT and/or vPvB properties (please refer to the explanatory text above Table 52 in the Annex XV report) at a concentration ≥ 0.1 % (w/w) that is why 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). Regarding the new OECD TG 314B study, ECHA is of the opinion that the outcome of this study will not change the P conclusion for MCCP. Indeed, according to REACH guidance Chapter R.7b, OECD TG 314B studies cannot be used on their own for PBT/vPvB assessment and may only be considered as a part of a weight-of-evidence approach. In particular, the half-lives determined from those tests are not suitable for comparison with the REACH Annex XIII criteria for persistence. These studies indeed do not employ relevant environmental conditions for assessing the persistence of the substance in the compartments relevant for the PBT/vPvB assessment, i.e.: natural surface water, sediment or soil. For the PBT/vPvB assessment it has to be demonstrated that the substance will indeed not persist in any of the environmental compartments (in our case MCCP have been demonstrated to be persistent in the sediment compartment). Therefore, not only exposure to natural water from STP effluents but also other possibilities of exposure (including indirect exposure and redistribution between environmental compartments) need to be taken into account for the PBT/vPvB assessment. Furthermore, REACH guidance Chapter R.7b further mentions/recommends that OECD TG 314 study does not give a direct measurement of degradation but rather removal of the test substance including both degradation and adsorption as characterised by a STP and it should not be used as a replacement for simulation tests for degradation in environmental compartments such as

			surface water, sediment or soil (i.e. OECD TG 309, 308 or 307 type studies).
5535 2021/04/23	Federchimica, Industry or trade association, Italy	MCCP is a UVCB substance as registered under REACH with EC number (287-477-0) and a CAS number (85535-85-9): so that MCCP is not a mixture or preparation of separately manufactured chloroalkane isomers or 'congeners'. We believe that SVHC proposal fails to treat in some points MCCP as a single substance instead of an unknown and variable composition substance. Further, the SVHC proposal has treated the grouping of constituents from chemical analyses (i.e congener groups) as if they are real and identifiable constituents of MCCP, which they are not. The reality is that MCCP under REACH is made from C14-17 normal paraffins, the starting feedstock has a natural distribution of the carbon chain lengths from C14 to C17. As such, there is only one meaningful variable on the composition of MCCP and it is chlorination by weight. This is the only parameter that can be controlled by the manufacturing process. These results clearly show that MCCP products below a certain chlorination level are readily biodegradable and/or inherently biodegradable. These data alone establish a basis for not considering all MCCP products as meeting the Article 57 criteria.	Please refer to our response to comment #5533 (see above response).
5536 2021/04/23	MCCP REACH Consortium of the	Please see attached comments from the MCCP REACH Consortium.	See our response to your comment in Part I 'General comments on the SVHC proposal'.

	Chlorinated Paraffins Industry Association, Industry or trade association, United States of America	*See the corresponding embedded attachment in table 1 of Part I:* 5536_MCCP REACH - SVHC Comments - Final 23-April-2021.pdf	
5541 2021/04/23	Caffaro Industrie S.p.A., Company, Italy	MCCP is a UVCB substance as registered under REACH with EC number (287-477-0) and a CAS number (85535-85-9): so that MCCP is not a mixture or preparation of separately manufactured chloroalkane isomers or 'congeners'. We believe that SVHC proposal fails to treat in some points MCCP as a single substance instead of an unknown and variable composition substance. Further, the SVHC proposal has treated the grouping of constituents from chemical analyses (i.e congener groups) as if they are real and identifiable constituents of MCCP, which they are not. The reality is that MCCP under REACH is made from C14-17 normal paraffins, the starting feedstock has a natural distribution of the carbon chain lengths from C14 to C17. As such, there is only one meaningful variable on the composition of MCCP and it is chlorination by weight. This is the only parameter that is can be controlled by the manufacturing process. These results clearly show that MCCP products below a certain chlorination level are readily biodegradable and/or inherently biodegradable. These data alone establish a basis for not considering all MCCP products as meeting the Article 57 criteria.	Please refer to our responses to comment #5533.

5542 2021/04/23	INOVYN, Company, Liechtenstein	The comments of INOVYN, as lead registrant for MCCPs, are attached and cover all areas of the proposal. *Confidential attachment removed*	See our response to your comment in Part I 'General comments on the SVHC proposal'.
5543 2021/04/23	PVC4Cables, Industry or trade association, Belgium	We leave it to other stakeholders, who have more data and knowledge, to comment on this point.	Noted, thank you for your comment.
5545 2021/04/23	Finland, Member State	We thank ECHA for this Annex XV report and the UK CA for conducting the substance evaluation on MCCP. We agree that MCCP meet the criteria for a PBT and/or vPvB substance in accordance with Annex XIII of the REACH Regulation, as specified in the Annex XV report, and that MCCP thereby fulfil the criteria set out in REACH Articles 57(d) and/or (e). We also agree with the conclusions on the P, B, and T properties of the specific congener groups of MCCP, as stated in the Annex XV report. We have the following specific comments on the Annex XV report: 3.1.2.1.1 Estimated data: comment: We note that according to ECHA guidance (R.11) Biowin models do not indicate "not P" but only "Potentially P or vP". If the screening thresholds for "potentially P or vP" are not met, the conclusion "not P" can still not be made based on QSARs only (see table R.11-4). In contrast, from screening tests, also a conclusion "Not P and not vP" is possible (table R.11-4). Therefore, we suggest to change the conclusion "not P" to "does not screen as P/vP" when considering the BIOWIN criteria only (at least page 30 and Table 11).	Thank you for your comment. 3.1.2.1.1 Estimated data: comment: We have implemented your suggested changes and additions in the text and Table 11 of section 3.1.2.1.1, as well as in Annex II.

		The guidance also states that "QSAR predictions can be used as part of a Weight-of-Evidence approach: predictions that the substance is not rapidly degradable would support the conclusion that the substance is potentially P/vP. In the contrary situation, predictions indicating that the substance could degrade rapidly would support the conclusion that the substance is not persistent. However, QSAR results alone are in most cases not sufficient to conclude on non-persistence but should be supported by additional information page 31: "However, the reliable predictions for C14Cl3, C15Cl3, C16Cl3 and C17Cl3 are already below the thresholds for screening as potentially persistent." comment: "below the thresholds" could be interpreted as not fulfilling the screening conditions. Therefore, the sentence could be made more easily understandable without specific knowledge of the thresholds, e.g. "However, the results of the reliable predictions for C14Cl3, C15Cl3, C16Cl3 and C17Cl3 are below the thresholds of the guidance, i.e., they fulfil the conditions for screening as potentially persistent." page 31: "This means that even if the predicted value may be overestimated for the congeners of higher degrees of chlorination, the trend is clear, indicating that MCCP congener groups with three chlorine atoms or more are not readily biodegradable and hence screen as potentially persistent."	

		comment: The "predicted value" could be replaced by "predicted biodegradability" or "predicted probability or rate of biodegradability" to make the sentence more concrete. Also, the assumed reason for the overestimation could be mentioned. We understand that the reason for the assumed potential overestimation is the assumption of additivity of the effect of chlorine fragments on biodegradability. Biowin guidance states "Group contribution models assume additivity of fragments no matter what their type and number, a simplifying assumption necessary to make the approach practical. This yields reasonable results most of the time, when small molecules contain only commonly found fragments that are present in small numbers. However, wrong predictions become more likely even for positive fragments if their frequency is high." 3.1.2.1.2 Screening tests comment: We note that "pass/fail" is used to indicate whether 60% degradation was reached within 28 days or 60 days (as explained in Table 24 footnote). In ECHA guidance (R.7b) it is indicated that "The prolongation of the test duration should only be considered if some initial, slow but steady, biodegradation was observed but did not reach a plateau by the end of the ready biodegradability test, i.e. after 28 days. However, a late acceleration of biodegradation is likely to reflect an adaptation of the microorganisms and in that case the prolongation of the test duration should not be regarded as adequate for the P/vP assessment. ".	3.1.2.1.2 Screening tests Thank you for your comments on the screening tests. References to the REACH guidance Chapter R.7b has been added to the support document.

