

## MCCP REACH Consortium

### Comments on the February 2021 Proposal for Identification of Substances of Very High Concern on Medium-Chain Chlorinated Paraffin 23 April 2021

#### Introduction

These are the comments of the MCCP REACH Consortium<sup>1</sup> (the “Consortium”) in response to 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, C<sub>14-17</sub>, 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 (C<sub>14-17</sub> 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 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.’ 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.

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 to 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,<sup>2</sup> the reality is that MCCP under REACH is made from C<sub>14-17</sub> normal paraffins. As such, there is only one meaningful variable on the composition

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<sup>1</sup> MCCP REACH Consortium represent the co-registrants of EC 24-477-0 under the REACH regulation. Current participants in the Consortium are Altair Chimica, Caffaro Industrie S.p.A., INOVYN, QUIMICA DEL CINCA S.L.U. and Vantage Leuna GmbH.

<sup>2</sup> ECHA 24 February 2014 SEV decision on “alkanes, C<sub>14-17</sub>, chloro (MCCP, Medium-chain chlorinated paraffins), CAS No 85535-85-9 (EC No 287-477-0).”

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.

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.).

On other endpoints, the data are less uniform and thus harder to fully evaluate. The 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.

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 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%<sup>3</sup> 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.

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<sup>3</sup> The REACH text uses 0,1%, though the SVHC proposal uses 0.1%. They are the same number.

## **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 C<sub>14-17</sub> 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 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 information<sup>4</sup> 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 C<sub>14</sub> to C<sub>17</sub>."

and

"MCCP are UVCB substances. MCCP contain linear chloroalkanes with carbon chain lengths predominantly within the range of C<sub>14-17</sub> 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, C<sub>14-</sub>

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<sup>4</sup> See items #1 and #2 in the ECHA 25 February 2014 Substance Evaluation decision for alkanes, C<sub>14-17</sub>, chloro (MCCP, Medium-chain chlorinated paraffins), CAS No 85535-85-9 (EC No 287-477-0).

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 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.

## **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 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’<sup>5</sup>. 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 constituents<sup>6</sup>. 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 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

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<sup>5</sup> For the purposes of chemical analysis of chlorinated paraffins, the terms ‘congeners’ and ‘congener group’ represent the same thing.

<sup>6</sup> See Tomy 1997 (Anal. Chem. 1997, 69, 2762-2771) for a method to calculate the number of possible isomers, which grows exponentially with each increase in carbon-number.

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.

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 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 - C<sub>14</sub> (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.

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.

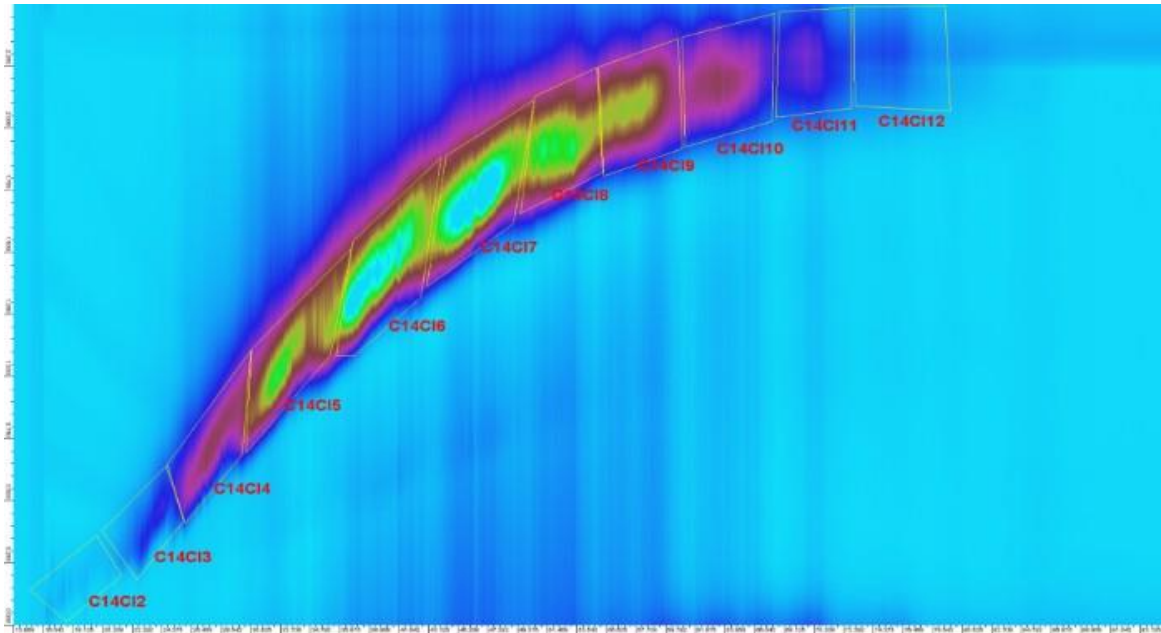
Whilst the available CP test data that have been developed utilising chemical analysis of congener groups provide some interesting insights, we still do not know if the same congener groups act similarly or differently in different chlorinated paraffin test material. Such data may be exceptionally difficult 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<sup>7</sup> on the chemical analysis of CPs showed considerable variability between different labs even using similar analytical methods.

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<sup>7</sup> L.M. van Mourik, I. van der Veen, S. Crum, J. de Boer. 2018. Developments and interlaboratory study of the analysis of short-chain chlorinated paraffins. *TrAC Trends in Analytical Chemistry*. Volume 102, Pages 32-40.

**Figure 1: Graphical Presentation of GCxGC-ECD results of Chlorinated Tetradecane (50% Cl)**

## GCxGC-ECD: C14 Cl 50%



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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 congener groups when the key metric in these studies is measured oxygen consumption and the resulting biodegradation of the overall test substance. 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 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.”

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.

### **3. 0.1% Substance trigger under REACH has been misapplied to congener groups**

At numerous places throughout the SVHC proposal it is noted that there are congeners or congener groups that are present “at a relevant concentration  $\geq 0.1\%$  (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.

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.

### **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 - and therefore the substance cannot be included on the Candidate List.

#### **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 C<sub>14-17</sub> range may also be present in the composition at lower concentration levels. However, the constituents within the C<sub>14-17</sub> 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 C<sub>14-17</sub> 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 C<sub>18</sub> and above may be present in other types of chlorinated paraffins than long-chain chlorinated paraffins (LCCP), 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 C<sub>10-13</sub> chlorinated alkyl chains corresponding to constituents of alkanes, C<sub>10-13</sub>, chloro (short-chain chlorinated paraffins or SCCP, CAS no. 85535-84-8) may as well be present in Alkanes, C<sub>14-17</sub>, 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 C<sub>14-17</sub> range (including C<sub>18</sub> and above and C<sub>13</sub> and below. In practice levels are less than 0.5% w/w. For the low carbon number range, this is principally C<sub>13</sub> 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 three substances were registered at 100% concentration (the SCCP registration is now inactive)

#### **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.



## 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:

“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.”

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-established<sup>8</sup> methodological concerns for poorly soluble, highly lipophilic substances.

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. Based on these 301 data it can be concluded that:

- 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

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<sup>8</sup> Detailed in prior submissions to ECHA, including December 2020 CfE submission and 2014 BoA case.

- 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).

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.

It should be further noted that to the extent environmental monitoring data are used in a P WoE assessment, the mere detection of a 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.

### **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 the assessment document. It is impossible to review and comment upon these aspects of the SVHC proposal.

### **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 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.

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 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.
- 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.