Risk Profile "Chlorinated paraffins with carbon chain lengths in the range C14-17 and chlorination levels at or exceeding 45% chlorine by weight" in Annex A, B or C to the Stockholm Convention on Persistent Organic Pollutants

Executive summary

[to be added]

1. Introduction

2. In April 2021, the United Kingdom of Great Britain and Northern Ireland submitted a proposal to list chlorinated paraffins (CPs) with carbon chain lengths in the range C_{14-17} and chlorination levels at or exceeding 45 per cent chlorine by weight in Annexes A, B and/or C of the Convention. The proposal was submitted in accordance with Article 8 of the Convention and was reviewed by the Persistent Organic Pollutants Review Committee (POPRC) at its seventeenth meeting held in January 2022.

1.1. Chemical identity

1.1.1. CAS number, chain length and chlorination

3. Chlorinated paraffins (CPs) are manufactured substances consisting of predominantly linear chloroalkanes, with different degrees of chlorination and chain length distributions depending on the application and feedstock. This proposal is for any CP product that has constituents with 14 to 17 carbon atoms (C_{14-17}) and a chlorination level at or exceeding 45% chlorine by weight (Cl wt.). These congeners are the principal constituents of substances called "medium-chain chlorinated paraffins" ("MCCPs") in Europe, North America and Australia, and major constituents of several products manufactured in Asia (e.g. CP-52). Due to the possible confusion regarding different product names, the proposal for listing is based on specific chain lengths and degrees of chlorination. Nevertheless, most of the available hazard and monitoring information is available from assessments on the substance called "MCCPs", and so the term "MCCPs" is used in these instances.

4. Key information for CPs with C_{14-17} chain lengths is provided in Table 1, based on Environment Agency (2019a). A non-exhaustive list of relevant CAS numbers is provided in Appendix 3, together with further information (such as additives). Around forty CAS numbers have been used to describe the CP family at various times. Some of these clearly cover CPs in the C_{14-17} range, and it is possible that some of the remainder may be used for products containing CPs in this range too.

Table 1: Substance identity

IUPAC name	Alkanes, C_{14-17}, chloro
CAS number	85535-85-9
EC number	287-477-0
Molecular formula	$C_xH_{(2x-y+2)}Cl_y$, where x = 14 to 17 and y = ≥5 to 17
Molecular weight range	370 - 826 g/mole (approximately)
Synonyms	Medium-chain chlorinated paraffins ("MCCPs"); Chlorinated paraffins, C_{14-17} (used in Annex VI of the EU CLP Regulation)

5. The predominant chain length of "MCCPs" is in the range C_{14-17}, reflecting the hydrocarbon feedstocks used in its manufacture within Europe, North America and Australia. Information presented in Environment Agency (2019a) indicates that chlorinated C_{14} carbon chain lengths are the dominant congener group in commercially supplied "MCCP" products. They also contain some constituents outside of the C_{14-17} range in small amounts.

6. CPs produced in Asian countries such as India and China are differentiated based on their chlorine content (or viscosity) rather than by the carbon chain lengths of their constituent congeners. An example is the product CP-52, which accounted for 80% of the total commercial CP production in China in 2005 (cited in Wei *et al.*, 2016). Li *et al.* (2018) cites data showing CP-42 and CP-52 accounts for >80% of Chinese production. CP-52 contains C_{9-30} chain lengths with a significant fraction in the range C_{14-17} (Castro *et al.*, 2018). Niu *et al.* (2021) noted marked variation in the C_{10-17} congeners in 7 different batches of CP-52, which was suggested to be due to the varying composition of n-alkane feedstock used for production. Li *et al.* (2018b) examined the congener profiles for three Chinese CP products. In the CP-52 sample, they found the predominant "MCCPs" chain length was C_{17}, however due the form of analysis used in the study this conclusion is uncertain. Li *et al.* (2018b) indicated that around 150 CP producers exist in China. Glüge *et al.* (2018) analysed 11 CP-52 mixtures from 9 Chinese producers, and found that MCCPs (with one exception) C_{14} was present between 29% and 67%, with a mean value of 57%. The $C_{14}Cl_{7-8}$ congeners were the most prevalent. Xia *et al.* (2021) analysed 18 commercial Chinese CP products, including 13 CP-52 products. They found "MCCPs" composed 34.3% to 69.1% of the CP-52 products with C_{14} congeners dominant, contributing 46.1%–79.5% of the total "MCCPs" detected. Wang *et al.* (2018) noted that C_{14} was the dominant "MCCPs" chain length in a wide range of Chinese polymer products. For both "MCCPs" and products such as CP-52, chain lengths below C_{14} are structurally analogous to the range described as short-chain chlorinated paraffins (SCCPs – see paragraph 10).

7. The chlorine content of commercial products (e.g. "MCCPs" and CP-52) varies according to the applications they are used for, but is generally within the range 40% to 63% by weight; the majority of products have a chlorine content between 45% and 52% by weight. The chlorination process is random, and so all of these products contain many thousands of constituents[1].

8. Table 2 indicates the structural formulae of possible constituents of the different product types (adapted from information originally presented in the EU Existing Substances Regulation assessments (EC, 2000 and 2005). The "blocks" in the table still contain large numbers of individual isomers. The main constituents in the majority of product types have between five and seven chlorine atoms per molecule. Nevertheless, it should be noted that percentage chlorine content only represents an average level of chlorination, and so a wider range of constituents may be present in any particular product.

Table 2: Theoretical chlorine content of constituents for C_{14-17} chain lengths

Chlorine content,% w/w	**C_{14}**	**C_{15}**	**C_{16}**	**C_{17}**
<40	$C_{14}H_{29}Cl$ to $C_{14}H_{27}Cl_3$	$C_{15}H_{31}Cl$ to $C_{15}H_{29}Cl_3$	$C_{16}H_{33}Cl$ to $C_{16}H_{30}Cl_4$	$C_{17}H_{35}Cl$ to $C_{17}H_{32}Cl_4$
40 - 45	$C_{14}H_{26}Cl_4$	$C_{15}H_{28}Cl_4$	$C_{16}H_{29}Cl_5$	$C_{17}H_{31}Cl_5$
45 - 50	$C_{14}H_{25}Cl_5$	$C_{15}H_{27}Cl_5$	$C_{16}H_{28}Cl_6$	$C_{17}H_{30}Cl_6$
50 - 55	$C_{14}H_{24}Cl_6$	$C_{15}H_{26}Cl_6$ & $C_{15}H_{25}Cl_7$	$C_{16}H_{27}Cl_7$	$C_{17}H_{29}Cl_7$
55 - 65	**$C_{14}H_{23}Cl_7$ to $C_{14}H_{21}Cl_9$**	**$C_{15}H_{24}Cl_8$ to $C_{15}H_{22}Cl_{10}$**	**$C_{16}H_{26}Cl_8$ to $C_{16}H_{23}Cl_{11}$**	**$C_{17}H_{28}Cl_8$ to $C_{17}H_{25}Cl_{11}$**

[1] Tomy *et al.* (1997) includes a formula for the calculation of the number of isomers.

Chlorine content,% w/w	C_{14}	C_{15}	C_{16}	C_{17}
>65	**$C_{14}H_{20}Cl_{10}$ and higher no. of Cl atoms**	**$C_{15}H_{21}Cl_{11}$ and higher no. of Cl atoms**	**$C_{16}H_{22}Cl_{12}$ and higher no. of Cl atoms**	**$C_{17}H_{24}Cl_{12}$ and higher no. of Cl atoms**

(**bold text** indicates those blocks within scope of the proposal)

9. Available regulatory laboratory testing for "MCCPs" has been undertaken using substances with a specified chlorine content, such as 50% Cl wt. The assessment approach for this proposal is aligned with these data. The exact constituents of "MCCPs" will always be variable and a block approach as shown in Table 2 is a recognised way of addressing this uncertainty. An alternative approach is to assess the substance based on the number of chlorine atoms per chain length. For laboratory studies this requires an assumption about which congeners were present in the test, and at what concentration, as in many cases congener-specific analysis is not available. Applying such an approach then requires an assumption of equality, rather than trends, across the different congeners to interpret each test for a specific property. Where congener-specific analysis is available, it also requires verification of the accuracy of the analysis to quantify the individual congener concentrations (including their representativeness where extrapolation from specific constituents to the whole congener group is made).

1.1.2. Structural formula

10. Two example structures of CPs with C_{14} and C_{17} chain lengths are shown in Figure 1 (hydrogen atoms have been removed for simplicity).

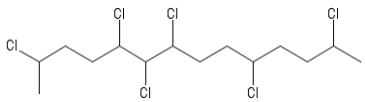

Figure 1:C14H24Cl6

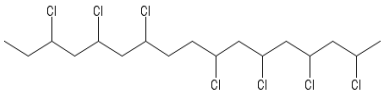

Figure 2:C17H29Cl7

1.1.3. Analogues

11. SCCPs (containing $C_{10\text{-}13}$ carbon chain lengths) and long-chain chlorinated paraffins (LCCPs, containing $C_{18\text{-}30}$ carbon chain lengths) are structural analogues registered under EU Registration, Evaluation, Authorisation and restriction of Chemicals (REACH). SCCPs was listed as a Persistent Organic Pollutant (POP) in 2017. Commercial "MCCPs" contains $C_{10\text{-}13}$ constituents that may be analogous to SCCPs, at levels typically below 1% by weight (often much lower), although the identity and actual concentration of the individual constituents is not known. The unintentional trace contaminant threshold specified in the Annex A listing of SCCPs is 1%. The Risk Management Evaluation (RME) of SCCPs indicated that "MCCPs" was one of the main alternatives to SCCPs (UNEP/POPS/POPRC.12/11/Add.3). The main uses of "MCCPs" (Section 2.1.2) are very similar to uses for SCCPs previously identified in the RME document.

12. HSE (2008) indicated that LCCPs based on a $C_{18\text{-}20}$ carbon chain length may contain up to 20% C_{17} CPs. A related report assessing LCCPs (Environment Agency, 2009) is currently being updated by the UK (Environment Agency, 2022 in prep.) following the substance evaluation of "MCCPs" in the EU. As pointed out in paragraph 5, some Asian products (e.g. CP-52) contain LCCP chain lengths together with MCCP and SCCP chain lengths (and $C_{<10}$ constituents) in a single product.

13. Further details of the analogues are provided in Appendix 3.

1.1.4. Physico-chemical properties

14. Key physico-chemical data are summarised in Table 3. The complexity and variability of the commercial substance means that many of the measured values represent averages. For example, the log K_{OW} will have a range covering several orders of magnitude, reflecting the wide variety of congeners present. This value may change for products with different degrees of chlorination.

Table 3: Physicochemical properties for CPs with C_{14-17} chain lengths

Property	**Value**	**Source of information/remarks**
Physical state at 20 °C and 101.3 kPa	Liquid	EC (2005)
Melting / freezing point	The pour point varies between -50 °C and +25 °C, depending on degree of chlorination	EC (2005)
Boiling point	Decomposition occurs at around 200 °C before boiling	EC (2005)
Vapour pressure	1.3×10^{-4} to 2.7×10^{-4} Pa at 20 °C for C_{14-17} chlorinated n-alkane, 52% Cl wt. 1.07×10^{-3} Pa at 45 °C, 6×10^{-3} Pa at 60 °C and 0.051 Pa at 80 °C for C_{14-17} chlorinated n-alkane, 52% Cl wt.; 2.27×10^{-3} Pa at 40 °C and 0.16 Pa at 80 °C for C_{14-17} chlorinated n-alkane, 45% Cl wt. $<1 \times 10^{-6}$ – 4.57 Pa for C_{14} with Cl_{1-12} $<1 \times 10^{-6}$ – 0.04 Pa for C_{15} with Cl_{1-13} $<1 \times 10^{-6}$ – 0.014 Pa for C_{16} with Cl_{1-13} $<1 \times 10^{-6}$ – 0.0042 Pa for C_{17} with Cl_{1-15}	Campbell and McConnell (1980) BUA (1992) as cited in EC (2005) Glüge *et al.* (2013); Predicted vapour pressure values using COSMOtherm[2].
Water solubility	0.0061 mg/L at 20 °C for C_{14} chlorinated n-alkane, 50% Cl wt. 0.005 - 0.027 mg/L at 20 °C for C_{15} chlorinated n-alkane, 51% Cl wt. 0.01 mg/L in freshwater and 0.004 mg/L in seawater at 16-20 °C for C_{16} chlorinated n-alkane, 52% Cl wt. 1.90 – 272 µg/L for C_{14} with Cl_{1-12} 0.50 – 68.1µg/L for C_{15} with Cl_{1-13} 0.15 – 42.2µg/L for C_{16} with Cl_{1-13} 0.72 – 12.7 µg/L for C_{17} with Cl_{1-15}	Unpublished (2019a); non-GLP[1] OECD Test Guideline (TG) 105. Analytical method: APCI-ToF-HRMS. Study considered to be reliable without restriction. Madeley *et al.* (1983a); non-standard method. Analytical method: thin-layer chromatography and radioactivity measurements. Key study used in EC (2005) and considered to be a realistic upper limit for this substance. Campbell and McConnell (1980); method unknown. Analytical method: radioactivity measurements Glüge *et al.* (2013); Predicted water solubility values using COSMOtherm[2].