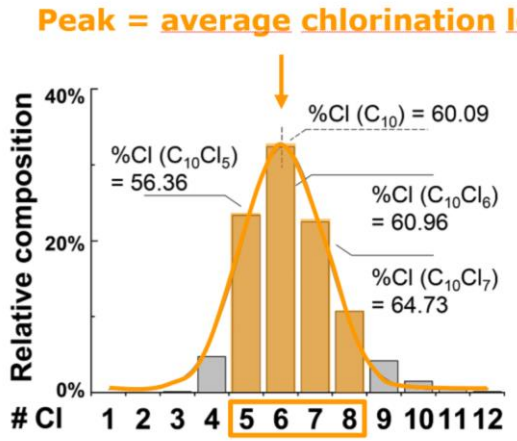
		It is also stated in the guidance that "The purpose of those enhancements should only be to compensate the poor bioavailability to the degrading microorganisms of poorly soluble and/or adsorptive substances, but should not be used to induce additional adaptation of the inoculum." We propose to consider including a remark that there are certain reservations for using the 60- day result, also considering that modification to increase bioavailability was used (even if bioavailability constraints could be possible even when modifications are used). The ultimate degradation kinetics reflect the degradation of the whole test substance and the constituents/fractions may differ in their bioavailability. For UVCB test substances it may be difficult to demonstrate whether the guidance preconditions (e.g., "some initial, slow but steady, biodegradation…")" for using the extended test period are fulfilled, at least when the primary degradation of the constituents/fractions is not measured. We have not studied the data sets of all the screening tests in detail. However, we note that at least for "C14 chlorinated n-alkane, 50% Cl wt. substance (average value)" (data presented on page 41), there is relatively slow degradation between days 0-7, fast degradation between days 7-28, with slower degradation from day 28 onwards. It could be argued that the kinetics deviate from the description in the guidance. Also, the available results for percentage	A remark has been added to Table 24 footnote but it refers to the difficulty to demonstrate whether the guidance pre-conditions for using the extended test period are fulfilled. Thank you for your comment. A text has been added to the support document regarding the difficulty to demonstrate whether the guidance pre-conditions for using the extended test period are fulfilled. We further looked at the kinetics of degradation for C14 chlorinated n-alkane, 50% Cl wt. substance and we did not see any deviation from the description in the guidance. Please note that according to the OECD

		degradation of the chlorinated paraffin (based on test material) for some of the screening tests indicate that the degradation of the test substance was not complete, even when the pass level for ultimate degradation was reached (Table 20), which is in line with the PBT guidance (R.11) which mentions that "If the test item composition does not consist of similar structures or is not well characterised, it may still contain a certain amount of constituents that are persistent although the amount of easily degradable constituents is high enough to lead to an overall degradation percentage sufficient to meet the criteria for ready biodegradation".	'the pass levels of either 60% (ThOD or ThCO2) or 70% DOC practically represent complete ultimate degradation of the test substance as the remaining fraction of 30-40% of the test substance is assumed to be assimilated by the biomass or present as products of biosynthesis' (Link to this source of information: https://www.oecd.org/chemicalsafety/testing/5598432.pdf). However, the OECD "Guidelines for the Testing of Chemicals, Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3 Part I: Principles and Strategies Related to the Testing of Degradation of Organic Chemicals" (OECD, 2006) indicate that ready biodegradability tests are intended for pure substances and are generally not applicable for complex compositions containing different types of congeners, like UVCB. For an UVCB substance, observed biodegradation may indeed represent the biodegradation of only some of its constituents. Furthermore, the PBT guidance (REACH Chapter R.11, ECHA, 2017b), indicates that if the test item composition does not consist of similar structures or is not well characterised, it may still contain a certain amount of constituents that are persistent although the amount of easily degradable constituents is high enough to lead to an overall degradation percentage sufficient to meet the criteria for ready biodegradation. For UVCB substances, there are uncertainties related to the screening tests where the contribution of the different congeners of MCCP to the overall degradation is unknown. That is why screening tests 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, are considered not sufficient to draw conclusions on the persistence of MCCP as a substance and in particular on the persistence of its different congener groups and individual constituents.
		page 49: "Congener group-specific analyses were presented for the extracted samples and no significant variation was observed between these extracts, the extracted spiked sand and the original test substance." comment: Does this mean that there was no significant variation in the proportions of the congener groups during the study duration? It could be clarified whether the congener groups were analysed both in the beginning and at the end of the study.	**Page 49:** It means that there was no significant variation in the concentrations of the C_{14} 50% Cl test material and in the concentrations of the congener groups of MCCP (including congener groups pattern) measured at the beginning and at the end of the study. The congener group pattern found in the spiked sediment matched the C_{14} 50% Cl test material. The average concentrations in the water-sediment system of the C_{14} 50% Cl test material at the beginning and end of the experiment (concentrations ranged from 4.6 to 6.4 µg/g) were in line with the spiked concentration of 5 µg/g. The concentrations of the C_{14} 50% Cl test material (total C_{14}) and the concentrations of each congener group of MCCP were measured at different time points during the experiment (at days: 0, 15, 30, 45, 60, 91 and 120). Text has been added to the support document as suggested.
		page 49: "The total water-sediment degradation half-lives under aerobic conditions for the C14 Cl3-14 congener groups (equivalent to 35.32–72.98% Cl wt.) have been derived using a first order kinetic and they are all above 180 days at 12°C."	**Page 49:** We agree with your comment that in absence of a decrease in concentrations, the rate constant k of the SFO model is not statistically different from zero and the half-live derived from the model is uncertain.

		comment: It is indicated in the Annex XV report that chemical analysis showed no observable biotransformation. Still, it is mentioned that first-order half-lives have been calculated. The model-derived half-lives or the associated statistical parameters are not included in the Annex XV report. However, if there is no decrease in concentration, then the rate constant k is likely to be statistically not different from zero and the half-life is not meaningful. We propose to consider presenting the results based primarily on the study duration, i.e. that the degradation half-life exceeds study duration (120 days) and, as no degradation was observed in 120 days, it can be reasonably assumed that the degradation half-life exceeds 180 days even if the exact half-life is not known. In the MSC support document for 2-Benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) (EC 222-346-6) it was stated: "Please note that not in all cases the DT50 was reached within the experimental period. Extrapolation of data is always insecure and thus respective DT50 should be interpreted with care. Nevertheless, it is possible to conclude on reaching certain trigger values although it is impossible to define exact values.". We recommend to follow the same line of reasoning here. **page 50**: "However, it is important to note that no study has observed yet degradation pathways that could lead a chain length reduction." comment: The screening tests described in this Annex XV report indicate significant CO2 production. This indicates that the chain length	However, ECHA run models for documentation purpose and in order to demonstrate that the DT50 values of MCCP and congener groups of MCCP are well above the threshold value of 180 days. First-order or bi-phasic models were run for each congener group of MCCP following the recommendations of the Generic Guidance Document for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (FOCUS, 2014) and as recommended in the PBT Guidance (REACH Chapter R.11, ECHA, 2017b). This information has been added to the support document in a new Annex (cf. Annex XII). We have changed the conclusion in the support document to reflect your comment. **Page 50**: This sentence has been deleted.

		must have been reduced in those studies. Consequently, we propose to modify or delete this sentence.	
5554 2021/04/23	Environment Agency, National Authority, United Kingdom	**General comment:** Where the text "is expected to contain" [specific congeners] is used in relation to a specific laboratory test, please be clear when this is speculation on the part of the dossier submitter. As noted below, the analytical ability to discern specific congeners is limited, particularly with less than 5 chlorine atoms, and so extrapolating from studies where this level of analysis has been provided is uncertain.	**General comment:** Text has been added to the support document to specify when the Gaussian distribution has been considered to describe the composition of chlorinated congeners. The average degree of chlorination of the testing materials is reported in the studies. However, further information on the composition of the testing materials is missing in many study reports. In these cases, we considered a Gaussian distribution to estimate for a given carbon chain length the composition (i.e. compositional profile) of the chlorinated congener groups. The distribution was expected to be centred between the congeners having a chlorine content just above and below the average degree of chlorination of the substance. The chemical analyses of commercial chlorinated paraffins in the literature have confirmed that the composition of chlorinated congeners with a given carbon chain length is following a Gaussian distribution. For a given carbon chain length, the numerical range of chlorine atoms around the peak of the Gaussian distribution was limited to 4 in order to ensure that all the constituents considered are present in proportions well above 0.1% (w/w). Therefore, we consider this is a robust approach. See below Figure 1 as an example of Gaussian distribution for a C_{10} chlorinated n-alkane, 60.09% Cl wt. (average value). For this chlorinated paraffin, the peak of the Gaussian distribution corresponds to the

			average chlorination level (60.09% Cl wt). Based on this average chlorination level and using a Gaussian distribution, the 4 predominant congener groups present in C_{10} chlorinated n-alkane, 60.09% Cl wt. are $C_{10}Cl_5$, $C_{10}Cl_6$, $C_{10}Cl_7$ and $C_{10}Cl_8$ (all centred around the average chlorination level).  **Figure 1.** Schematic Gaussian distribution of $C_{10}Cl_m$ in the C_{10} 60.09% Cl reference standard. The curve is the Gaussian peak, the center of which is 60.09%Cl. The columns represent one possible relative composition of each $C_{10}Cl_m$ calculated from the eq 4 setting σ_i of 0.05. *Source: Yuan et al., 2017a* Reference: Yuan B, Bogdal C, Berger U, MacLeod M, Gebbink WA, Alsberg T, de Wit CA (2017a). Quantifying short-chain chlorinated paraffin congener groups. Environmental

		p17 (table 1) / p150 (table 47) / p170 (table 51): We recommend that the table indicates the extent to which an end point conclusion e.g. P or B is reliant solely or partially on QSAR supporting evidence generated for the lower chlorinated congeners (Cl3 and Cl4). We would like to see further evidence that there is enough robust data to justify the addition of chlorination levels less than 45% Cl wt. to conclude PBT for MCCPs at all chlorination levels	Science & Technology, 51, 10633-10641. Available at: https://pubs.acs.org/doi/pdf/10.1021/acs.est.7b02269 **Pages 17/150/170:** We do not see the need to add this information to the Tables you are referring to as the weight-of-evidence approach applied for concluding on the P and B properties is already detailed/explained in the text (see in particular sections: '3.1.4 Summary and discussion on degradation' and '3.4.5 Summary and discussion of bioaccumulation'). ECHA is of the opinion that enough evidence has been brought to conclude that MCCP should be identified as a PBT/vPvB substance based on the available information as we know that MCCP contain congener groups with PBT and/or vPvB properties (see Table 1 in the SVHC dossier) at a concentration ≥ 0.1 % (w/w). We know that the congener groups of MCCP having PBT and/or vPvB properties were present at a concentration ≥ 0.1 % (w/w) based on chemical analyses performed by laboratories or by using a Gaussian distribution when this information was missing in the test reports/articles. Please refer to the above response where the Gaussian distribution is further explained/detailed. It is important to note that for a given carbon chain length, the numerical range of chlorine atoms around the peak of the Gaussian distribution was limited to 4 in order to ensure that all the constituents considered are present in proportions well above 0.1% (w/w). Therefore, we consider this is a robust approach. **p22 [section 1]:**

		p22 [section 1]: Brandsma et al. (2017), Yuan et al. (2019) and Krätschmer and Schächtele (2019) document the caution that must be applied when comparing homologue and congener level characterisation of CPs. For example lower resolution methods e.g. GC-ECNI/LRMS and GC-ECD (common method up to 2011, and still in use) have insufficient sensitivity to identify and quantify congeners with fewer than 5 chlorine atoms. There are three types of quantification and qualification referenced in the text of the SVHC dossier: Bogdal et al. 2015 - pattern deconvolution Yuan et al. 2017 - homologue specific Chen et al. 2011 - linear regression The pros and cons of these are discussed in Krätschmer and Schächtele (2019). These three different types of qualification must be compared carefully when applying a generalisation about chlorination degrees. We would recommend reflecting this uncertainty in the dossier and presenting clearly that caution should still be used around interpretation of HRMS methods e.g. Krätschmer et al. (2018). For example Bogdal et al. (2015) also only reports greater than or equal to Cl5 and states: "Response Factors and Patterns of Technical CP Formulations. The sensitivity of the APCI-qTOF-HRMS method depends on the chlorine content of the CPs, particularly for SCCPs. For SCCPs, the difference in sensitivity by a factor of 50 between the 49%Cl and the 70%Cl formulation is comparable to ECNI based methods. For MCCPs,	ECHA was aware of the uncertainty around the chlorination degree and referred to the challenges in determining the precise composition of chlorinated paraffins in the SVHC dossier. We acknowledge that there are a number of challenges in the analysis of chlorinated paraffins (CP), especially their characterisation (identification of constituents/groups of constituents) and quantification. However, based on the comments received on the call for evidence (ECHA, 2020), it seems that as part of the substance evaluation process the registrants have commissioned one laboratory to develop new analytical method such as two-dimensional GC-MS methods. According to comments received by industry, it seems that "deconvolution of individual chlorination level (e.g. -Cl_4, -Cl_5, -Cl_6 etc.) is now possible although each peak still represents a large family of structural isomers of the same empirical formula. However, groups of isomers of the same carbon chain length and chlorination level can now be followed" (ECHA, 2020). Similarly, MCCP REACH Consortium (see comment #5536) indicate in their comments that based on the outcome of a GCxGC-ECD analysis of congener groups "it is possible to make some reasonable separations between the congener groups'. MCCP REACH Consortium reported in Figure 1 (see in attachment of comment #5536) a graphical presentation of GCxGC-ECD results of chlorinated tetradecane (50% Cl wt.). Figure 1 indicates that $C_{14}Cl_2$ to $C_{14}Cl_{12}$ congener groups of MCCP have been identified in the chlorinated tetradecane (50% Cl wt.). All these comments demonstrate that even if there are challenges in the

		the difference in response by a factor of 4 between the 45%Cl formulation and the 56%Cl formulation in our study is smaller than for ECNI based methods. The lower response factors for technical CP formulations with a low chlorine content is also reflected in the chlorination degree calculated on the basis of the APCI-qTOF-HRMS measurements (Table 1). For the SCCP 49%Cl, MCCP 45%Cl, and LCCP 40%Cl formulations, the chlorination degree determined by our method was higher than the manufacturer's specifications" [chlorination level]. Another point to consider is that many of the commercial products that have been analysed are from different manufacturers and an element of variation will always be observed (the values generated in quantification and qualification of MCCPs in many academic publications is declared to be related to the commercial products they have used to build the external calibration curves). References used above: Yuan, B., D. Muir, et al. (2019). "Methods for trace analysis of short-, medium-, and long-chain chlorinated paraffins: Critical review and recommendations." Analytica Chimica Acta 1074: 16-32. Krätschmer, K., C. Cojocariu, et al. (2018). "Chlorinated paraffin analysis by gas chromatography Orbitrap high- resolution mass spectrometry: Method performance, investigation of possible interferences and analysis of fish samples." Journal of Chromatography A 1539: 53-	analysis of MCCP, new analytical methods exist and based on these new methods, groups of isomers of the same carbon chain length and chlorination level can be identified. It is worth noting that in the substance evaluation report for MCCP (EA, 2019), reference is made to recent inter-laboratory studies where a technique that makes use of APCI-TOF showed for instance good results among the techniques considered (van Mourik *et al.*, 2018). This is the same technique that was used for the analyses of samples in the three studies[2] performed in response to the initial Substance Evaluation decision by the same contract laboratory on behalf of the Registrants. The results of these studies were used for the PBT assessment of MCCP. Furthermore, studies from Yuan *et al.* (2020) for determining the CP composition from the congener group level to actual isomeric discrimination by using MS spectrometry and nuclear magnetic resonance spectroscopy (NMR) are also reported in the literature. It seems that some novel techniques are currently available that can provide precise data on the composition of chlorinated paraffins at the congener group level (including chlorinated paraffins having a low chlorination level). Despite the challenges in determining the precise composition of chlorinated paraffins, ECHA is still of