Property	Value	Source of information/remarks
Partition coefficient n-octanol/water (log K_{OW})	6.58 ± 0.09 for C_{14} chlorinated n-alkane, 50% Cl wt.	Unpublished (2019b); non-GLP OECD TG 123 (slow stir). Analytical method: APCI-ToF-HRMS. Very little variability in K_{OW} was observed between differently chlorinated congener groups. Study considered to be reliable without restriction.
	6.30 (5.56 - 7.71) C_{14}, 47.0% Cl wt. 6.65 (5.84 - 7.81) C_{15}, 50.4% Cl wt. 6.81 (5.78 - 8.38) C_{16}, 61.0% Cl wt. 6.67 (5.57 - 7.90) C_{14-17}, 46.7% Cl wt.	Hilger *et al.* (2011a); reverse-phase HPLC method based on OECD 117 using UV detection. Considered to be reliable with restrictions as a non-GLP study.
	7.2 (4.7-8.3) for C_{16} chlorinated n-alkane, 35% Cl wt.	Fisk *et al.* (1998a); key study used in EC (2005). Analytical method: high performance liquid chromatography (HPLC). Study considered to provide indicative information only (due to lack of information about internal standards and reference substances).
	5.52 to 8.21 for C_{14-17} chlorinated n-alkane, 45% Cl wt.; 5.47 to 8.01 for C_{14-17} chlorinated n-alkane, 52% Cl wt.	Renberg *et al.* (1980); non-GLP non-guideline study. Analytical method: reversed-phase high performance thin layer chromatography (RP-HPTLC). Study considered to provide indicative information only. (due to lack of information about internal standards and reference substances).
	7.93 – 10.21 for C_{14} with Cl_{1-16} 8.49 – 10.91 for C_{15} with Cl_{1-17} 9.04 – 11.16 for C_{16} with Cl_{1-16} 9.60 – 11.84 for C_{17} with Cl_{1-18}	Endo (2021); Predicted log K_{OW} with COSMOTherm[2]. Fuller résumé in Table 16.
	6.2 – 8.25 for C_{14} with Cl_{1-14} 6.63 – 8.76 for C_{15} with Cl_{1-15} 7.07 – 9.28 for C_{16} with Cl_{1-16} 7.33 – 9.8 for C_{17} with Cl_{1-17}	Predicted log K_{OW} with log P methods of ACD Percepta[3] (provided in ECHA, 2021)
	7.94 – 9.1 for C_{14} with Cl_{4-10} 8.43 – 9.84 for C_{15} with Cl_{4-11} 8.92 – 10.36 for C_{16} with Cl_{4-12} 9.59 – 11.04 for C_{17} with Cl_{5-13}	Predicted log K_{OW} using KOWWIN v1.68[4] within EPIWIN™. Fuller résumé in Table 17. Based on Glüge *et al.* (2013), the COSMOtherm results are preferred to the EPIWIN results.

Note: GLP – Good Laboratory Practice.

[2] COSMOconfX 20, TURBOMOLE 7.4 and COSMOthermX 20 (all from COSMOlogic, Biovia, Dassault Systemes)

[3] ACD/Labs release 2019.2.1, Advanced Chemistry Development, Inc., 2019

[4] Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11. United States Environmental Protection Agency, Washington, DC, USA.

1.2. Conclusion of the Review Committee regarding Annex D information

15. At its seventeenth meeting, the POPRC evaluated the proposal to list chlorinated paraffins with carbon chain lengths in the range C_{14-17} and chlorination levels at or exceeding 45 per cent chlorine by weight in Annex A, B and/or C to the Convention. The Committee decided that, in accordance with paragraph 4 (a) of Article 8 of the Convention, it was satisfied that all the screening criteria specified in Annex D to the Convention were fulfilled for the C14 chain lengths (decision POPRC-17/x). The Committee noted that information relating to the screening criteria on bioaccumulation for chlorinated paraffins with carbon chain lengths in the range C15–17 was less certain, but the information relating to the remaining screening criteria specified in Annex D was conclusive. The Committee decided that more detail on bioaccumulation data should be included in the draft risk profile.

1.3. Data sources

16. The draft risk profile on chlorinated paraffins with carbon chain lengths in the range C_{14-17} and chlorination levels at or exceeding 45 per cent chlorine by weight is based on the following data sources:

    (a) Proposal to list chlorinated paraffins with carbon chain lengths in the range C_{14-17} and chlorination levels at or exceeding 45 per cent chlorine by weight in Annex A, B or C to the Convention submitted by the UK;

    (b) Information presented at the seventeenth meeting of the POPs Review Committee (POPRC-17) and its pre-meeting;

    (c) Information submitted in accordance with Annex E to the Convention by the following Parties and observers: Belarus, Canada, European Union, Germany, Monaco, the Netherlands, Norway, Sweden, New Zealand and Chlorinated Paraffins Industry Association (CPIA);

    (d) Peer-reviewed scientific literature, and grey literature;

    (e) Registration dossier submitted for MCCPs under the EU's REACH Regulation;

    (f) UK Substance Evaluation report for "MCCPs" (Environment Agency, 2019a);

    (g) European Chemicals Agency (ECHA) Substance of Very High Concern support document for "MCCPs" (ECHA, 2021a); and

    (h) Environment and Climate Change Canada review (Environment Canada, 2008).

1.4. Status of the chemical under national regulations and international forums

17. "MCCPs" (alkanes, C_{14-17}, chloro; CAS no. 85535-85-9) was assessed in Europe under the Existing Substances Regulation (EC) No. 793/93 (EC, 2005; EC, 2007; HSE 2008), and via a transitional Annex XV dossier under the REACH Regulation (Environment Agency, 2010). Subsequently "MCCPs" underwent Substance Evaluation under REACH, and the published report prepared by the UK concludes that it meets the REACH Annex XIII criteria for Persistent, Bioaccumulative and Toxic (PBT) and very Persistent, very Bioaccumulative (vPvB) properties (Environment Agency, 2019a). "MCCPs" was subsequently identified as a Substance of Very High Concern due to its PBT/vPvB properties in the EU (ECHA, 2021a). This Risk Profile is principally based on the REACH Substance Evaluation report, which focused on the assessment of environmental endpoints. A further analysis prepared by Germany indicates concern for several uncontrolled risks for human health from "MCCPs", and uncertainty for specific toxicological endpoints (BAUA, 2020; Zellmer *et al.*, 2020).

18. A proposal for an EU restriction of "MCCPs" in electrical and electronic equipment under the Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2011/65/EU) was prepared by Sweden in 2018 (KEMI, 2018). As part of preparatory work, a supporting report suggested risks to workers in certain scenarios where Personal Protective Equipment was not worn, and also environmental risks for some specific scenarios (KEMI, 2017).

19. The Australian Department of Health published a hazard assessment of "MCCPs" in June 2020 (NICNAS, 2020). The review concluded that "MCCPs" meets Australia's domestic PBT criteria, and that some congener groups may meet the Annex D screening criteria for POPs under the Stockholm Convention.

20. Environment and Climate Change Canada reviewed the CPs group in 2008 (Environment Canada, 2008). The review concluded that "MCCPs" is "toxic"[5] as defined in paragraphs 64 (a) and (c) of the Canadian Environmental Protection Act, 1999.

2. Summary information relevant to the risk profile

2.1. Sources

2.1.1. Production and trade

21. Within the EU, there are 11 active REACH Registrants of "MCCPs" listed on the ECHA dissemination portal (ECHA, 2022a). The registered tonnage lies in the band 10 000 – 100 000 tonnes per year. Most "MCCPs" used in the EU is manufactured within the EU with only a small proportion (<10%) imported from outside the bloc. "MCCPs" may also be imported into the EU in finished or semi-finished articles (e.g. textiles or electrical items). The total mass of "MCCPs" entering the EU in imported articles is unknown, so it is not possible to gain a full insight into stocks and mass flows. KEMI (2018) estimated that the EU imported approximately 2 100 tonnes of "MCCPs" in electrical cables in 2014. "MCCPs" are a grandfathered REACH registration in the UK (UK Chemicals Agency, 2021). There are 549 notifiers of "MCCPs" in ECHA's Classification & Labelling Inventory (ECHA 2022b), which suggests a large number of downstream users in Europe (there is no lower supply threshold for the inventory, so some notifications may be for low volumes, but verification is not possible).

22. Glüge *et al.* (2018) cite production volumes of "MCCPs" outside Europe: North America, 17 800 tonnes in 1998; Russia, 21 000 tonnes in 2007 and 27 000 tonnes in 2011; Thailand, 20 000 tonnes in 1994; and China, 600 000 tonnes in 2013, extrapolated from CP-52 production. Some of these values are more than 20 years old, and so current supply volumes may have changed. Glüge *et al.* (2018) suggest that Chinese production may have continued to increase after 2013, based on the supply trend prior to that year. In Australia, the total annual introduction volumes in 2002 and 2006 were between 1 000 and 9 999 tonnes (NICNAS, 2020), which are thought to mainly reflect Australian manufacture (Pers Comm., 2021). Manufacture in India, possibly at a significant supply volume, is also suggested (Lassen *et al.*, 2014), but information specific to CPs with C_{14-17} chain lengths is not available. In the Republic of Korea, 36.55 tonnes of "MCCPs" were manufactured in 2018 (Annex E information, Republic of Korea).

23. In Canada, 550 tonnes of "MCCPs" were supplied in 2017, a decline of 28% since 2013 (Annex E information, Canada). The Republic of Korea imported 4 342 tonnes of "MCCPs" in 2018 (Annex E information, Republic of Korea). Sales and emissions from "MCCPs" in products decreased slightly from 2010-2019 in Norway (Annex E information, Norway). No manufacture or supply of "MCCPs" has taken place in New Zealand, but products containing the substance (based on 3 CAS numbers) are approved for import (Annex E information New Zealand).

24. Based on the available data, current global production of CPs with C_{14-17} chain lengths could be in the region of 750 000 tonnes per year.

2.1.2. Uses

25. Based on the EU REACH registration information, the substance has several uses, such as:

- a secondary plasticizer in PVC, adhesives, sealants, paints and coatings;
- a flame retardant in PVC and rubber compounds, adhesives, sealants, paints and coatings, and textiles;
- an extreme pressure lubricant and anti-adhesive for metal working fluids;
- a waterproofing agent for paints, coatings and textiles; and

[5] The substance is entering, or may enter, the environment in quantities or concentrations or under conditions that: have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or constitute or may constitute a danger in Canada to human life or health.

- a carrier solvent for colour formers in paper manufacture.

26. Former uses reported in EC (2005) were for leather fat liquors and carbonless copy paper. These are no longer included in the latest REACH registration dossiers. However, it is possible that these uses continue outside Europe.

27. The use (and import) of "MCCPs" in metal working fluids, PVC, rubber/elastomers, paints/coatings, adhesives/sealants and flame retardants were reported in Norway and Canada (Annex E submissions). Chloroparaffins CP-66T and CP-470A are used in Belarus, although the use is not stated (Annex E submission). Recent research in waste goods has indicated the presence of "MCCPs" in furniture textiles, end-of-life-vehicles, WEEE, PVC cabling and several other PVC products (NEA, 2021).

28. In Belgium (and expected to reflect Dutch supply too), "MCCPs" are used in PVC, rubber consumer products and toys. They were detected in two rubber ducks, one PVC pool mat, one PVC jump rope and one item of clothing of unknown composition. All products were produced outside of Europe except one where the country of origin is unknown (Annex E submission (Netherlands); McGrath *et al.,* 2021).

29. "MCCPs" are used in new and used do-it-yourself spray one-component polyurethane foams (Brandsma *et al.,* 2021). "MCCPs" are also used in domestic and polymeric food-related products in China, in polyethylene terephthalate (PET), polypropylene (PP), polyethylene (PE) and food packaging (Wang *et al.,* 2018) as well as in PP and PE animal feed packaging (Su *et al.,* 2020). Kutarna *et al.* (2022) detected "MCCPs" in consumer cables such as headphones, and toys and toy packaging.

30. Further uses of "MCCPs" include in kitchen appliances (Sprengel and Vetter, 2021a), mobile phone protective cases (Li *et al.,* 2021), plastic sports courts and synthetic turf (Wang *et al.,* 2018), and in dishcloths analysed after 14 days of use (Vetter *et al.,* 2017).

2.1.3. Releases to the environment

31. As part of the Risk Management Options Analysis for "MCCPs" in the EU, the release estimates for the different lifecycle stages were estimated based on information[6] in the REACH Registrants' Chemical Safety Reports (Environment Agency, 2019b). The values are provided in Table 4 and Table 5. A total of 305 tonnes per year is estimated to be emitted to the environment. The total estimated release to surface water in Table 5 takes account of the removal of "MCCPs" from aqueous waste streams by wastewater treatment plants. This diverts approximately 149 tonnes per year of "MCCPs" to sludges, which may be landfilled, used in agriculture or incinerated. Based on this information, if the proportion of "MCCPs" released per year in the EU (305 t/y) is applied to the estimated global supply tonnage[7], this suggests between 2 800 and 28 000 tonnes per year is being released to the environment at a global scale. Clearly the global tonnage is an approximation, and this calculation assumes that the EU use pattern and emission controls are similar across the world (which is unlikely to be the case).

Table 4: Estimated total releases of "MCCPs" to the EU environment by use (from all lifecycle stages)

Use	Total releases per year (tonnes)
"MCCPs" manufacture	0
PVC and rubber (formulation, conversion, service life)	41
Adhesives/sealants (formulation, use, service life)	126
Metalworking fluids (formulation and use)	100
Textiles (formulation and service life)	13
Paints/coatings (formulation, use, service life)	10
Paper manufacturing/recycling	15
Total	305

[6] Tonnage relevant for the lifecycle and quoted emission factor.

[7] 305 tonnes/year released from the range of 10 000 to 100 000 tonnes supplied in the EU applied to the estimated global use volume of 750 000 tonnes/year.

Table 5: Estimated total releases of "MCCPs" to the EU environment from all lifecycle stages

Release route	Total releases per year (tonnes)
Water	4
Air	91
Soil	61
Sewage sludge*	149

* which may be used in agriculture, landfilled or incinerated

2.2. Environmental fate

2.2.1. Chemical analytical challenges

32. The highly complex nature of CPs means that there are considerable analytical challenges associated with their detection and quantification. Only limited information is available on the actual carbon chain length distribution and chlorine contents of the CPs detected in environmental samples, although advances in analytical methodologies have meant that more detail has been possible in some of the more recent studies. The current recommended analytical method is APCI-QToF-HRMS[8]. In an inter-laboratory comparison by van Mourik *et al.* (2018), the most commonly used analytical technique for SCCPs analysis – GC-ECNI-LRMS[9] – showed the largest variation, and the same is likely to be true for longer chains. High Resolution Mass Spectrometry (HRMS) was recommended to be used in future. The degree of chlorination can also be important, especially if the substance in a sample differs from the analytical standards used. Based on work of Brandsma *et al.* (2017), Bogdal *et al.* (2015) and Yuan *et al.* (2017), there remains uncertainty with the identification and quantification of "MCCPs" congeners with less than 5 chlorine atoms. Furthermore, some commonly used low resolution mass spectrometry methods may be subject to interferences from both the matrix and other contaminants (such as chlordanes, polychlorobiphenyls and toxaphenes) unless highly efficient sample clean-up procedures are used. Measured values reported in academic literature pre-2011 should be considered indicative but not quantitative. After 2011, detections of "MCCPs" in biota and the environment are considered to be semi-quantitative in the following discussion.

2.2.2. Persistence

2.2.2.1. Abiotic data

33. Data for photodegradation in air are discussed in the Long-Range Transport Section. There are no reliable data for photodegradation in other media such as water. Due to their structure, CPs are not expected to hydrolyse significantly.

2.2.2.2. Biotic data

2.2.2.2.1. Biotic screening data

34. Environment Agency (2019a) details several biodegradation screening studies performed in the same laboratory to investigate the influence of chain length and chlorination level on biodegradation potential of CPs with $C_{14\text{-}17}$ chain lengths. These were mostly[10] based on the OECD TG 301 (ready biodegradation) using

[8] APCI-QToF-HRMS: Atmospheric-Pressure Chemical Ionization Quantitative Time of Flight High Resolution Mass Spectrometry

[9] GC-ECNI-LRMS: Gas Chromatography Electron Capture Negative Ionisation Low Resolution Mass Spectrometry

[10] A number of studies used pre-adapted inoculum, which is not appropriate for current REACH Annex XIII assessments and is similarly not considered appropriate for the Annex D screening criteria. Three tests were also performed using OECD TG

modified conditions by including a surfactant (alkylphenol polyalkoxylate) to increase bioavailability, and in some cases an extended time period for the test. A summary of all the test results is provided in Appendix 4 (Table 11). The summary below focuses on tests where the conditions are judged suitable for the Annex D/E assessment.

35. Under the conditions of these studies, C_{14} chlorinated n-alkanes with a chlorine content of 41.3% and 45.5% were readily biodegradable within 28 days (>60% mineralisation). C_{14} chlorinated n-alkane, 50% Cl wt. failed to meet the 60% pass threshold within 28 days but did meet it after 56 days.

36. Both a 55% and 60% Cl wt. C_{14} chlorinated n-alkane failed to meet the pass threshold of 60% degradation even after 60 days. A C_{15} chlorinated n-alkane, 51% Cl wt. also failed to meet the pass threshold after 60 days.

37. $C_{14\text{-}17}$ chlorinated n-alkane, 45.5% Cl wt. achieved 51% degradation after 28 days (and so was not readily biodegradable), although a test using an extended timescale was not available. $C_{14\text{-}17}$ chlorinated n-alkane, 51.7% Cl wt. was not readily biodegradable in 28 days (achieving 27% degradation) and although it was extensively degraded over an extended period (57% degradation after 60 days) it still failed to meet the pass threshold. $C_{14\text{-}17}$ chlorinated n-alkane, 63.2% Cl wt. only achieved 10% degradation under the same conditions.

38. In summary, these ready biodegradation studies indicate that substances with a lower level of chlorination can be extensively degraded by micro-organisms under conditions of enhanced bioavailability. The trend in the data shows that degradability reduces as the number of chlorine atoms per molecule increases. There are no screening degradation data for specific C_{16} or C_{17} substances alone. However, it should be noted that the mixture of $C_{14\text{-}17}$ substances at the same level of chlorination were less degradable than their C_{14} or C_{15} counterparts. This suggests that these longer chain lengths are less degradable (i.e. otherwise the mixtures would be more degradable than reported). This observation fits with the general environmental fate expectation that degradation decreases with increasing carbon chain length, due to decreasing water solubility (Glüge *et al.*, 2013) and greater adsorption capacity (Gawor and Wania, 2013) than the C_{14} substances. In the case of simple hydrophobic substances such as "MCCPs", water solubility will be inversely proportional to K_{OW}, and K_{OC} will be proportional to K_{OW}. As can be seen from the predicted log K_{OW} values in Table 16 there is a clear increasing trend in log K_{OW} values with increasing carbon chain length.

39. It should be noted that it is not possible to extrapolate information from these screening tests to an environmental half-life.

40. A GLP test according to OECD TG 314B "biodegradation in activated sludge" has recently been performed using a 52% Cl wt. $C_{14\text{-}17}$ substance. The test material was radiolabelled using tritium, and the 28-day test was conducted using Triton X-100 solubiliser (Eurofins EAG Agroscience, 2022). The test concentration was 54.7 µg/L, the inoculum concentration was 2.5 g/L (as suspended solids) and solubiliser concentration was 322 µg/L. The test temperature was between 19.5 °C and 21.3 °C. The study suggested 87.4% mineralisation (based on formation of ^3H_2O) in 24 hours under the conditions of the test. This contrasts with the significantly more limited degradation observed in other screening studies. There was no specific analysis to confirm if the measured mineralised radioactivity related to parent substance (instead only to the kinetics of the radio tracer). This is an important drawback of the study since tritium is known to exchange with hydrogen atoms of protein related substances – of which there would be many present in the test system (Nivesse *et al.,* 2021). The test guideline also does not offer the option of a solubiliser to administer the substance to the test vessels. Furthermore, the conditions are considerably more favourable to biodegradation compared to other (standard) screening studies (e.g. the concentration of suspended solids is approximately 300 times that of the OECD 310). Due to these factors, the results of the study are not currently considered to be reliable for the purposes of this assessment. It should also be noted that the OECD TG 314B does not provide a measure of ready biodegradability nor a relevant environmental half-life.

302A (Inherent Biodegradability: Modified SCAS Test); the high inoculum concentrations used in these studies mean that the results are not relevant for persistence assessment. In both cases these data are not summarised in this proposal.

2.2.3. Environmental simulation data

41. An OECD TG 308 (aerobic and anaerobic transformation in aquatic sediment systems) study has been conducted using non-radiolabelled C_{14} chlorinated n-alkane, 50% Cl wt., in accordance with GLP (Unpublished, 2019c and 2019d). This is described in detail in Environment Agency (2019a). The test was conducted under aerobic conditions using two types of sediment and a nominal test substance concentration of 5 µg/g dry weight (dw) in sediment. Test vessels were sacrificed on days 0, 15, 30, 45, 60, 91 and 120 (the test guideline specifies that the test should not be run for longer than 100 days). Chemical analysis was performed using APCI-ToF-HRMS. Apart from a single measurement at 91 days, the mean measured concentrations from all sampling intervals did not deviate by greater than 8% (calculated relative standard deviation; RSD) of the applied nominal concentration. Congener-specific analyses[11] for the extracted samples showed no significant variation between these extracts, the extracted spiked sand and the original test substance. Overall the chemical analysis showed no observable biotransformation in two different sediments, and so the sediment half-life was >120 days at 12 °C. The study is assessed to be reliable without restriction.

2.2.4. Environmental compartment monitoring

42. Environmental monitoring data are summarised in Section 2.3.1 and Appendix 6. CPs have been detected in sediment cores taken from several locations around the world, and this Section focuses on these studies as they are relevant to the laboratory data summarised in Section 2.2.2.2.2.

43. Iozza *et al.* (2008) took a sediment core covering the period 1899 – 2004 from Lake Thun, Switzerland in May 2005. The lake is located in a rural, densely populated alpine catchment area without any known point sources (e.g. metal or polymer industries). The level of "MCCPs" measured using GC-ECNI-LRMS in the sediment core showed an increasing trend from 1965 onwards reaching a level of 26 µg/kg dw in the surface layer (i.e. 2004). Concentrations between 15 and 20 µg/kg dw were evident in the samples dated to the 1980s. The C_{14} carbon chain length was the most abundant constituent present (accounting for 41 to 64% of the total "MCCPs"), although all chain lengths could be detected in all cores. Chlorine content was higher from the cores dated between 1994 and 2004 (generally between 53.3% and 56.6% by weight).

44. Chen *et al.* (2011) took a sediment core from the Dongjiang River within Dongguan in the Pearl River Delta area of south China. The sediment core was thought to contain about 15 years of deposition. Using GC-ECNI-LRMS analysis, the concentrations of "MCCPs" were higher in the upper layers of the core than in the deeper layers; 1 400 to 3 800 µg/kg dw between 0 and 32 cm depth compared with 1 100 to 1 400 µg/kg dw between 36 and 68 cm depth. The increasing concentrations in the upper layers were thought to be a result of increasing use of "MCCPs" in the area. The "MCCP" concentrations in the lower layers were relatively constant. It was noted that there was a higher relative abundance of C_{16} and C_{17} substances in the upper layers (from 0 cm to around 44 cm depth) than in the lower layers, with the relative proportion of C_{14} substances being slightly higher in the lower layers than the upper layers. It was suggested that this may reflect changes in the composition of "MCCPs" used in the area over time. Nevertheless, the C_{14} chain length dominated with around 60% of the total "MCCPs" detected. Similar to Iozza *et al.* (2008), higher levels of chlorination were seen for more recent cores.

45. Sediment cores were taken by Yuan *et al.* (2017) at three different locations in Sweden (downstream of a wastewater treatment plant, near to an industrial wood processing area, and to a steel factory). Using APCI-QToFMS analysis, the authors detected "MCCPs" at concentrations of < 6.5 to 93 µg/kg dw. This included detection in sediment from cores dated as 1954 and 1960. Furthermore, temporal trends could be seen indicating a decrease in SCCPs reflecting their restriction, and a concurrent increase in "MCCPs". At a congener level all four "MCCPs" carbon chain lengths were detected and presented as summed total "MCCPs" concentrations. The C_{14} congener dominated in two of the cores (up to 89%), but all four congeners were evenly distributed in the steel factory core.

46. Sediment cores were taken from 2 urbanised coastal locations: Hong Kong waters (1 core, taken in 2004) and Tokyo Bay (2 cores taken in 2012) by Zeng *et al.* (2017a). These were analysed for SCCPs and "MCCPs" using GC-ECNI-LRMS. "MCCPs" were detected in horizons that were estimated to have been deposited in

[11] As per paragraph 31, there maybe uncertainty regarding the analysis of lower chlorinated congeners (<5 chlorine atoms).

the late 1950s in both locations. Surface concentrations were 20.3 µg/kg dw in Hong Kong waters, and 7.9 and 29.3 µg/kg dw in the Tokyo Bay (2-4 cm) cores, although these represent different sampling times so are not comparable. The maximum historic concentration in the cores were from the late 1980s: 180 µg/kg dw in the Tokyo Bay cores, and 7.3 µg/kg dw in the Hong Kong core. Declines in both SCCPs and "MCCPs" concentrations were noted in Tokyo Bay from the 1990s to more recent periods, which were suggested by the authors to reflect declining manufacture and use due to regulatory controls introduced in the early 2000s. However, in both cores the concentration in the uppermost core slice are within an order of magnitude of the levels in core slices from the previous 8 years. Recent trends in the Hong Kong core cannot be discerned due to the older core sampling date. At a congener level all four "MCCPs" carbon chain lengths (and $Cl_{5\text{-}10}$) were detected and presented as summed total "MCCPs" concentrations. From a figure in the supplementary information, C_{14} was the most prevalent chain length (66.8% - 79% -), with the remaining chain lengths detected between 7.0% and 28.1%.

47. Zhang *et al.* (2019) took sediment cores from the deepest location of 9 lakes in China, including 2 located in areas remote from industry (Lake Qinhgai and Lake Bosten, situated in the Tibetan Plateau and Mengxin lake regions of north-western China were remote from areas of industry). Most cores were taken in 2006 and cover a period from about 1930. Complementary surface sediment samples were taken in 2018 and 2019, together with four shallower sediment cores taken between 2011 and 2019 from the non-remote lakes. All cores were analysed for CPs using UPLC-QToFMS[12] (analysis appears to have been performed in 2019). "MCCPs" concentrations are presented as total "MCCPs" based on summed congener level analysis. Concentrations were low or below 5.0 µg/kg dw (the limit of detection) until the 1970s, after which the lowest surface "MCCPs" concentrations (35 to 269 µg/kg dw) were observed in the remote lakes, with higher surface "MCCPs" concentrations in lakes near to larger cities and manufacturing industries (643 to 3 390 µg/kg dw. For the more contemporary cores from non-remote lakes, "MCCPs" concentrations in the top slice are similar to those in the slices representing the early 1990s. The homologue profile of "MCCPs" was noted to be similar in nearly all lakes, with the C_{14} chain length and the Cl_7 and Cl_8 chlorination levels dominant. The authors indicate the distribution observed is similar to CP-42, a commercial Chinese product. "MCCPs" as a proportion of overall detected CPs in the cores was noted to be increasing, with SCCPs decreasing. Zhang *et al.* (2019) also proposed that the presence of CPs in the two remote lakes (in cold areas at high elevations) could be the result of long-range atmospheric transport through cold trapping and deposition.

48. "MCCPs" were detected at concentrations ranging from 750 to 1 200 µg/kg dw in sediment cores from Lake St. Francis, downstream of Cornwall, Ontario, Canada (Muir *et al.*, 2002). Based on the data, Environment Canada (2008) estimated the half-life of "MCCPs" in sediments to be longer than 1 year.

49. In summary, measurable levels of "MCCPs" are present in deeper (older) sediment layers that are of the same order of magnitude as levels in surface (recent) layers. This provides indirect evidence that the substance may be persistent in sediments over many years. It is acknowledged that degradation conditions (e.g. redox potential) will vary with depth, and levels will also depend on the environmental emission at the time of deposition. Where congener analysis was performed, all four carbon chain lengths were detected. C_{14} was generally the dominant chain length, with the chain length profile noted to align with commercial CP products in several papers.