[2] Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308); Bioaccumulation in Fish: Aqueous and Dietary Exposure (OECD TG 305); and Partition Coefficient (1-Octanol/Water): Slow-Stirring Method (OECD TG 123).

		61. Brandsma, S. H., L. Van Mourik, et al. (2017). "Medium-Chain Chlorinated Paraffins (CPs) Dominate in Australian Sewage Sludge." Environmental Science and Technology 51(6): 3364-3372. Krätschmer and Schächtele (2019). Interlaboratory studies on chlorinated paraffins: Evaluation of different methods for food matrices. Chemosphere (234) 252-259.	the opinion that the specifications of the chlorine content for a commercial product can still be used to identify the different groups of congeners that are expected to be present in its composition. It is worth noting that, where further information on the composition of the testing materials was missing in the study reports, the considerations made around the Gaussian distribution are related to the synthesis of this type of substances (in particular the low positional selectivity of the chlorine addition) and the overall profile of the congener groups distribution for a given carbon number. The numerical range of chlorine atoms around the peak of the Gaussian distribution was then limited to 4 in order to ensure that all the constituents considered are present in proportions well above 0.1% (w/w). Therefore, we consider this is a robust approach. References: EA (2019). Substance evaluation conclusion and evaluation report for Medium-chain chlorinated paraffins /Alkanes, C_{14-17}, chloro EC No 287-477-0, Environment Agency, December 2019 available at: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e3841 ECHA (2020). Call for evidence to support the preparation of an SVHC Annex XV report by ECHA on Alkanes, C14-17, chloro (EC number: 287-477-0; CAS number: 85535-85-9). The call for evidence started on 11/11/2010 and ended on 15/12/2020. Available at: https://echa.europa.eu/previous-calls-for-

			comments-and-evidence/-/substance-rev/26701/term van Mourik LM, van der Veen I, Crum S, de Boer J (2018). Developments and interlaboratory study of the analysis of short-chain chlorinated paraffins. Trends in Analytical Chemistry, 102, 32 - 40. Yuan B, Lysak DH, Soong R, Haddad A, Hisatsune A, Moser A, Golotvin S, Aryropoulos D, Simpson AJ, Muir CG (2020). Chlorines are not evenly substituted in chlorinated paraffins: A predicted NMR pattern matching framework for isomeric discrimination in complex contaminant mixtures. Environmental Science and Technology Letters, 7, 496–503. Available at: https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.0c00244 **Page 37 [Section 3.1.2]:** The screening studies using chlorinated paraffins were not excluded from the weight-of-evidence for persistence. They were used in the P assessment but a low weight has been assigned to this information considering that it is not possible to draw conclusions from these studies on the ready biodegradability of a specific congener group present in the test substance. We demonstrated in the SVHC report that the results of the OECD TG 301D for the C_{14} chlorinated n-alkane, 55.0% Cl wt. and the C_{14} chlorinated n-alkane, 60.2% Cl wt. substances indicate that these substances and hence also their constituents are potentially persistent (see results in Table 24). Based on the screening test results for C_{14} chlorinated n-alkane, 55.0% Cl wt., also
		p37 [Section 3.1.2]: The OECD document states "Although these tests are intended for pure chemicals, it is sometimes relevant to examine the ready biodegradability of mixtures of structurally similar chemicals like oils and surface-active substances (surfactants). Such substances often occur as mixtures of constituents with different chain-lengths, degree and/or site of branching or stereo-isomers, even in their most purified commercial forms. Testing of each individual component may be costly and impractical". This definition (e.g. different chain-lengths) suggests that the screening studies using	

		chlorinated paraffins should not be excluded from the weight of evidence for persistence. The applicability of screening studies to UVCBs should be considered on a case-by-case basis. **p48 [Section 3.1.2.1.3]:** As no significant variation in concentration was observed between the samples of day 0 and day 120 of the exposure period, it is unclear how kinetic modelling can be performed.	the C_{14} congener groups with 4 to 12 chlorine atoms, which are constituting the substance, screen as potentially persistent. It is worth noting that C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C14 chlorinated n-alkane, 50% Cl wt. also contain C_{14} congener groups (at a relevant concentration ≥0.1% (w/w)) with 5, 6, 7 and/or 8 chlorine atoms as C_{14} chlorinated n-alkane, 55.0% Cl wt. As a conclusion, these substances (C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt.) cannot be rated as ready biodegradable (respectively rated as 'not P') as they always will contain congener groups that screen 'potentially persistent'. This information is confirmed by the outcome of the OECD TG 308 study which shows that all congener groups of MCCP with C_{14} carbon chain length and chlorine substitution numbers from 3 to 14 (i.e. $C_{14}Cl_{3\text{-}14}$) have P/vP properties. This is further supported by QSAR predictions (BIOWIN 2, 3 and 6) which indicate that the $C_{14\text{-}17}$ congener groups of MCCP with three chlorine atoms or more are potentially persistent. **Page 48 [Section 3.1.2.1.3]:** We acknowledge that the UK is of the opinion that a qualitative analysis would have been sufficient here considering that no significant variation in concentration was observed between the samples at the beginning and at the end of the test. However, ECHA run models for documentation purpose and in order to demonstrate that the DT_{50} values for MCCP and congener groups of MCCP are well above the threshold value of 180 days. First-order or bi-phasic

			models were run for each congener group of MCCP following the recommendations of the Generic Guidance Document for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (FOCUS, 2014) and as recommended in the PBT Guidance (REACH Chapter R.11, ECHA, 2017b). This information has been added to the support document in a new Annex (cf. Annex XII).
		Analytical identification and quantification of the individual congeners in the test followed the described method of Brandsma et al. (2017) and should be considered reliable for congeners with greater than or equal to 5 chlorine atoms. However, as noted above, references including Brandsma et al. (2017) indicate that identification of congeners with less than chlorine 5 atoms should be treated cautiously. Therefore we suggest that there is some uncertainty in the interpretation of the persistence of these lower chlorine congeners in the study, and this should be considered in the dossier. Please also see our previous comment about page 22. Furthermore, the absence of variation between QC and exposure samples at the different time points should also be considered. For example, concentrations presented in the definitive report are identical to the nominal concentration. This suggests that:	The APCI-TOF-HRMS was used as analytical method for the OECD TG 308 study (Unpublished, 2019c). Quantification was performed against external standards. This technique can also detect the lower chlorinated congers (Cl_2–Cl_4), and SCCP, MCCP and LCCP can simultaneously be analysed in one single run (EFSA, 2020). Furthermore, the information provided in the literature on the quantification of the congener groups in chloroparaffins shows that the results obtained have in common a correlation of the compositional distribution to a Gaussian curve. Such distribution is also expected on the basis of the chemistry of these substances. Although there may be uncertainties in the analytical data ECHA would like to highlight that the composition reported in the OECD TG 308 study is also consistent with a Gaussian distribution that is centred on the average degree of chlorination indicated. Therefore, the analytical measurements from the OECD TG 308 study (Unpublished, 2019c) are considered to be adequate for the P assessment of MCCP (including for lower chlorine congeners).