50. "MCCPs" have been detected to a limited extent in several studies analysing marine sediment collected in the Arctic. These are described in more detail in Section 2.3.1.4.1.

2.2.5. Persistence synthesis

51. The key data are the absence of transformation of a C_{14} chlorinated n-alkane, 50% Cl wt. substance after 120 days at 12 °C in a reliable OECD TG 308 study involving two different sediment types, performed to GLP under aerobic conditions. The absence of degradation at 120 days in the study suggests that it is very unlikely that significant degradation would subsequently occur between 120 and 180 days. This hypothesis is supported by the sediment core monitoring data, where levels of "MCCPs" in recently deposited horizons

[12] Ultra-Performance Liquid Chromatography to Quadrupole Time-Of-Flight Mass Spectrometry

are of a similar order of magnitude to those horizons in the same core which represent deposition from 8 or more years ago. While a modified screening biodegradation test using C_{14} chlorinated n-alkane, 50% Cl wt. indicated extensive biodegradation after 56 days, no degradation occurred in the OECD TG 308 study using a very similar test substance. Since the simulation test is more environmentally relevant, it is given the greatest weight in the assessment of persistence. The negligible degradation rate in aerobic sediment may reflect a reduction in bioavailability caused by adsorption.

52. All of the substances that were tested in the modified and enhanced ready tests (Section 2.2.2.2.1) and shown to be less degradable than C_{14} chlorinated n-alkane, 50% Cl wt. are likely to therefore have similar or longer sediment half-lives as the C_{14} (50% Cl wt.) congener block. Given the predicted and observed trends in physico-chemical properties (Table 3), it can be reasonably expected that $C_{15\text{-}17}$ constituents with similar or higher chlorine contents to C_{14} chlorinated n-alkane, 50% Cl wt. will be equally or more adsorptive to sediment. They are therefore likely to be equally or more persistent in sediment (i.e. the sediment half-lives will exceed 180 days). This hypothesis is supported by the detection of all four relevant chain lengths in the older horizons of sediment cores where congener level analysis was performed. Furthermore, where the comparison was made, the chain length profile in the sediment cores is similar to commercial CPs – i.e. the profile appears unchanged following emission, suggesting that degradation has not occurred.

53. "MCCPs" have also been detected in remote regions such as sediments in Lake Qinhgai and Lake Bosten in China, and the Arctic. Such detection far away from point sources suggests that the "MCCPs" can persist following deposition as a result of long-range transport. Further supporting data from surface sediment sampling is provided in Section 2.3.1.4.

54. C_{14} chlorinated n-alkanes with a low chlorine content (≤45% Cl wt.) are readily biodegradable. In contrast, a $C_{14\text{-}17}$ chlorinated n-alkane, 45.5% Cl wt. was not readily biodegradable although there was extensive mineralisation (51%) after 28 days. It is possible that adsorption could cause these substances to have longer sediment half-lives than expected, but no robust data are available to allow a conclusion to be drawn. Given that the test results for these specific C_{14} constituents would meet the OECD definition of "readily biodegradable", chain lengths below 45% Cl wt. are excluded from this proposal. Whilst it is possible that more highly chlorinated (persistent) constituents might be present in the <45% Cl wt. fraction used in the screening studies, the high level of mineralisation attained in these specific screening studies suggests that the concentration of any potentially persistent constituents present is likely to be low, and therefore not considered relevant.

55. Overall, the half-life for sediment is assessed to exceed 180 days for $C_{14\text{-}17}$ all chain lengths with chlorination levels ≥45% Cl wt. Lower chlorination levels are not considered to be persistent based on the currently available information, and these are excluded from this proposal.

2.2.6. Bioaccumulation

2.2.6.1. Screening information

56. As shown in Table 3, the constituents of CPs with $C_{14\text{-}17}$ chain lengths have a range of log K_{OW} values, but all measured and predicted values exceed 5. C_{14} chlorinated n-alkane, 50% Cl wt. has a reliable measured log K_{OW} of 6.6. Hilger *et al.* (2011a) determined a range of measured log K_{OW} values between 5.56 and 8.68 for C_{14-16} chain lengths with different chlorination levels. Predictions of log K_{OW} using COSMOtherm and ACD labs software show good agreement with the available measured data (Glüge *et al.*, 2013; Endo 2021; ECHA 2021; Gawor and Wania, 2013). In comparison, predictions of physico-chemical properties using EPIWIN™[13] provide poorer agreement[14] (Glüge *et al.*, 2013; Environment Agency 2019a). The predictions indicate that log K_{OW} values are relatively independent of chlorine content for a given carbon chain length, up to a chlorine content of 55% Cl wt. Log K_{OW} is likely to increase with chlorine content above 55% Cl wt.

[13] Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11. United States Environmental Protection Agency, Washington, DC, USA.

[14] Based on log KOW values for 29 "MCCPs" congener groups using COSMOtherm and EPISuite™.

for a given chain length. In other words, there is little change in log K_{OW} values from Cl_1 to around Cl_5, and then an increase above this level of chlorination. Log K_{OW} also increases with increasing carbon chain length. Kow. Further details of predictions of log K_{OW} for specific congeners using COSMOtherm can be found in Table 16.

2.2.6.2. Aquatic fish bioaccumulation studies

57. A reliable fish bioconcentration study with Rainbow Trout (*Oncorhynchus mykiss*) was conducted according to OECD TG 305 and GLP using a ^{14}C radio-labelled C_{14} chlorinated n-alkane, 45% Cl wt. product (Unpublished, 2010a and 2010b). This is detailed in Environment Agency (2010). The test used a single measured aquatic exposure concentration of 0.34 µg/L during uptake, which was well below the water solubility limit. Dimethyl formamide was used as a solvent (0.004 mL/L). The fish were exposed to the substance for 35 days followed by a 42-day depuration period, under flow-through conditions. In follow-up analytical work, it was determined that around 79% of the measured radioactivity was likely to be parent substance (Unpublished, 2010b). The remaining 21% was associated with non-polar non-extractable metabolites. These were not further identified, and so it is not known whether these are toxic or accumulative. For the purpose of this proposal, the fish bioconcentration factor (BCF) is calculated using a conservative assumption that all measured radioactivity is relevant. The growth-corrected and lipid-normalised kinetic BCF is therefore 14 600 L/kg. If the apparent metabolites are ignored, the value would be around 11 530 L/kg for parent substance alone. The study is assessed to be 'reliable without restriction', although the lipid-normalised "steady state" BCF (BCFss) of 3 230 L/kg derived in the original study report should be treated as unreliable because fish growth was significant and so a true steady state had not been reached.

58. A reliable fish dietary bioaccumulation test with Rainbow Trout (*O. mykiss*) was conducted according to OECD TG 305 and GLP using a C_{14} chlorinated n-alkane, 50% Cl wt. substance in a flow-through system (Unpublished, 2019e and 2019f). A dosed treatment containing the test substance at a nominal concentration of 15 µg/g, and a positive control treatment dosed with both a nominal 15 µg/g of test substance plus 3 µg/g of hexachlorobenzene (HCB) were used. An uptake period of 14 days was followed by 56 days of depuration during which the fish were fed non-dosed food. Chemical analysis was performed using APCI-QToF-HRMS. The growth-corrected depuration half-life was 108.9 days and the growth-corrected and lipid-normalised kinetic biomagnification factor (BMF_{KgL}) was 0.468 (Unpublished, 2019e). As shown in Environment Agency (2019a), the 15 models within the OECD TG 305 BCF estimation tool (OECD 2017a) all predict that the BCF significantly exceeds 5 000 L/kg. For HCB (positive control), the growth-corrected depuration half-life was 26 days and the BMF_{KgL} was 1.41. The study is assessed to be reliable without restrictions. As stated in the OECD guidance for the TG 305 '*it has been recognised that regulatory trigger values based on BCF (e.g. 2 000 or 5 000 L/kg) do not necessarily correspond to dietary BMFs from the dietary study greater than 1, especially in very small fish in the exponential phase of growth*' (OECD 2017b). For example Inoue *et al.* (2012) performed a regression of analysis comparing measured laboratory dietary BMFs and BCFs for nine bioaccumulative substances and found that a BCF value of 5 000 L/kg corresponded to a dietary BMF_{KgL} of around 0.3 in juvenile Common Carp (*Cyprinus carpio*).

59. Several more studies provide information about fish bioaccumulation for other relevant constituents, which are described below and summarised in Table 6. These are considered to be of lower reliability than the two studies summarised above, but still provide useful information.

Table 6: Results of additional fish bioaccumulation studies of lower reliability

% Cl wt.	C_{14}	C_{15}	C_{16}	C_{17}	C_{18}[†]
<40			>5 000 L/kg Fisk *et al.*, 1996[#]		
40 - 45	*>5 000 L/kg* *Fisk et al., 1998b*[#]				
45 - 50					>5 000 L/kg Fisk *et al.*, 2000[#]

% Cl wt.	C_{14}	C_{15}	C_{16}	C_{17}	C_{18}†
50 - 55		2 072 L/kg* Thompson *et al.*, 2000			
55 - 65	>5 000 L/kg Fisk *et al.*, 2000#				
>65			>5 000 L/kg Fisk *et al.*, 1996#		

Note: italics: may be unreliable. * Not lipid corrected. # Extrapolated from a dietary test. † Not a constituent of "MCCPs" but provides an upper boundary.

60. The bioaccumulation of a C_{15} chlorinated n-alkane, 51% Cl wt. substance in Rainbow Trout (*O. mykiss*) was measured by Thompson *et al.* (2000). This was a GLP study performed according to OECD TG 305. It used flow-through exposure and a ^{14}C radiolabelled test substance. Two test concentrations (nominally 1 µg/L and 5 µg/L) were used, although the higher concentration was considered to have exceeded the water solubility limit as lower BCF values were determined. Fish lipid content was not measured so lipid normalisation is not possible. BCF values were calculated based on total radioactivity in fish and mean-measured water concentrations. The growth-corrected kinetic BCF for the low concentration was 2 072 L/kg, and the growth corrected depuration half-life was 29 days. While the BCF value is significantly lower than for a lower chlorine content C_{14} substance (see paragraph 56), the depuration half-life suggests significant concern for bioaccumulation (a depuration half-life around 8 to 10 days is indicative of a lipid-normalised and growth-corrected BCF above 5 000 L/kg according to the analysis in Environment Agency (2012) and discussed in OECD (2017b)). The apparent and unexplained disparity between BCF value and depuration half-life indicates that the test results should be treated with caution. It is considered to be a supporting study.

61. Fisk *et al.* (1996, 1998b and 2000) performed a series of fish dietary bioaccumulation studies using Rainbow Trout (*O. mykiss*) from which BCF values can be derived using the OECD estimation tool (OECD, 2017a). These used C_{14} (in two separate studies), C_{16} and C_{18} chain lengths with varying chlorination levels[15], and several SCCP chain lengths, some of which were run together in the same experiment. The test substances were specifically synthesised and had chlorine atoms on the terminal carbon atoms (which could have affected metabolic potential). The tests were not conducted to a standard test guideline or GLP, and key information to validate the studies run in 1996 and 1998 is not available. In particular Fisk *et al.* (1998b) which used only C14 chain lengths for "MCCPs" may be unreliable as key details regarding feeding rate, feed husbandry and fish replicate numbers are not provided. Although several important details are missing for the Fisk *et al.* (2000) study (e.g. demonstrating food homogeneity, measurement of oxygen content and water temperature), information about other key aspects of the study (e.g. control validity and consistency of test substance uptake) suggests that it was likely to have been adequately performed. In Fisk *et al.* (1996) mortality was observed in one of the two control groups[16] (16%), the high and low $C_{16}H_{31}Cl_3$ treatments (5-8%) and one of the SCCP exposures (19%). Fisk *et al.* (1996) indicate that the mortality was due to fin rot. The current OECD TG 305[17] has a 10% threshold for mortality in the controls, which can be interpretted across both control tanks (average mortality was 7%) or for an individual tank. The chemical analysis used in all of the tests suggests that measurements would have been semi-quantitative, so some caution is needed regarding the exact results. It is also not possible to check the raw data used for the growth correction or lipid normalisation that was performed. Overall, these studies are assessed to be of unknown reliability. Further

[15] $C_{14}H_{26}Cl_4$ 42% Cl wt.; $C_{14}H_{25}Cl_5$ 48% Cl wt. (two different isomers); $C_{14}H_{24}Cl_6$ 53% Cl wt. (two different isomers); $C_{14}H_{23.3}Cl_{6.7}$ 55% Cl wt.; $C_{16}H_{31}Cl_3$ 35% Cl wt. (two different isomers); $C_{16}H_{21}Cl_{13}$ 69% Cl wt. (three different isomers); $C_{18}H_{31.4}Cl_{6.6}$ 48% Cl wt.

[16] Two control groups with different numbers of fish were used.

[17] Paragraph 24: *The mortality or other adverse effects/disease in both control and treated fish is less than 10% at the end of the test; where the test is extended over several weeks or months, death or other adverse effects in both sets of fish should be less than 5% per month and not exceed 30% in all. Significant differences in average growth between the test and the control groups of sampled fish could be an indication of a toxic effect of the test chemical*.

information is currently being sought (March 2022) which may address the uncertainties (including the mortality), and therefore study reliability. The results from these studies indicate that depuration half-lives were between 29 and 91 days, with estimated BCF values exceeding 5 000 L/kg for all constituents. The C_{18} result suggests that a similar result would have been seen if a C_{17} constituent had been tested. The findings of Fisk *et al.* (1998) using C_{14} 42 – 53% Cl wt. constituents are consistent with the results of the two reliable fish bioaccumulation studies that cover similar levels of chlorination for the same C_{14} chain length. This provides some confidence that the methodology used by Fisk *et al.* (1996, 1998b and 2000) gave results that are broadly comparable to more recent bioaccumulation studies, and so the results for other chlorination levels or carbon chain lengths are useable.

62. Collectively the four laboratory studies (Fisk *et al.* (1996, 1998b and 2000) and Thompson *et al.* (2000)) are considered to indicate that constituents with carbon chains longer than C_{14} may have significant bioaccumulation potential in fish, but this cannot currently be confirmed definitively based on laboratory data alone. They are considered to be supporting studies.

63. The bioaccumulation data for "MCCPs" was considered in a review article by Thompson & Vaughan (2014), but the publication does not provide any additional experimental data. The review was made prior to the most recent fish bioaccumulation (and sediment degradation) study being available, and before the publication of OECD (2017b) (which provides guidance for interpreting laboratory fish dietary studies).

64. The results of an analysis using the BAT v2.0 tool have been provided (CPIA Annex E submission). This provides a review and interpretation of nearly all of the available laboratory bioaccumulation data and one of the field biomagnification studies, together with several *in silico* models. The BAT report does not provide any new experimental data, and the main technical points raised for the existing measured data are already discussed in Environment Agency (2019a) and this Risk Profile. The fugacity ratio concept included in the output has not been recognised or validated for regulatory purposes within the UK or EU, and the weight-of-evidence approach used in the tool relies on a single study (Houde *et al.,* 2008; see paragraph 72) and predicted data for 88% of the overall evidence base, which is not considered to provide a reasonable reflection of the data. Therefore the BAT report is not discussed further in this document at this point.

2.2.7. Other aquatic taxa of potential concern

65. Castro *et al.* (2019) determined BCF values considerably above 5 000 L/kg for a $C_{13\text{-}18}$ chlorinated n-alkane (45% Cl wt.) substance in a non-standard, non-GLP laboratory bioaccumulation study using the water flea *Daphnia magna*. However, there is significant uncertainty around the result due to the single water concentration measurement and use of dry weight rather than wet weight animal concentration measurements. Congener level chemical analysis was made using APCI-QTOF-MS. The following congeners were detected in the animals: C_{14} ($Cl_{4\text{-}7}$), C_{15} ($Cl_{3\text{-}8}$), C_{16} ($Cl_{3\text{-}8}$), C_{17} ($Cl_{3\text{-}8}$). The study author has indicated that the analysis should be treated as semi-quantitative as the method does not allow for quantification of single congeners (Castro Pers. comm 2021).

66. Renberg *et al.* (1986) and Madeley & Thompson (1983) used a $C_{14\text{--}17}$ chlorinated n-alkane (52% Cl wt.) and a C_{16} chlorinated n-alkane (34% Cl wt.) in non-standard, non-GLP bioaccumulation tests using Blue Mussel *Mytilus edulis*. The bioaccumulation factors (BAFs) exceeded 2 000 L/kg and 5 000 L/kg, respectively. The age of these two studies, together with the use of nominal exposure concentrations exceeding the water solubility limit (making it unclear if the resulting BAF is over or under-estimated when adsorption to food is included) means that their reliability is considered to be low.

67. These three studies are not considered sufficiently reliable to support the proposal, but they do indicate a concern that other aquatic taxa besides fish may experience high bioaccumulation of CPs with $C_{14\text{-}17}$ chain lengths.

68. A biota-sediment accumulation factor (BSAF) of 4.4 on a lipid-normalised basis was determined for a C_{16} chlorinated n-alkane, 35% Cl wt. in a study using the sediment-dwelling oligochaete *Lumbriculus variegatus*; the BSAF for a C_{16} chlorinated n-alkane, 69% Cl wt. substance was 0.6 (Fisk *et al.*, 1998a). As the gut contents of the organisms were not purged prior to analysis, the bioaccumulation could be significantly overestimated, and therefore the study results are considered to be of low reliability.

69. In summary, laboratory bioaccumulation studies using fish indicate high levels of bioaccumulation for different constituents of CPs with $C_{14\text{-}17}$ chain lengths. In particular, reliable aqueous and dietary exposure

studies for C_{14} chain lengths with chlorine contents in the range 45-50% Cl wt. have measured or extrapolated BCF values above 5 000 L/kg. Several other supporting fish bioaccumulation studies that were not performed to current test guidelines nor to such a high standard as the modern tests for C_{14}, suggest BCF values ranging from around 2 000 L/kg to above 5 000 L/kg for carbon chains longer than C_{14}. Other available laboratory bioaccumulation data for invertebrates are less reliable but suggest that the concern for high bioaccumulation may not be limited to fish.

2.2.7.1. Field biomagnification and monitoring studies

70. The Swedish Environmental Protection Agency (1998) found no evidence for biomagnification in a fish to seal food chain for CPs based on the results of Jansson *et al.* (1993) (the levels found in the fish were higher than in seals by an order of magnitude on a lipid weight basis). The actual CPs determined in the Jansson *et al.* (1993) study were of unspecified carbon chain length, with between 6 and 16 chlorine atoms per molecule, and so may have included CPs other than C_{14-17}. Due to the age of the study, and analytical methods available at that time, the results should be treated with caution.

71. Muir *et al.* (2002) found no indication of biomagnification in three Lake Trout – fish food chains but did suggest BMFs above 1 for "MCCPs" in a fish – invertebrate food chain. Furthermore, there were some indications that the actual bioaccumulation seen in fish was higher than would be expected by bioconcentration processes alone (although it should be noted that there is considerable uncertainty in these data).

72. A similar study (possibly including some of the same information as Muir *et al.*, 2002) was published by Houde *et al.* (2008). In this study C_{14}, C_{15}, C_{16} and C_{17} CP levels were determined in samples of biota collected in Lake Ontario and northern Lake Michigan, North America between 1999 and 2004. The data were presented as mean concentrations over the period 1999 to 2004. The highest average concentrations were found in Slimy Sculpin, and Rainbow Smelt (0.11 mg/kg). When "MCCPs" was detected, C_{14} CPs were the predominant constituents found in samples from Lake Michigan. However, samples from Lake Ontario generally showed that C_{15} constituents were present at similar, and in several cases higher, concentrations than the C_{14} constituents in those samples. An indication of potential variability is that the mean concentration of "MCCPs" in Lake Trout from Lake Ontario reported by two different papers was 25 µg/kg in 1998, 15 µg/kg in 2001 and 8 µg/kg in 2004 (Muir *et al.*, 2002; Ismail *et al.*, 2009).

73. Houde *et al.* (2008) compared these biota concentrations with the mean level of "MCCPs" determined in water samples from 2004 (0.9 pg/L). Based on these results, lipid normalised BAFs (expressed as log BAF_{lipid}) for C_{14} and C_{15} CPs were determined as 6.2 and 6.6 in plankton, 7.0 and 6.8 in Alewife, 7.4 and 7.2 in Slimy Sculpin, 7.4 and 7.1 in Rainbow Smelt and 6.8 and 6.5 in Lake Trout, respectively. Again the lipid-normalised BMF values for total "MCCPs" were below 1 in food chains consisting of Lake Trout – Alewife (BMF 0.22 - 0.25), Lake Trout – Rainbow Smelt (BMF 0.14) and Lake Trout – Slimy Sculpin (BMF 0.11 - 0.94). The lipid-normalised BMF was above 1 for the Slimy Sculpin – *Diporeia* food chain in Lake Ontario (BMF 8.7), but below 1 in the same food chain from Lake Michigan (BMF 0.88). The BMF for Slimy Sculpin – *Diporeia* in Lake Ontario was based on the detectable concentration in one sample only, so there is uncertainty about its representativeness. Trophic magnification factors (TMFs) were determined to be in the range 0.06 to 0.36 for fourteen individual constituents in the C_{14} to C_{16} chain length range for the Lake Ontario food chain (a similar analysis could not be carried out for Lake Michigan samples), suggesting trophic dilution was occurring overall. When considering these data it should be noted that the water concentrations relate to samples collected in 2004 whereas the biota samples were taken between 1999 and 2004. No information was provided about how the dissolved concentration in water varied between 1999 and 2004 and so this means that the reported BAFs in particular are highly uncertain.

74. Yuan *et al.* (2019) analysed for CPs with a chain length up to C_{30} in the Swedish environment using APCI-QToF-MS. Numerical values are provided in Appendix 6. In the marine food web, concentrations of C_{14-17} congeners from tissue samples of White-tailed Sea-eagles, Grey Seal, Harbour Seal and Harbour Porpoise (around 0.2 to 0.5 mg/kg lw) were generally similar to or higher than those in Herring (around 0.03 to 0.44 mg/kg lw). "MCCPs" were reported as summed congeners, and the authors detected all four "MCCPs" chain lengths (chlorination levels detected varied from Cl_{4-7} up to Cl_{8-10}), including in top predators. Using data from Yuan *et al.* (2019), de Wit *et al.* (2020) estimated the biomagnification potential for CPs where they were definitively measured in predator-prey species sourced from identified spatial areas. These were calculated using the mean lipid normalised concentrations of specific CPs. Ratios of mean lipid weight

concentrations of SCCPs, "MCCPs" and LCCPs for possible predator/prey pairings range from 1.5–5.0 for SCCPs, 0.40–3.1 for "MCCPs" and 0.90–3.3 for LCCPs. The highest ratios for "MCCPs" were seen for Harbour Seal/Herring (2.4) and Sea Eagle/Guillemot pairs (3.1). Lower BMF values for "MCCPs" were found in: Guillemot/Herring pairs (0.4), Sea Eagle/Eeider pairs (1.1), Grey Seal/Herring (1.4) and Harbour Porpoise/Herring pairs (1.8). These values should be considered with considerable caution as they are based on tissue measurements which may not be representative of whole-body burdens, and small sample numbers (just 2 samples in some cases). Also the predators and their potential prey were not collected at exactly the same sites or times, and no biogeochemical trophic position proxies were available to determine trophic level. In addition, the temporal trends of the CPs in the Baltic Sea are unknown. Taken together Yuan *et al.* (2019) and De Wit *et al.* (2020) are considered to provide strong evidence that "MCCPs" constituents can accumulate in a wide range of aquatic species and are found in tissues of organisms at the top of the food chain. However, further contemporaneous data from biota within the same specific food webs and supporting stable isotope data would be required to strengthen the evidence and confirm biomagnification between predator and prey species.

75. Du *et al.* (2019, 2020) conducted two studies sampling and analysing CP at a congener level in biota in the paddy fields of the Yangtze Delta using APCI-QTOF-MS. In the first study, pooled muscle, liver and unfertilised egg samples of the Black-spotted Frog were analysed. Total "MCCPs" concentrations were measured spanning < LOD and 50 ng/g ww (Du *et al.*, 2019). In the second study pooled muscle, liver and adipose tissues from two snake species (terrestrial Short-tailed Mamushi and the semi-aquatic Red-backed Rat Snake) were analysed. Total MCCP concentrations were between 0.17 and 14.0 mg/kg lw (Du *et al.*, 2020). The dominant "MCCPs" homologue was C_{14}. All four chain lengths were detected in tissues with C_{14} the most abundant, and congener-specific analysis indicated uptake variation between tissue types. Congeners were dominated by Cl_{5-6} isomers. Du *et al.* (2020) calculated mean BMF values for "MCCPs" of 1.8 (maximum BMF 2.8) in the Black-spotted Frog – Red-backed Rat Snake food chain based on muscle concentrations. Both species were sampled at the same times and place in 2011. Measurement of $\delta^{13}C$ and $\delta^{15}N$ indicated that the two species were part of the same food chain. Calculations of BMFs were from tissue specific concentrations (not whole body), and sample numbers for the snakes were low. It is not possible to verify that the snakes exclusively ate frogs (in a different paper, Du *et al.,* 2018 indicates that the Red-backed Rat Snake eats frogs, snail, small fish such as Pond Loach and eels). There is therefore uncertainty in the reliability of the reported BMFs. Nevertheless, the study indicates the possibility of biomagnification. Furthermore, the high concentrations (up to 14 mg/kg lw) of "MCCPs" measured in tissues in contaminated areas including those of predators indicate that the substance is bioavailable.

76. Huang *et al.* (2017) studied the bioaccumulation and biomagnification of SCCPs and "MCCPs" in biota from Liaodong Bay, north China, by sampling 10 species of fish and 5 invertebrates (covering trophic levels between 2.31 and 3.81 based on $\delta^{15}N$) in July 2014. Analysis was performed using 2D GC-HRMS. MCCPs were detected in all samples with the highest and lowest concentrations measured in Turbot (mean 5 097 ± 2 242 ng/g lw) and Mantis Shrimp (16.72 ng/g lw), respectively. Congener profiles were dominated by C_{14} homologues (60.7-96.5%), followed by C_{15} (6.7-24.0%), C_{16} and C_{17}. "MCCPs" chain lengths were predominantly chlorinated with 7 to 9 atoms (90.1%). BAFs were not calculated for MCCPs as water concentrations were not available. Trophic magnification factors of MCCP congeners ($C_{14-17}Cl_{5-10}$) ranged from 0.23 to 2.92, but none were statistically significant ($p < 0.05$), and nearly all of the plots had very low r^2 values. The ΣMCCPs TMF was similarly not significant. Around one quarter of the SCCPs congener plots had $r^2 > 0.5$ and TMFs above one (and were statistically significant). The TMF for ΣSCCPs was not however statistically significant. The authors concluded that biomagnification of "MCCPs" in fish was not occurring, but was for SCCPs. Given the limited number of fish samples at the higher trophic level (2-3 fish in several instances), absence of defined predator-prey relationships in the sampled biota (including for example ^{13}C analysis), and the quality of the correlations for both substances, there is uncertainty associated with the conclusions of the study. Overall, the data are given a low weight in the assessment.