		• The extraction efficiency was 100% • There is no decrease in 'concentration' with time of congener levels due to sorption mechanisms implying that no non-extractable residues were formed. Both of these points affect the confidence in both the extraction method and method of data correction using the internal standard, which may need to be followed up with the study authors. **p53 [Section 3.1.4:** The screening biodegradation studies indicate a clear trend in degradation of MCCPs based on the level of chlorination. We suggest this trend is an important part of the evidence, particularly the two tests indicating "ready biodegradation" of the	We understand that you could make the prior assumption that MCCP (including congener groups of MCCP) will form NER due to their high potential of adsorption. However, this is contradicted by the results of the study. We believe the study is valid because we did not find any serious deficiencies. We consider that factual results of the study should supersede this prior assumption. Reference: EFSA [European Food Safety Authority] (2020). Scientific opinion on the Risk assessment of chlorinated paraffins in feed and food. EFSA Panel on Contaminants in the Food Chain (CONTAM): Schrenk D, Bignami M, Bodin L, Chipman JK, del Mazo J, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Leblanc JC, Nebbia CS, Ntzani E, Petersen A, Sand S, Schwerdtle T, Vleminckx C, Wallace H, Brüschweiler B, Leonards P, Rose M, Binaglia M, Horváth Z, Ramos Bordajandi L and Nielsen E. EFSA Journal 2020; 18(3): 5991, 220 pp. doi: 10.2903/j.efsa.2020.5991. Accessed (23 December 2020) at: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.5991 **Page 53 [Section 3.1.4]:** We demonstrated in the SVHC report that the results of the OECD TG 301D for the C_{14} chlorinated n-alkane, 55.0% Cl wt. and the C_{14} chlorinated n-alkane, 60.2% Cl wt. substances indicate that these substances and hence also their constituents are potentially persistent (see results in Table 24). Based on the screening test results for C_{14} chlorinated n-alkane, 55.0% Cl wt. and

		lower chlorinated C14 substances. We recommend this be reflected in the dossier. **p89 [Section 3.4.2.2]:** The BMF study states: "It is worth noting, that BMF value could not be derived for C14Cl3, C14Cl4, C14Cl12, C14Cl13 and C14Cl14 as these congeners either were not detected and/or not enough frequently detected during the depuration phase". As per the comments above about the analytical identification of individual congeners:	also C_{14} congener groups with 4 to 12 chlorine atoms, which are constituting the substance, screen as potentially persistent. It is worth noting that C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt. also contain C_{14} congener groups (at a relevant concentration ≥0.1% (w/w)) with 5, 6, 7 and/or 8 chlorine atoms as C_{14} chlorinated n-alkane, 55.0% Cl wt. As a conclusion, these substances (C_{14} chlorinated n-alkane, 41.3% Cl wt., C_{14} chlorinated n-alkane, 45.5% Cl wt. and C_{14} chlorinated n-alkane, 50% Cl wt.) cannot be rated as ready biodegradable (respectively rated as 'not P') as they always will contain congener groups that screen 'potentially persistent'. This information is confirmed by the outcome of the OECD TG 308 study which shows that all congener groups of MCCP with C_{14} carbon chain length and chlorine substitution numbers from 3 to 14 (i.e. $C_{14}Cl_{3-14}$) have P/vP properties. This is further supported by QSAR predictions (BIOWIN 2, 3 and 6) which indicate that C_{14-17} congener groups of MCCP with three chlorine atoms or more are potentially persistent. **Page 89[Section 3.4.2.2]:** Even if the method employed for the BMF study was identical to that of the OECD TG 308, the matrices in these two tests were different (water-sediment for the OECD TG 308 versus fish for the OECD TG 305). These two different matrices will behave differently due to the solvents used for the extraction. This is confirmed by the concentrations found in the water-sediment system where all congeners were detected while in the

		the method employed for the BMF study was identical to that of the OECD TG 308 and therefore should be treated with caution. We would recommend re-plotting the data presented in Figure 2 so that the Y-axis is on the same scale. **p120 [Section 3.4.4] [Du et al, 2020]:** The study cited is a field study. We suggest that the dossier should not combine methods used to evaluate laboratory bioaccumulation studies (exposure solely via diet) with field studies (dietary and aqueous exposure) in this way, as the form of exposure is not the same. Various guidance, including ECHA's R11 guidance, specifically treats BMF values from the two types of study separately. **p120 [Section 3.4.4] [Du et al, 2020]:** In Table 45 please could the source/origin of the estimated Log KOW values be clarified? **p121 [Section 3.4.4] [Du et al 2019 / 2020]:** There are a low number of predators sampled (9), and the BMF values calculated are from muscle concentrations, not whole body (which is unknown). We, therefore, think there are significant uncertainties with using the BMF values. We note the dossier assigns a low weight to this study as well. Given this, we suggest that the level of analysis performed in the SVHC dossier to calculate congener specific BMF values is an over-extrapolation, to the extent that the values are not reliable.	fish some of the congeners were not detected and/or not enough frequently detected during the depuration phase. **Page 120 [Section 3.4.4] [Du et al, 2020]:** We do not understand your comment because the description of the Du *et al.* (2020) study is reported in the section 'field study'. **Page 120 [Section 3.4.4] [Du et al, 2020]:** According to Du et al (2020), the log kow values were predicted for all detected CP congener groups by the Moriguchi log P (Mlog P) model from the VEGA platform. This information has been added to the Table. **Page 121 [Section 3.4.4] [Du et al 2019/2020]:** Please note that the BMF values reported in Table 45 are based on the muscle and the liver tissues and that the interpretation of the BMF values was done by combining both BMF values (from the muscle and the liver tissues). BMF values in the muscles and livers of the snakes-frogs both indicate that biomagnifcation of congeners of MCCP occurs in snakes. It is mentioned in the SVHC report that the lipid normalised concentrations of MCCP in snake and frogs follow the same pattern with highest concentrations of MCCP found in the muscles (muscle > liver > adipose for the snakes and muscle > liver > eggs for frogs). We reported transparently in the SVHC report that the

			sample size of the snakes was small compared to the one for the frogs and that the BMFs do not refer to the whole body weight of the snakes and frogs. This study was used as supporting information with a low weight given in the weight-of-evidence approach for concluding on the bioaccumulation potential of the substance. Both BMF values (from the muscle and the liver tissues) indicate a potential of bioaccumulation and this study has been assessed as reliable with restrictions. For this reason, we consider these data suitable to be a low weighing part of the WoE assessment for concluding on the B. **Page 17/176 (PBT/vPvB conclusion):** As already mentioned above $C_{14}Cl_3$ and $C_{14}Cl_4$ congeners were detected/quantified in the OECD TG 308 study. The P/vP conclusion for $C_{14}Cl_3$ and $C_{14}Cl_4$ based on the OECD TG 308 study is considered to be reliable. The P and B conclusions for $C_{14}Cl_3$ and $C_{14}Cl_4$ are based on a WoE approach which means that their P and B conclusions were not solely based on the OECD TG 305/308 studies. For the B assessment, we do not understand why you are claiming that we do not have specific data for $C_{14}Cl_3$ and $C_{14}Cl_4$ as this is incorrect. Please refer to our WoE for these specific congeners as reported on pages 131-132. The vPvB conclusion for the $C_{14}Cl_3$ congener group is sufficient for regulatory action (no need for the T criterion to be fulfilled). Concerning the T assessment of the $C_{14}Cl_4$ congener group, enough information is available to conclude that it meets the T criterion. Indeed, we have demonstrated that the $C_{14}Cl_4$
		p17/176: (PBT/vPvB conclusion) Due to uncertainty in definitive detection/quantification of the C14Cl3 and C14Cl4 congeners in both the P and B definitive tests (OECD TG 308 and 305) the conclusions presented on page 17 (Table 1) should be considered very carefully. Equally, the lack of definitive B and T data for these specific congeners should be specifically highlighted and caveated in the proposal.	