77. Liu *et al.* (2020) studied the biomagnification of "MCCPs" in a terrestrial food web covering 7 species of insect, 2 amphibians, 1 lizard and several insectivorous birds. Biota were sampled over 14 months across an area where e-waste recycling and farming were taking place in Guangdong Province, south China. "MCCPs" were analysed using GC/MS-ECNI. Congener level analysis covering C_{14-17} and Cl_{5-10} detected all congeners in all organisms, with $C_{14}Cl_{7-9}$ the most abundent "MCCPs" homologues. The calculated TMF for the insect – amphibian/lizard food chain for the sum of "MCCPs" was 2.45. A significant, positive correlation was noted between $\delta^{15}N$ and the percentage chlorination of "MCCPs". This suggests that higher biomagnification

potential was linked to higher levels of chlorination. The paper provides evidence that the amphibians were in the same food chain as the insects. However, the numbers of amphibians and lizards sampled are low compared to the number of insects, BMFs were calculated from predator muscle tissue but insect whole body, sampling took place at different times over more than one year, and the range of trophic levels occupied by single predator species (1.7 to 3.8) was higher than expected (so birds were excluded from the TMF calculations). There is therefore uncertainty in the derived TMF values, which are assigned a low weight for this assessment.

78. Zeng *et al.* (2017b) collected 4 mollusc species, 7 crustacean species, and 16 fish species from the subtropical Hong Kong waters of the South China Sea and analysed these for "MCCPs". These values were then compared to average concentrations of the CPs in blubber from two cetacean species: Finless Porpoise (5.5 mg/kg lw) and 3 Indo-Pacific Humpback Dolphins (47 mg/kg lw) sampled in the same year and region and detailed in an earlier paper (Zeng *et al.*, 2015) described in Section 2.3.1.6.2. BMFs and TMFs were calculated using the fish muscle tissue, the mollusc soft tissue and the cetacean blubber concentrations (all lipid weight). Calculated BMF and TMF values exceed 1. While the concentrations in the mammals are notably higher than the prey, there is considerable uncertainty for whether the mammals exclusively consume these prey items in the sample area or would have also consumed prey from a wider – and possibly more contaminated – area (for example the Dolphin is indicated to prefer feeding in brackish estuarine waters, which would appear to be some distance from the prey sampling site). Further uncertainty results from the low sample numbers of the predators; the use of a single pooled value for each predator in the TMF calculation; and the use of tissue rather than whole body concentrations. Therefore the BMF and TMF values are not considered to be reliable. Nevertheless, the high average concentrations observed in the cetaceans' blubber suggest the possibility of high bioaccumulation resulting from exposure to "MCCPs". Chain length level analysis indicated uptake of all four chain lengths in both cetacean species, with C_{14} the most prevalent.

79. Harju *et al.* (2013) collected Ringed Seal plasma, Polar Bear plasma, Black-legged Kittiwake eggs, Common Eider eggs, Glaucous Gull plasma and Atlantic Cod liver and whole Polar Cod from Svalbard (in the Norwegian Arctic) and analysed these for CPs and several other contaminants using GC/HRMS. Samples were collected in 2012 (except for the seal samples which were collected in 2010). Measured concentrations ranged from 100 – 740 µg/kg lw (Seal, plasma), <LOD - 600 µg/kg lw (Bear, plasma), 0.26 – 17.31 ng/g ww (Kittiwake, egg), 1.10 - 16.62 ng/g ww (Eider, egg), <LOD – 1 300 ng/g lw (Gull, egg), < LOD – 0.94 ng/g ww (Atlantic Cod, liver), and 1.51 ng/g ww (mean only) (Polar Cod, whole fish pooled). The estimated TMFs were 2.3 for SCCPs and 2.0 for "MCCPs". The TMF for PBDE-47 in the study was 1.1. Due to the complex nature of SCCPs and "MCCPs" and variability between samples for a species, the authors indicate that a TMF > 1 can only be applied as an indication for bioaccumulation of S/"MCCPs" (it is further noted that the r^2 coefficient for the concentration / trophic position plot was 0.52 for SCCPs and 0.31 for "MCCPs"). The authors indicate that the tissues used have a much shorter turn-over than their preferred muscle tissue, which is longer. The use of tissue, particularly different tissues, rather than whole body concentrations also causes uncertainty, as does the unknown temporal variability of the sampling (not just the seals). Overall, there is uncertainty in the derived TMF values, which are assigned a low weight for this assessment.

80. Wang *et al.* (2021) evaluated the environmental fate of CPs in a constructed wetland ecosystem in Beijing Olympic Forest Park, China. A more detailed review is provided in UNEP/POPS/POPRC.17/INF/5. Total "MCCPs" concentrations in the wetland plants were in the range 21 to 785 µg/kg dw. High BCF values in the plants were estimated, although there were a number of uncertainties associated with these. Nevertheless, the results suggest that "MCCPs" are bioavailable to aquatic plants.

2.2.7.2. Terrestrial organisms

81. An earthworm-soil accumulation factor of 2.4 for adults and 2.3 for juveniles was determined for a C_{15} chlorinated n-alkane, 51% Cl wt. in a 56-day study using *Eisenia fetida* (Thompson *et al.*, 2001). This is assessed to be reliable with restrictions.

82. Yuan and de Wit (2018) and Yuan *et al.* (2019) analysed biota samples from Sweden for CPs with a chain length up to C30 using APCI-QTOF-MS. In the terrestrial food web, Bank Voles were found to contain the lowest amounts of "MCCPs" among the studied species. The detected concentrations of MCCP in muscle were comparable in Eurasian Lynx and Grey Wolf (0.75 – 0.83 mg/kg lipid), whilst Moose muscle contained the highest concentrations (1.6 mg/kg lipid). "MCCPs" were also detected in muscle or eggs of terrestrial birds of prey (Tawny Owl, Eagle Owl, Marsh Harrier, Golden Eagle and Peregrine Falcon) up to 0.72 mg/kg

lipid. “MCCPs” were reported as summed congeners, and the authors detected all four “MCCPs” chain lengths (chlorination levels detected varied Cl_{4-7} up to Cl_{8-10}), including in top predators.

83. Several other studies have indicated that “MCCPs” can undergo maternal transfer to birds’ eggs (a sensitive life stage), the highest reported concentration being 0.135 mg/kg ww (e.g. Heimstad *et al.*, 2018 & 2020; Ruus *et al.*, 2018; Green *et al.*, 2018; Yuan *et al.*, 2019).

2.2.7.3. Mammalian data relevant to bioaccumulation

84. Laboratory data for mammals were assessed in EC (2007). Mammalian studies using radiolabelled “MCCPs” have shown that absorption following oral exposure is significant (probably at least 50% of the administered dose; however, the concentration reached in the organism is generally lower than that in food). Following absorption there is an initial preferential distribution of the radiolabel to tissues of high metabolic turnover/cellular proliferation. Subsequently there is a re-distribution of radiolabel to fatty tissues where half-lives of up to 8 weeks have been determined for abdominal fat. Of special interest is the study by CXR Biosciences Ltd (2005a) that found that a steady state concentration in white adipose tissue was reached after approximately 13 weeks’ dietary exposure. The elimination from this tissue was found to be biphasic with an initial half-life of 4 weeks followed by a much slower elimination.

85. Dong *et al.* (2020) extrapolated results from a rat physiologically-based pharmacokinetic (PBPK) model to a human PBPK model. Based on a comparison of volumes of distribution and half-lives, CPs were predicted to accumulate in the liver and fat. The authors estimated the half-life of “MCCPs” in humans to be 1.2 years, which is much longer than in rats.

86. Human tissue monitoring is summarised in Section 2.3.2. This includes multiple studies detecting “MCCPs” in breast milk, and in some instances, other tissues such as blood.

2.2.7.4. Other data relevant to bioaccumulation

87. As described in Section 2.3.1, a number of environmental monitoring studies provide chemical analysis for “MCCPs” at a congener level. Where this relates to either environmental matrices such as sediment and soil, or an emission points such as wastewater treatment plants, the shorter “MCCPs” chain lengths predominate, particularly C_{14}. The biota monitoring where congener level information is available shows a similar pattern. Glüge *et al.* (2018) noted that $C_{14}Cl_{7-8}$ was the most prevalent in environmental samples and the most prevalent congeners in the CP-52 commercial samples that they analysed. Xia *et al.* (2021) also noted the prevalence of C_{14} congeners in both the commercial products and sediment, food and human tissue monitoring, with two CP-52 commercial samples identified as the main likely sources.

2.2.7.5. Bioaccumulation synthesis

88. The constituents of CPs with C_{14-17} chain lengths have a range of log K_{OW} values, but all measured values exceed 5. Predicted data, which align well with the measured congener level information, indicate all chain lengths will have log K_{OW} values exceeding 5.

89. Two reliable fish bioaccumulation studies conducted according to OECD TG 305 and to GLP show that a C_{14} chlorinated n-alkane, 45% Cl wt. product has a measured BCF value significantly in excess of 5 000 L/kg in Rainbow Trout, and that a C_{14} chlorinated n-alkane, 50% Cl wt. substance has a calculated BCF from dietary exposure significantly in excess of 5000 L/kg.

90. Supporting laboratory evidence indicates that there may be a high bioaccumulation potential in fish for CPs with chain lengths longer than C_{14}. They are an aqueous exposure test performed with a C_{15} chlorinated n-alkane, 51% Cl wt. substance and a series of dietary bioaccumulation studies using C_{14}, C_{16} and C_{18} chain lengths with different levels of chlorination. The dietary studies are of unknown reliability, but measured and estimated BCF values range from around 2 000 L/kg to above 5 000 L/kg. Additionally, all substances had long depuration half-lives (consistent with a BCF exceeding 5 000 L/kg). Invertebrate data also suggest that other taxonomic groups might bioaccumulate C_{14-17} CPs significantly. However, these invertebrate studies

are all of lower reliability and are therefore considered to carry a lower weight in this assessment. There are eight available field bioaccumulation studies where BMFs or TMFs both above and below 1 were calculated. All of these have major methodological limitations (particularly limited sample numbers, use of samples collected at different times, and reliance on single tissue concentrations), which affects their reliability. Nevertheless, while the food chain data are not definitive in terms of demonstrating a high bioaccumulation potential, they show that "MCCPs" can accumulate throughout the food chain, including in top predators.

91. Aquatic and terrestrial biota monitoring is summarised in Section 2.3.1.6. Despite the general uncertainty in the available data due to the analytical challenges described in paragraph 31, CPs with C_{14-17} chain lengths are present in a wide range of organisms living and feeding in locations that are close to input sources (i.e. industrial and urban areas), including at sensitive life stages such as birds' eggs. Biota concentrations can exceed 1 mg/kg lw in contaminated areas, for example 14 mg/kg lw in Chinese snake species. Whilst more limited in number, "MCCPs" have also been detected in samples from remote regions, including the Arctic, as well as in top predators. Only limited information is available on the actual carbon chain length distribution and chlorine contents of "MCCPs" detected in most environmental samples, although advances in analytical methodologies have meant that this has been increasingly possible in more recent studies. C_{14} chain lengths are frequently the predominant constituents of "MCCPs" when more detailed information is available for biota although C_{15}, C_{16} and C_{17} chain lengths are also detected. The C_{14} chain length is a significant constituent of commercial product types in Europe and the USA (see paragraph 4). The pattern is less certain in the Asian products such as from China (paragraph 5), nevertheless in Chinese soil and sediment, the C_{14} does appear to predominate. Where the observed congener patterns in biota are available, these are similar to the congener patterns found in either commercial products or environmental matrices (i.e. there appears to be little relative enrichment of one congener compared to others). This suggests that the bioaccumulation behaviour of the longer chains may be similar to C_{14}. There is good evidence that C_{14} CPs bioaccumulate significantly in fish in the laboratory, and so based on the biota measurements, it is reasonable to expect that the higher chain lengths could exhibit similar levels of bioaccumulation. This hypothesis is supported by the Fisk *et al.* (1996, 1998 and 2000) fish dietary bioaccumulation studies, and the invertebrate bioaccumulation study of Castro *et al.* (2019), where high levels of bioaccumulation of the longer chain lengths were observed in laboratory animals (although the studies themselves are of unknown or low reliability).

92. "MCCPs" are detected in human breast milk, and other tissue such as blood.

93. "MCCPs" have been shown to have relatively long elimination or depuration half-lives in fish and mammals. The substance is estimated to have a half-life in humans of 1.2 years based on PBPK modelling.

94. Overall, there is good evidence from across the screening data, laboratory tests and field biomonitoring data, that all chain lengths meet the bioaccumulation criteria of the Convention.

2.2.8. Potential for long-range environmental transport

2.2.8.1. Atmospheric half-life

95. No measured atmospheric half-lives are available for CPs with C_{14-17} chain lengths. AOPWIN v1.92[18] has been used to make predictions of the hydroxyl radical rate constant (k_{OH}) to estimate atmospheric half-lives. The model is based on a training set of 667 organic chemicals, of which 1-chlorohexane is the closest analogue to the chlorinated C_{14-17} structures. Using a hydroxyl radical concentration of 5 x 10^5 OH/cm^3 (ECHA, 2016[19]) atmospheric half-lives for 14 representative constituents of "MCCPs" covering all chain lengths with >45% Cl wt. were estimated from the predicted k_{OH}. The various half-lives were above or slightly below 2 days (37 – 140 hours) as detailed in Table 13 in Appendix 5. These estimates should be treated with caution, as the closest chlorinated alkane in the model training set is a C_6 alkyl substance with a

[18] Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11. United States Environmental Protection Agency, Washington, DC, USA.

[19] The value used is taken from ECHA (2016), rather than the hydroxyl concentration used within the AOPWIN model. The selected value (5 x 10^5 OH/cm^3) may not be typical of northern latitudes since hydroxyl radical concentrations decline with latitude.

single chlorine atom, and there are no measured data with which to directly compare the current estimates. For a given chain length, increasing the chlorination level increases the half-life as fewer C-H bonds exist for reaction with the hydroxyl radicals. For a given chlorination level, increasing the chain length will decrease the half-life as more C-H bonds are available for reaction. This can also be seen in the half-lives for SCCPs, where estimated atmospheric half-lives ranged between 1.2 to 15.7 days (28.8 to 377 hours) (UNEP, 2015). The high adsorption of CPs to atmospheric particles at low temperatures, typical of conditions at high latitudes, may also limit the atmospheric oxidation pathway.