			congener group was present in the test material C_{14-17}, 52% Cl wt. which meets the T criterion. The $C_{14}Cl_4$ congener group has been detected in *Daphnia magna* in a bioaccumulation test. This indicates that this group of congeners is bioavailable to *Daphnia magna* and is taken up by this organism. Since all the group of congeners present in the C_{14-17}, 52% Cl wt testing material are structurally similar and differ only in carbon chain length and number of Cl atoms, they can be expected to exert toxic effects by the same mode of action. It is therefore reasonable to assume that all congeners present in the C_{14-17}, 52% Cl wt. substance test material (including $C_{14}Cl_4$) contributed equivalently to the observed toxicity.
5555 2021/04/23	Environment Agency, National Authority, United Kingdom	General comment: Where the text "is expected to contain" [specific congeners] is used in relation to a specific laboratory test, please be clear when this is speculation on the part of the dossier submitter. As noted below, the analytical ability to discern specific congeners is limited, particularly with less than 5 chlorine atoms, and so extrapolating from studies where this level of analysis has been provided is uncertain. p17 (table 1) / p150 (table 47) / p170 (table 51): We recommend that the table indicates the extent to which an end point conclusion e.g. P or B is reliant solely or partially on QSAR supporting evidence generated for the lower chlorinated congeners (Cl3 and Cl4). We would like to see further evidence that there is enough robust data to justify the addition of chlorination levels less than 45% Cl wt. to conclude PBT for MCCPs at all chlorination levels	Please see above our responses to your comment.

		p22 [section 1]: Brandsma et al. (2017), Yuan et al. (2019) and Krätschmer and Schächtele (2019) document the caution that must be applied when comparing homologue and congener level characterisation of CPs. For example lower resolution methods e.g. GC-ECNI/LRMS and GC-ECD (common method up to 2011, and still in use) have insufficient sensitivity to identify and quantify congeners with fewer than 5 chlorine atoms. There are three types of quantification and qualification referenced in the text of the SVHC dossier: Bogdal et al. 2015 - pattern deconvolution Yuan et al. 2017 - homologue specific Chen et al. 2011 - linear regression The pros and cons of these are discussed in Krätschmer and Schächtele (2019). These three different types of qualification must be compared carefully when applying a generalisation about chlorination degrees. We would recommend reflecting this uncertainty in the dossier and presenting clearly that caution should still be used around interpretation of HRMS methods e.g. Krätschmer et al. (2018). For example Bogdal et al. (2015) also only reports greater than or equal to Cl5 and states: "Response Factors and Patterns of Technical CP Formulations. The sensitivity of the APCI-qTOF-HRMS method depends on the chlorine content of the CPs, particularly for SCCPs. For SCCPs, the difference in sensitivity by a factor of 50 between the 49%Cl and the 70%Cl formulation is comparable to ECNI based methods. For MCCPs,	

		the difference in response by a factor of 4 between the 45%Cl formulation and the 56%Cl formulation in our study is smaller than for ECNI based methods. The lower response factors for technical CP formulations with a low chlorine content is also reflected in the chlorination degree calculated on the basis of the APCI-qTOF-HRMS measurements (Table 1). For the SCCP 49%Cl, MCCP 45%Cl, and LCCP 40%Cl formulations, the chlorination degree determined by our method was higher than the manufacturer's specifications" [chlorination level]. Another point to consider is that many of the commercial products that have been analysed are from different manufacturers and an element of variation will always be observed (the values generated in quantification and qualification of MCCPs in many academic publications is declared to be related to the commercial products they have used to build the external calibration curves). References used above: Yuan, B., D. Muir, et al. (2019). "Methods for trace analysis of short-, medium-, and long-chain chlorinated paraffins: Critical review and recommendations." Analytica Chimica Acta 1074: 16-32. Krätschmer, K., C. Cojocariu, et al. (2018). "Chlorinated paraffin analysis by gas chromatography Orbitrap high- resolution mass spectrometry: Method performance, investigation of possible interferences and analysis of fish samples." Journal of Chromatography A 1539: 53-61. Brandsma, S. H., L. Van Mourik, et al. (2017). "Medium-Chain Chlorinated Paraffins (CPs)	

		Dominate in Australian Sewage Sludge." Environmental Science and Technology 51(6): 3364-3372. Krätschmer and Schächtele (2019). Interlaboratory studies on chlorinated paraffins: Evaluation of different methods for food matrices. Chemosphere (234) 252-259. p37 [Section 3.1.2]: The OECD document states "Although these tests are intended for pure chemicals, it is sometimes relevant to examine the ready biodegradability of mixtures of structurally similar chemicals like oils and surface-active substances (surfactants). Such substances often occur as mixtures of constituents with different chain-lengths, degree and/or site of branching or stereo-isomers, even in their most purified commercial forms. Testing of each individual component may be costly and impractical". This definition (e.g. different chain-lengths) suggests that the screening studies using chlorinated paraffins should not be excluded from the weight of evidence for persistence. The applicability of screening studies to UVCBs should be considered on a case-by-case basis. p48 [Section 3.1.2.1.3]: As no significant variation in concentration was observed between the samples of day 0 and day 120 of the exposure period, it is unclear how kinetic modelling can be performed. Analytical identification and quantification of the individual congeners in the test followed the described method of Brandsma et al. (2017) and	

		should be considered reliable for congeners with greater than or equal to 5 chlorine atoms. However, as noted above, references including Brandsma et al. (2017) indicate that identification of congeners with less than chlorine 5 atoms should be treated cautiously. Therefore we suggest that there is some uncertainty in the interpretation of the persistence of these lower chlorine congeners in the study, and this should be considered in the dossier. Please also see our previous comment about page 22. Furthermore, the absence of variation between QC and exposure samples at the different time points should also be considered. For example, concentrations presented in the definitive report are identical to the nominal concentration. This suggests that: • The extraction efficiency was 100% • There is no decrease in 'concentration' with time of congener levels due to sorption mechanisms implying that no non-extractable residues were formed. Both of these points affect the confidence in both the extraction method and method of data correction using the internal standard, which may need to be followed up with the study authors. p53 [Section 3.1.4: The screening biodegradation studies indicate a clear trend in degradation of MCCPs based on the level of chlorination. We suggest this trend is an important part of the evidence, particularly the two tests indicating "ready biodegradation" of the lower chlorinated	

		C14 substances. We recommend this be reflected in the dossier. p89 [Section 3.4.2.2]: The BMF study states: "It is worth noting, that BMF value could not be derived for C14Cl3, C14Cl4, C14Cl12, C14Cl13 and C14Cl14 as these congeners either were not detected and/or not enough frequently detected during the depuration phase". As per the comments above about the analytical identification of individual congeners: the method employed for the BMF study was identical to that of the OECD TG 308 and therefore should be treated with caution. We would recommend re-plotting the data presented in Figure 2 so that the Y-axis is on the same scale. p120 [Section 3.4.4] [Du et al, 2020]: The study cited is a field study. We suggest that the dossier should not combine methods used to evaluate laboratory bioaccumulation studies (exposure solely via diet) with field studies (dietary and aqueous exposure) in this way, as the form of exposure is not the same. Various guidance, including ECHA's R11 guidance, specifically treats BMF values from the two types of study separately. p120 [Section 3.4.4] [Du et al, 2020]: In Table 45 please could the source/origin of the estimated Log KOW values be clarified? p121 [Section 3.4.4] [Du et al 2019 / 2020]: There are a low number of predators sampled (9), and the BMF values calculated are from muscle	

		concentrations, not whole body (which is unknown). We, therefore, think there are significant uncertainties with using the BMF values. We note the dossier assigns a low weight to this study as well. Given this, we suggest that the level of analysis performed in the SVHC dossier to calculate congener specific BMF values is an over-extrapolation, to the extent that the values are not reliable. p17/176: (PBT/vPvB conclusion) Due to uncertainty in definitive detection/quantification of the C14Cl3 and C14Cl4 congeners in both the P and B definitive tests (OECD TG 308 and 305) the conclusions presented on page 17 (Table 1) should be considered very carefully. Equally, the lack of definitive B and T data for these specific congeners should be specifically highlighted and caveated in the proposal.	

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

Specific comments on use, exposure, alternatives and risks

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5467 2021/04/19	CHEM Trust Europe , National NGO, Germany	MCCP are of global concern as they were found in biota from remote regions, including from the Arctic and Antarctic, indicating long-range environmental transport. Furthermore, monitoring data show that concentrations of MCCP have increased in biota and in sediment	Thank you for your comment.

		over the last years - probably due to increased replacement of SCCP. CHEM Trust believes regulatory measures at EU and global level are long overdue in order to reduce emissions and exposures to these persistent, bioaccumulative and toxic contaminants.	
5474 2021/04/21	KÖMMERLING CHEMISCHE FABRIK GMBH, Company, Germany	We would like to thank ECHA for this opportunity to comment on the preparation of a Substance of Very High Concern (SVHC) Annex XV report on Alkanes, C14-17, chloro, (MCCP; EC 287-477-0; CAS 85535-85-9) under the REACH Regulation. MCCP is a significant commercial product in Europe, the ECHA public dissemination website indicates that the registered tonnage lies in the band 10 000 – 100 000 tonnes per year. It is used predominantly as a plasticiser and flame retardant in PVC, polymers and rubber (ca. 64 % of its overall use) and in the manufacture of adhesives and sealants (ca. 27 %). The remaining uses (smaller 10 %) are in metalworking fluids, paints, textiles and paper products. KÖMMERLING occupies an outstanding position on the globally growing market for adhesives and sealants for energy-efficient applications, whether as the global techno-logy leader for insulating glass sealants as the European market leader for adhesives for the production of cooling vehicles or as the leading provider of sealants for thin-film photovoltaic modules. Our	Thank you for the information submitted. Comments regarding use, exposure, alternatives, socio-economic impacts and risks, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance. As regards the initiative to submit the substance to the SVHC identification process in accordance with REACH Art. 59, please note that the European Commission requested ECHA to prepare an Annex XV dossier for MCCP.

		product portfolio offers premium solutions for all kinds of glazing. We have revolutionised the market for insulating glass sealants several times already. Energy efficiency plays a major role in our everyday lives today; to sustainably protect our natural resources, this importance will increase even further. All these technologies are inconceivable without innovative adhesives and sealants. Energy efficient glazing helps to keep heat inside and can lead to a reduction of energy consumption and thus, a reduced carbon footprint. Consequently, it has a direct effect on climate change. High performing components for energy efficient glazing, like MCPP-containing sealants, are part of the solution to the problem. Use: Within our product adhesives & sealants portfolio, MCCPs play a significant role as a component for our double and triple glazed windows sealants. Generally, sealants are considered to be materials that are installed into a gap or joint to prevent water, wind, dirt or other contaminants from passing through the joint or crack. The function of MCCP is as a plasticiser for polysulfide-based sealants. Formulators of adhesives and sealants often customize polymers, which results in new polymer species. Such customisation is required in order to fulfil technical feasibility and customer requirements as well as regulatory needs. Without such customised polymers, end users would be left with products of higher	

		hazard profile or insufficient perfor¬mance. To allow for customization, the variety of ingredients at the disposal of the adhesives and sealants industry should be ensured. The users of MCCP-containing sealants are manufacturers of insulating glass and window manufacturers, so the use category is either professional or industrial. Applications of those sealants are not designed for consumers and therefore consumer exposure is not relevant. Alternatives: The on-going discussion about chlorinated paraffins has led to intensive substitution research, but there are currently no suitable drop-in alternatives for all applications available. Compared to alternative systems based on other compounds, MCCPs provide the best compatibility with the polysulfide polymer technology. MCCP provide very good adhesion and mechanical properties as well as UV stability to the sealant, very low migration potential and the price of MCCP is much lower compared to potential alternatives. In conclusion, MCCPs provide a much better performance at a much lower cost. Both potential alternatives have twice the costs in sourcing, while the load level in formulations is the same. In addition, it should be noted, that there are various MCCP manufacturers in the EU resulting in an independence of non-EU sources, enabling a second supplier strategy. Furthermore, the feedstock of needed n-paraffin grade for MCCP	

		manufacturing is high enough and secured. However, the supply situation for alternatives is much more critical, since in some cases only one supplier exists, located in non-EU. Finally, it should be noted as well, that the potential alternatives are under regulatory scrutiny in the EU as well, opening the floor for regrettable substitution. Some of the plasticisers which were used in the past, have already been banned or restricted. Moreover, the use of MCCP does not lead to any odour of the cured sealant, contrary to potential alternatives – which might cause customer claims and demonstrating its higher volatility (consequently, higher workers and consumer exposure and higher release to the environment than MCCP). Depending on the application, there are in certain cases as well other polymer systems available. However, those systems do have other limitations, e.g. on gas permeation rate, migration potential, UV stability, performance, costs or the use of other hazardous substances in their formulations. Socio-Economic Impact: Due to the wide use of MCCPs in adhesives and sealant, any regulatory action or ban on the substance could have significant socio-economic impacts in the EU. SMEs account for a great number of the users along the supply chain. Substitution would mean a lot of research and development and time needs to be spend to reformulation of sealants and adhesives and changing other raw materials. The	

		reformulation rarely results in a product with exactly the same properties and often leads to an inferior product. Moreover, adverse impacts through increased costs of alternatives would occur, even if those drop-in alternatives existed. Also, the sealant market could be impacted by cheaper products coming from outside the EU still using MCCPs. Quantities of MCCPs used in our formulations result in a significant volume of adhesives and sealants, so any ban in our applications would have a considerable impact on the profitability and efficiency of our industry. Please note, that the COVID-19 pandemic has already a substantial negative impact on our business in particular and the economy in general. It is therefore doubtful that additional and unnecessary regulatory measures should be taken for proven safe uses. Exposure: The exposure potential to man and the environment resulting from manufacture and use of industrial and professional sealants is considered to be negligible. The sealants are likely to be applied by a caulking gun in larger applications which would lead to limited exposure. Evaluations and assessments demonstrate, that exposure from formulations and use of sealants is negligible and that PEC/PNEC ratios (RCR) are significantly below 1. Modelled occupational exposure data demonstrate for sealant applications insignificant risk.	