96. Li *et al.* (2014) reported predicted hydroxyl rate constant values for 9 SCCP congeners and half-life values in the atmosphere. They developed a density functional theory (DFT) method for predicting k_{OH} values for 6 CPs through comparison with experimental values. Comparing the k_{OH} values for 9 SCCPs reported by Li *et al.* (2014) with those predicted from AOPWIN v1.92, the resulting AOPWIN v1.92 half-life predictions are lower for 6 of the SCCPs, higher for 2 SCCPs and similar for 1. For the 6 SCCPs where AOPWIN v1.92 predicted a lower value in air than Li *et al.* (2014), the difference in the two methods broadly increased with percentage chlorination. The biggest difference between predictions was noted for 1,1,1,2,3,9,11,11,11-nonachloroundecane at 68.4% chlorination. This comparison suggests that it is possible that AOPWIN v1.92 may under-predict atmospheric half-life values for "MCCP" congeners.

2.2.8.2. Modelling of long-range environmental transport

97. The OECD P_{OV} & LRTP Screening Tool (OECD, 2006) has been used to estimate the long-range transport potential (LRTP) of a representative range of C_{14} C_{15}, C_{16} and C_{17} constituents of "MCCPs" with differing degrees of chlorination. The input parameters use log K_{AW}, log K_{OW} and log K_{OA} values predicted by COSMOtherm (Glüge, Pers. Comm., 2021 & 22), and environmental fate values predicted by EPISuite™, including the predicted atmospheric half-lives described in the previous section. These are all detailed in Appendix 5.

98. The results from the OECD screening tool for the 14 constituents show that the Characteristic Travel Distance (CTD) and Transfer Efficiency (TE %) increases with percentage chlorination of the constituents (~40% to ~67%) with a predicted TE % ranging between 1% and 13% for the majority of the constituents. CTD and TE % also increases with increasing carbon chain length with the most heavily chlorinated longest carbon chain length constituents having the largest predicted LRTP. More details are provided in Table 16 of Appendix 5.

99. For further comparative and sensitivity considerations, the results of four constituents illustrating the lower and higher end of the LRET range (and terminal and non-terminal chlorination patterns) are shown in Table 7 and discussed below.

Table 7: Predictions from the OECD screening tool for four representative "MCCP" constituents

Predictions	C_{14} constituent (52.6% Cl wt.)		C_{17} constituent (51.6% Cl wt.)	
	Non-terminal chlorine (MCCP-1)	Terminal chlorine (MCCP-2)	Non-terminal chlorine (MCCP-3)	Terminal chlorine (MCCP-4)
Characteristic Travel Distance (CTD) (km)	1 603	1 466	2 826	2 821
Transfer Efficiency (TE) (%)	3.95	3.10	12.41	12.39
Overall persistence, P_{OV} (days)	518	518	519	519

100. To provide a comparison, data for SCCPs (which is already listed as a POP) have also been considered. SCCPs with >48% Cl wt. were the focus of the Risk Profile (UNEP, 2015). The LRTP modelling for this substance (referred to as "SCCP 5" below) used an atmospheric half-life value of 88.8 hours (Wegmann *et al.*, 2007), although the specific congener modelled is not stated. Two further SCCP constituents have been modelled, with a chlorination level of 61%, which is considered to be representative of the typical 50% to 70% chlorination levels used for most commercial SCCP products (the input parameters are provided in Table 15 in Appendix 5). The input parameters for these constituents rely on physico-chemical and atmospheric half-life values predicted by EPISuite™ produced during the nomination. These predictions and the two figures (which have MCCPs plotted using physico-chemical data derived using EPIWIN™) will be updated to COSMOtherm predictions during the intercessional work.

101. Similar to the MCCPs modelling, the SCCP congeners are modelled with both terminal and no terminal chlorine atoms. These four constituents have predicted atmospheric half-lives between 84.7 and 144.3 hours. All five SCCP constituents have been run in the OECD P_{OV} & LRTP Screening Tool together with the four MCCPs constituents[20]. These results together with those for other available POP reference chemicals in the database (aldrin, a-HCH, HCB, PCB-28, PCB-101 and PCB-180) are shown in Figure 2. Figure 3 provides a zoomed extract of Figure 2 to show the CP positions. These indicate that the LRTP of "MCCPs" is similar to, but slightly less than, SCCPs. Given the lower atmospheric half-life predicted for the C_{14} and C_{17} constituents compared to SCCPs, this position is not surprising.

102. As noted in Section 2.2.3.1 COSMOtherm is preferred to EPISuite™ to predict physico-chemical values for CPs. A sensitivity analysis between the use of EPISuite™ and COSMOtherm physico-chemical values to model the LRET is provided in Table 16 and Table 17.

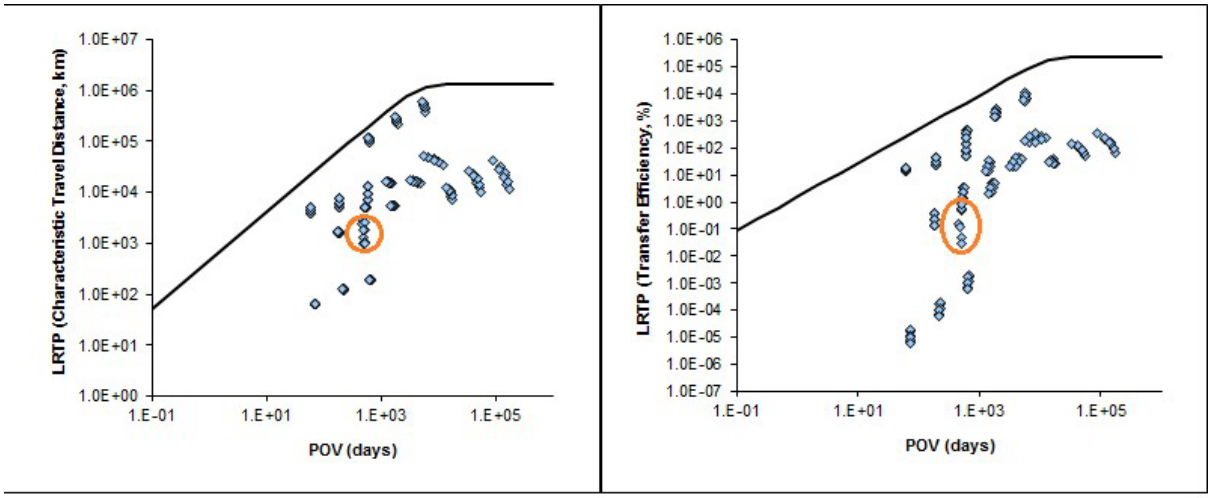

Figure 3: Output plots of CTD and TE for 4 MCCP and 5 SCCP constituents (within orange circle) (derived using inputs from EPISuite™)

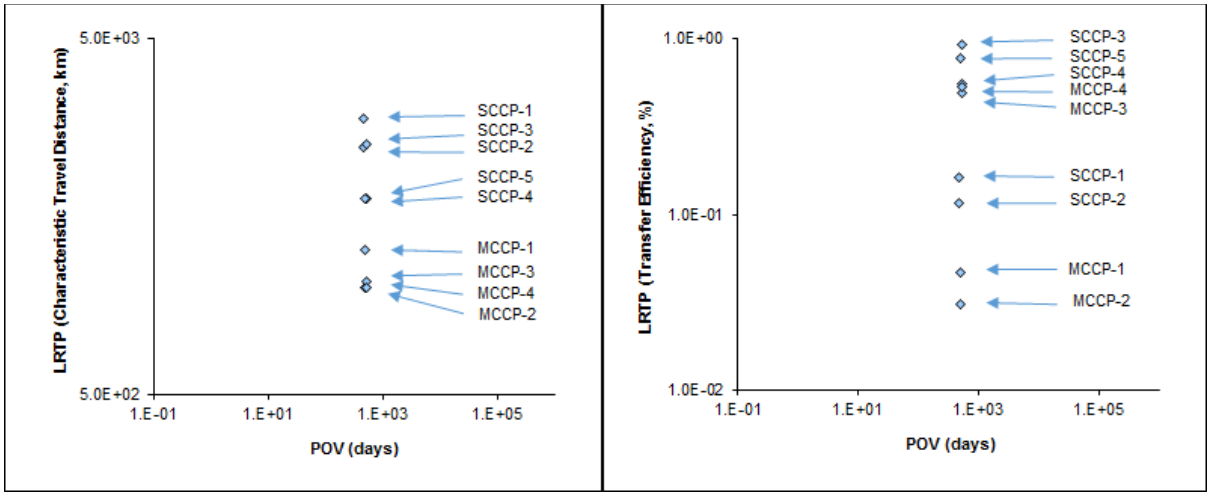

Figure 4: Output plots for CTD and TE for 4 MCCP and 5 SCCP constituents (expanded view of figure 2, with labelled constituents) (derived using inputs from EPISuite™)

[20] NB: currently the SCCPs physico-chemical predictions are made using EPIWIN™. New COSMOtherm predictions will be provided in due course. Figures 2 and 3 are also a legacy from the previous modelling of the "MCCPs" LRET using EPIWIN™ and will be updated once the SCCPs data are received.

103. The high K_{OW} and low vapour pressure values of "MCCPs" suggests that it will strongly partition to organic matter, including adsorption into and onto aerosol particles in air, as well as to suspended solids in water. Long range transport of CPs with $C_{14\text{-}17}$ chain lengths to remote regions is likely to be governed by the relative proportions present in the gaseous and sorbed-to-particulates atmospheric phases with subsequent deposition to soil, vegetation and water when conditions permit. CPs with $C_{14\text{-}17}$ chain lengths are also likely to be transported via water while adsorbed to suspended particles. In relation to atmospheric LRET, sorption to particulates reduces the potential for photodegradation during atmospheric transport relative to the gaseous phase. COSMOtherm predictions by Endo (2021) shows that K_{OA}, and hence sorption to particles, increases with both increasing chlorination and increasing carbon chain length (see Table 16 and Figure 4, Figure 5, Figure 6 and Figure 7 in Appendix 5). The high log K_{OA} value suggests that the proportion of CPs with $C_{14\text{-}17}$ chain lengths present in the gas phase is very low. As COSMOtherm estimates higher log K_{OA} values than EPISuite™ based on the respective predictive physico-chemical parameters, the OECD Screening Tool predicts a very high binding potential to particles for $C_{14\text{-}17}$ chain lengths compared to EPISuite™ (see Figure 11 in Appendix 5), which results in the greater LRET predicted by COSMOtherm values.

104. A final consideration is the fraction sorbed to airborne particulates (phi) predicted within the OECD screening tool itself, which affects the LRET modelling using EPISuite™ physicochemical values. The OECD Tool predicts the fraction in aerosols in air to be between 0.73% and 33% for $C_{14\text{-}17}$ chain lengths at ~52% Cl wt., 0.04% to 2.1% at ~42% Cl wt. and 75% to 100% at ~66% Cl wt. respectively when using physico-chemical values from EPISuite™ . The AEROWIN v1.0 model (also within EPISuite™), has three methods for estimating the fraction sorbed to airborne particulates (phi) from the predicted substance properties. Using the same physico-chemical properties, the phi values predicted by AEROWIN v1.0 for CPs with $C_{14\text{-}17}$ chain lengths at ~52% Cl wt. (1.68% to 63.8%) are higher than predicted by the OECD Tool for $C_{14\text{-}17}$ chain lengths at ~52% Cl wt. and this trend is repeated for the other levels of chlorination. This implies that a lower proportion of the CPs with $C_{14\text{-}17}$ chain lengths may be available for degradation in air than is predicted by the OECD Tool and therefore the long-range transport potential in air is potentially underestimated. Little effect of changing phi is seen when using the COSMOtherm values due to the already high particle sorption. Phi values for "MCCPs" and SCCPs are discussed further in Appendix 5.

105. The absence of degradation in the OECD TG 308 study could be a result of strong binding to the sediment phase, and consequent lack of bioavailability. This adsorption would also then suggest the level of gaseous partitioning may be over-estimated by the OECD tool. Jiang *et al.* (2021) indicate that "MCCPs" detected in Antarctica were present as 72.1% gas phase and 27.9% in the particle phase (based on 3 commercial products with 42%, 52% and 57% Cl wt. as the analytical standards). Greater partitioning of higher molecular weight CPs was shown by Al Saify *et al.* (2021) in air sampling development work using the same analytical standards, where "MCCPs" in the gaseous phase was exclusively 42% Cl wt., whereas more than half of the particle-bound "MCCPs" was composed of congeners with 52 to 57% Cl wt.

106. Gawor and Wania (2013) analysed predictions of log K_{AW} and log K_{OA} for a number of complex halogenated chemical mixtures, including CPs, to forecast their fate including LRET. They suggest that substances with a log K_{OA} between 6.5 and 10 are "multiple hoppers" (which undergo repeated cycles of deposition and re-evaporation to reach higher latitudes). Substances with log $K_{OA} \geq 10$ are likely to be "single hoppers" (sorbed to aerosols, which would need to undergo LRET without being deposited along the way in order to accumulate in remote locations like the Arctic). They expect "MCCPs" with around 4 to >6 chlorine atoms" would be single hoppers based on the authors' prediction of log K_{OA} >10 (estimated using ACD labs software). Using experimental data (see Table 14) for the C_{14}, 51% Cl wt. constituent, a log K_{OA} of 8.58 can be estimated which suggests that the KOA predicted by ACD labs is over-estimated for "MCCPs" and the experimental data suggests the C_{14} constituent would be a multiple hopper on the basis of the log K_{OA}. Gawor and Wania (2013) concluded that "MCCPs" with ~5–6 and ~6–7 chlorine atoms, respectively, were predicted to have the highest LRET potential (see further discussion in Appendix 5).