		Therefore, the use of MCCP in adhesive and sealant applications is considered to be safe and brings significant benefits. The attached confidential document outlines emission/exposure reduction measures, we as a responsible formulator have implemented. Risk Management Measures: The current responsible processing and uses of MCCP down the value chain does not support future inclusion in the Authorisation List (REACH Annex XIV). The requirements for Authorisation should not apply for save uses, like in sealant systems. To our mind all safe uses should be allowed and more risky uses with potential for exposure or emissions should be restricted. Therefore, the REACH Restriction process – as well considering the socio-economic impacts – seems for us the more proportionate risk management and regulatory measure. A targeted Restriction could be limited to those uses where there is actual potential for exposure. This would maximise human health and environmental protection and prevent disproportionate regulation with significant economic and societal cost. This means that we support the objective to risk management via a REACH restriction. However, as REACH restriction can be applied to substances not listed as SVHC, we consider unnecessary the SVHC listing of MCCP in order to avoid the stigmatization of the substance. *Confidential attachment removed*	

5477 2021/04/22	Germany, Member State	Numerous data and studies show that MCCPs have PBT/ vPvB properties. Therefore, these substances will persist for a long time in the environment and human exposure will occur.	Thank you for your comment.
5533 2021/04/23	Altair Chimica S.p.A., Company, Italy	*See the corresponding embedded attachment in table 1 of Part I:* 5533_Altair Chimica - Comments to SVHC proposal-23042021.pdf	Please refer to our responses to your comments in the Table 'Specific comments on the justification'.
5535 2021/04/23	Federchimica, Industry or trade association, Italy	Pag. 185 At section 9.1 "Use in PVC", quote: "According to a consultation reported in KEMI (2018), the content of the secondary plasticiser can reach up to 20% of the PVC sheathing or insulation of electric cables." we must emphatize the fact that the typical content of MCCPs in PVC cables is around 5% w/w, according to the recent survey conducted by Intertek and sponsored by CAPG (Chloro-alkanes product group, Euro Chlor) in order to conduct a life-cycle assessment as concrete response to RoHS, Annex II proposal for MCCPs. About exposure we underline that the MCCPs are manufactured and used minimizing every possible release to the environment. The MCCP are manufactured and used in closed systems. The emissions are monitored and periodically reported according the regional and national laws. About alternatives we think that these are not comparable in terms of product performance, costs and reliability: moreover, these alternatives aren't one-to-one substitutes for MCCPs, but they must be used in tandem. The	Thank you for the information submitted. Comments regarding uses, exposure, alternatives and socio-economic impacts, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance.

		other big issue is that the biggest part of these alternatives were not tested for prolonged time in these applications (e.g. more than 20 year in a cable, as done with MCCPs) so, currently, we don't really know if they will work or not. Moreover, a consistent part of these alternatives has hazardous properties and / or informations on their environmental or human health hazard are lacking. It also of paramount importance to consider that an alternative additive with a minor compatibility with the plastic could exude from the plastic itself. On the contrary the MCCP are highly compatible with other additives and the PVC plastic; thanks to this property the exude and the emission to the environment is highly unlikely. As regards Italy, we made a calculation focused on PVC cable producers, as regards economics and recycling, as below: - Italy accounts for 50 producers of cables. With MCCPs listing, and with no reliable alternatives, it is very likely that producers or will have to invest a lot of millions in order to change row material polymers (no more PVC but other polymers) or they will probably have to cease their production. - in Italy we recycle about 30ktons of PVC cables, certified: with MCCPs listing these won't be recycled anymore. This will translate in, about: € 20 million turn-over losses, € 6 million increasing waste disposal costs and 200 job losses.	
5536			

2021/04/23	MCCP REACH Consortium of the Chlorinated Paraffins Industry Association, Industry or trade association, United States of America	*See the corresponding embedded attachment in table 1 of Part I:* 5536_MCCP REACH - SVHC Comments - Final 23-April-2021.pdf	See our response to your comment in Part I 'General comments on the SVHC proposal'.
5541 2021/04/23	Caffaro Industrie S.p.A., Company, Italy	The MCCPs are manufactured and used minimizing every possible release to the environment. The MCCP are manufactured and used in closed systems. The emissions are monitored and periodically reported according the regional and national laws. The alternatives are not comparable in terms of product performance, costs and reliability: moreover, these alternatives aren't one-to-one substitutes for MCCPs, but they must be used in tandem. The other big issue is that the biggest part of these alternatives were not tested for prolonged time in these applications (e.g. more than 20 year in a cable, as done with MCCPs) so, currently, we don't really know if they will work or not. Moreover, a consistent part of these alternatives has hazardous properties and / or informations on their environmental or human health hazard are lacking. It also of paramount importance to consider that an alternative additive with a minor compatibility with the plastic could exude from the plastic itself. On the contrary the MCCP are highly compatible with other additives and the PVC	Thank you for the information submitted. Comments regarding measures to minimise emissions and alternatives, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance.

		plastic; thanks to this property the exude and the emission to the environment is highly unlikely.	
5542 2021/04/23	INOVYN, Company, Liechtenstein	*Confidential attachment removed*	See our response to your comment in Part I 'General comments on the SVHC proposal'.
5543 2021/04/23	PVC4Cables, Industry or trade association, Belgium	At section 9.1 "Use in PVC" it is mentioned that "the content of the secondary plasticiser can reach up to 20% of the PVC sheathing or insulation of electric cables." We would like to emphasise that the average content of MCCPs in PVC cables is around 5-6% w/w. The MCCPs are manufactured and used in closed systems, minimising every possible release to the environment. The emissions are monitored according to the regional and national laws. The alternatives may not be comparable in terms of performance, costs and reliability during the use for prolonged time in the cable applications (e.g., more than 20 years, as in current formulations with MCCPs) To substitute MCCPs it would be necessary to use two or more additives. Some of these could present hazardous properties. MCCPs are perfectly compatible with PVC matrix and do not have tendency to migrate into water in which they are insoluble.	Thank you for the information submitted. Comments regarding use, emissions and alternatives, if relevant, may be considered at later stages of the risk management process but are not relevant for the identification of the substance as a SVHC which is based on the hazard properties of the substance.
5544 2021/04/23	City of Stockholm, Environment and Health Administration,	In the City of Stockholm, there have been several investigations in preschool environments (Larsson et al 2017, 2018, Giovanoulis et al 2019, Langer et al 2021). In	Thank you for the information submitted. Comments regarding exposure, if relevant, may be considered at later stages of the risk management process but are not relevant for the

	Regional or local authority, Sweden	addition (unpublished results), MCCPs were included in some of the studied preschools, among other hazardous substances. Sampling of deposited indoor dust was performed by the Environment and Health Administration, and the dust was subsequently analysed by Dr. Bo Yuan at the University of Stockholm (Department of Environmental Science). MCCPs predominate in almost all indoor dusts and account for an average of 59% of total chlorinated paraffins (sum of short-, medium- and long-chain CPs). On average, the indoor dust samples contain 37 000 ng/g dust of MCCP (n=13, min=12 000 ng/g, max=84 000 ng/g). In addition, several building materials have been analysed. An insulation material known to contain MCCPs (according to the building material declaration) was analysed and the results showed that the material contains approximately 11% MCCP (by weight, n=6). In a room in one specific preschool, where this insulation material was very abundant, the deposited dust (sampled from above floor shelves) contained 150 000 ng/g dust of MCCP. In comparison to the average MCCP concentration found in the 13 preschools studied, the dust from this room contains 4 times higher concentrations, most likely due to MCCP diffusing from the insulation material to the indoor air and further to the indoor dust. References Larsson K, de Wit CA, Sellström U, et al. Brominated Flame Retardants and	identification of the substance as a SVHC which is based on the hazard properties of the substance.

		Organophosphate Esters in Preschool Dust and Children's Hand Wipes. Environ Sci Technol. 2018;52:4878-4888 Larsson K, Lindh CH, Jönsson BAG, et al. Phthalates, non-phthalate plasticizers and bisphenols in Swedish preschool dust in relation to children's exposure. Environ Int. 2017;102:114–124 Giovanoulis G, Nguyen MA, Arwidsson M, et al. Reduction of hazardous chemicals in Swedish preschool dust through article substitution actions. Environ Int. 2019;130:104921 Langer S, de Wit C, Giovanoulis G, Fäldt J, Karlson L. The effect of reduction measures on concentrations of hazardous semivolatile organic compounds in indoor air and dust of Swedish preschools. Indoor Air, 2021. Available online: https://doi.org/10.1111/ina.12842.	