107. The long-range atmospheric transport potential for CPs with $C_{14\text{-}17}$ chain lengths has also been assessed by Environment Canada (2008). They concluded that the atmospheric half-lives for vapour phase "MCCPs" ranged from 2.7 to 7.1 days (64.8 to 170.4 hours). The longest half-lives were for constituents with the highest chlorine contents and shorter chain lengths, although the specific constituents are not specified. The sensitivity of the OECD tool to this range of half-lives is shown in Table 18 in Appendix 5. It can be seen that CTD increases significantly, and TE also increases with a longer half-life, but there is little change to

P_{OV}. Environment Canada (2008) further concluded that "MCCPs" have estimated vapour pressures and Henry's Law constants in the range of values for several POPs that are known to undergo long-range atmospheric transport, such as lindane, heptachlor and mirex.

2.2.8.3. Air monitoring data

108. Several monitoring studies have reported the detection of "MCCPs" in the air of remote areas such as the Arctic, Antarctic and the high-altitude Tibetan Plateau, which provides evidence of long-range transport occurring (Bohlin-Nizzetto *et al.*, 2014, 2015, 2017, 2018, 2019, 2020; Bohlin-Nizzetto & Aas, 2016; Jiang *et al.*, 2021; Ma *et al.*, 2014; Wu *et al.*, 2020a). These are summarised in Appendix 6. Concentrations in Antarctica (~10 pg/m^3) were lower than those in the Arctic (~200 pg/m^3). Higher concentrations were observed in the Tibetan Plateau than the Polar regions, although the years that were monitored do not fully overlap. Congener-specific information indicated that in the Antarctic the $Cl_{7–8}$ congeners were dominant in the particulate phase, with $Cl_{6–7}$ predominating in the gas phase (Jiang *et al.,* 2021). In the Tibetan Plateau, the authors comment that the dominant congeners were the same as those detected in soils at an e-waste dismantling site, and the Pearl River Delta in China (Wu *et al.,* 2020a).

109. The values observed at Svalbard between 2013 and 2019 by Bohlin-Nizzetto *et al.* (2020) were noted to be similar to monitoring of rural air in Canada, but significantly lower than measurements in urban and rural sites in China and India (see Appendix 6 for other air monitoring data). Furthermore the levels of "MCCPs" were generally an order of magnitude higher than the concentrations of most of the other studied POPs (including polybromodiphenyl ethers (PBDEs) such as decabromodiphenyl ether), but 1 to 2 orders of magnitude lower than concentrations of summed PAHs. Jiang *et al.* (2021) similarly found that concentrations of "MCCPs" in the Antarctic exceeded those of PBDEs and polychlorinated biphenyls (PCBs).

110. Bohlin-Nizzetto *et al.* (2020) note that 42% of "MCCP" samples in 2019 had higher or similar concentrations to SCCPs, which is different to previous years where <10% of "MCCP" values exceeded SCCP concentrations. Jiang *et al.* (2021) also record a significant increasing trend in the ratio of total "MCCPs" to total SCCPs from 2014 to 2018 detected in both aerosol particle and gaseous phases in Antarctica, although "MCCPs" concentrations remain significantly below SCCPs. Wu *et al.,* (2020a) similarly note an increasing trend in their measurements of "MCCPs" at the Tibetan Plateau. This presumably reflects changing emission scenarios.

111. Data from the Chinese Bohai Sea (Ma *et al.*, 2018) provide further supporting evidence of the potential mechanisms of LRET as the researchers detected "MCCPs" in air samples (both gaseous and particulate) and seawater samples (both dissolved and particulates). Several studies summarised in Section 2.3.1.6.2 detected "MCCPs" in marine biota indicating exposure via sea water.

112. Iozza *et al.* (2009a and 2009b) detected "MCCPs" at concentrations of 0.0052 to 0.095 mg/kg in 8 samples of spruce needles (*Picea alpestris*) collected from the European Alps in October 2004. C_{14} substances with 6 to 8 chlorine atoms per molecule predominated, although 5, 9 and 10 chlorine atom substances (and substances with longer chain lengths) were also detectable at a few percent relative abundance. Wang *et al.* (2016) measured "MCCP" concentrations in Masson Pine (*Pinus massoniana*) needles from Shanghai, China. The measured concentrations were 0.012 to 33.5 mg/kg dw with a geometric mean value of 0.7 mg/kg dw. The details of the analytical method were not available. These findings are likely to reflect atmospheric deposition rather than plant uptake. The detection of "MCCPs" in tree bark by Niu *et al.* (2021) summarised in Section 2.3.1.6.2 provides further supporting evidence of atmospheric deposition. According to Glüge *et al.* (2018), "MCCP" concentrations in air measured in Asia and Europe are in the same order of magnitude as SCCP concentrations measured at the same locations and points in time. "MCCP" concentrations in air in the Arctic are, however, around one order of magnitude lower than the SCCP concentrations which indicates a slightly lower long-range atmospheric transport potential of "MCCPs" compared with SCCPs (Glüge *et al.*, 2018). This observation aligns with monitoring data above, and the OECD model prediction for LRET for "MCCPs" and SCCPs.

2.2.8.4. Other environmental monitoring data

113. Section 2.3.1.4.1 details the detection of "MCCPs" in Arctic sediment, specifically in surface marine sediments from the Norwegian Sea, and to a more limited extent the Barents Sea, over a number of years (Bakke *et al.,* 2008; Boitsov and Klungsøyr, 2018; Boitsov *et al.,* 2019). As there are no obvious significant

local sources of "MCCPs" in these locations this suggests detection of the substance is likely to have resulted from long range environmental transport. As described in Section 2.3.1.6.1 a number of monitoring studies detect "MCCPs" in other matrices or biota at remote locations. The biota studies include Reth *et al.* (2006), Harju *et al.,* (2013), Green *et al.* (2018, 2019), Schlabach *et al.* (2018), Wu *et al.* (2020a) and Casa *et al.* (2019). This indicates that "MCCPs" transported to remote locations is bioavailable to the biota living there. Several of the studies noted that the "MCCPs" concentrations detected in biota were either close to those of SCCPs or similar.

2.2.8.5. Long range transport synthesis

114. The predicted atmospheric half-life for relevant C_{14} and C_{17} constituents are between 37 and 140 hours. It is difficult to validate these estimated values due to the lack of experimental data, and so they are considered uncertain. The modelled C_{14} constituents are at or above the 48-hour threshold of Annex D. The longer chain lengths are below 48 hours at lower levels of chlorination, but these constituents are less relevant for (gaseous) atmospheric photodegradation as a greater fraction will be adsorbed to aerosols. More highly chlorinated constituents will be more photolytically stable and more adsorptive.

115. Using the OECD Screening Tool and EPISuite™ predicted physico-chemical properties, the LRET for these constituents are comparable to, but slightly below those for SCCPs, which is a POP. It also falls within the range of other listed POPs. CPs with C_{14-17} chain lengths have low volatility and are expected to adsorb strongly to particulates. Given the relatively high gaseous fraction predicted for the C_{14} constituents in the OECD Screening Tool, it is not clear how well the adsorption of the constituents is actually modelled. Several lines of evidence from other models and experimental data suggest that the fraction adsorbed to aerosols could be higher. Using COSMOtherm predicted physico-chemical properties, the LRET potential modelled by the OECD Screening Tool is greater, due to a greater proportion absorbed to aerosols. The atmospheric transport of airborne particulates provides a potential route for long range transport, and this is supported by the detection of "MCCPs" at low levels in air samples taken in remote locations. These include 5 years' monitoring in the Arctic and Antarctica, and recent sampling at the Tibetan Plateau. "MCCPs" monitoring at both Svalbard and the Tibetan Plateau suggests levels in air are increasing at these remote locations. The ratio of "MCCPs" to SCCPs is also observed to be increasing in Antarctic air. The levels of "MCCPs" observed in both these remote locations was noted to be higher than some listed POPs such as PBDEs.

116. The modelled comparability to SCCPs is further supported by the detection of "MCCPs" in environmental samples from remote regions, including in top predators. In some instances, the levels of "MCCPs" were indicated to be close to or similar to SCCPs.

117. Overall, the evidence demonstrates that long-range environmental transport occurs. Limited biota monitoring data indicate detection of "MCCPs" in remote areas, with similar concentrations to SCCPs suggested in some studies. Air sampling data are also limited to specific locations, but the available information confirms the potential for transport via this medium. The predicted atmospheric half-life of a range of constituents is around 2 days with values above and below the threshold. It remains unclear how accurate these predictions are, and to what degree the gaseous transport of CPs with C_{14-17} chain lengths is relevant compared to adsorption to particles.

118. In conclusion, the limited data indicate that there is both a pathway and delivery of CPs with C_{14-17} chain lengths to remote locations. The concern is that the characteristics of these constituents, while slightly less efficiently transported over long distances than SCCPs, appear to be similar to that POP.

2.3. Exposure

2.3.1. Environmental monitoring data

119. Appendix 6 provides a summary of all cited environmental monitoring data, based on Environment Agency (2019a) and more recent studies. This also includes details of number and species sampled, as well information on carbon chain length and chlorination where this was included in the analysis. Several studies are described in Sections 2.2.2.2.3, 2.2.3.4, 2.2.4.3 and 2.2.4.4 rather than this section.

2.3.1.1. Ambient air

2.3.1.1.1. Remote

120. Section 2.2.4.3 details studies where "MCCPs" were detected in the air of remote regions such as polar areas and the Tibetan plateau. These provide evidence of long-range transport occurring (Wu *et al.*, 2019; Ma *et al.*, 2014; Bohlin-Nizzetto *et al.*, 2014, 2015, 2017, 2018, 2019, 2020; Bohlin-Nizzetto & Aas, 2016; Jiang *et al.*, 2021). It is also notable that for all three locations, concentrations of "MCCPs" are reported to be rising over time.

2.3.1.1.2. Other

121. "MCCPs" have been detected in India, Pakistan, China, Chinese Bohai Sea, Norway, Sweden and the UK. "MCCPs" can be detected in air sampled in urban areas at concentrations up to around 12 ng/m^3. Since 2012, no significant trends over time for "MCCPs" have been observed in the Swedish national monitoring program for air and deposition (Sweden Annex E information).

2.3.1.2. Water

2.3.1.2.1. Remote

122. No remote water monitoring data have been located.

2.3.1.2.2. Other

123. The available European monitoring data generally show widespread occurrence of "MCCPs" in water (at concentrations typically up to a few µg/L).

2.3.1.2.3. Wastewater and landfill leachate

124. Several Norwegian studies have analysed WWTP sludge for "MCCPs" reporting concentrations up to 17 mg/kg (Thomas *et al.,* 2011; Norsk Vann, 2018; Fjeld, 2005; Ruus *et al.,* 2018). Several other authors have detected "MCCPs" in UK, Swedish and Swiss sewage sludge at similar concentration ranges (Stevens *et al.,* 2003; Olofsson *et al.*, 2012, Bogdal *et al,.* 2015). There has been no clear change in the concentrations of "MCCPs" measured in the Swedish national monitoring programme since 2004 (Sweden Annex E information).

125. Brandsma *et al.* (2017) found that "MCCPs" were the dominant CPs in sludge samples collected from 15 different WWTPs in Australia. "MCCPs" were detected in all studied sludge samples with concentrations ranging from 0.54 to 3.65 mg/kg dw, using APCI-QToF-MS. All four chain lengths were detected although C_{14} and C_{15} chain lengths dominated all of the samples. Chlorination ranged from $Cl_{5\text{-}9}$.

2.3.1.3. Sediment

2.3.1.3.1. Remote

126. The MAREANO (Marine AREA database for Norwegian waters) program has analysed for a number of contaminants including CPs (using ECNI-HRMS) in surface marine sediment collected from several locations within the MAREANO area. In a pilot study between 2009 and 2015, concentrations of SCCPs and "MCCPs" in the ten marine sediment samples could be detected but were all below their limits of quantification (1393 and 19 µg/kg dw) (Boitsov *et al.,* 2016). Based on these findings, Boitsov *et al.* (2019) sampled marine sediment from 8 locations in 3 areas near Svalbard and analysed for CPs. Levels of SCCPs and "MCCPs" were mostly below their LOQs (although, the LOQs were higher than the previous study – 96 and 334 µg/kg). "MCCPs" were quantified at two locations (410 and 536 µg/kg dw). Boitsov and Sanden (2020) did not detect either SCCPs or "MCCPs" in sediment samples from 7 locations near Bjørnøya and Svalbard in 2019 (LOQ = 20 and 6.9 µg/kg dw). More recent sampling from 7 locations in the Norwegian Sea in 2020 detected "MCCPs" at all sites, with concentrations between 25 and 529 µg/kg dw (Boitsov & Sanden, 2021).

127. Bakke *et al.* (2008) collected surface marine sediment samples from the Barents Sea in 2006 and 2007, and analysed for CPs using ECNI-HRGC/HRMS. "MCCPs" was detected in one sample at 4.8 µg/kg dw. Further

marine sediment sampling for "MCCPs" from the eastern Barents Sea in 2017 detected "MCCPs" at one location (2.8 mg/kg dw), however the LOQ was relatively high: 655 µg/kg (Boitsov and Klungsøyr, 2018).

2.3.1.3.2. Other

128. "MCCPs" have been widely detected in river and marine sediment at concentrations typically up to around 2 mg/kg dw, although up to 65 mg/kg dw has been reported near industrial areas. Sampling locations include China, Hong Kong, Japan, Sweden, Norway, UK, Germany, the Netherlands, Canada, Australia, Switzerland, Czech Republic, Irish Sea and the Baltic Sea. In 2018, the median concentration of "MCCPs" in the suspended particulate matter of several German rivers was 170 ng/g dw (Yuan *et al.,* 2022).

129. Chen *et al.* (2011) sampled surface sediment several locations around the Pearl River Delta in China in 2009 and analysed for SCCPs and "MCCPs" using GC-ECNI-LRMS analysis. The sites included the ponds and rivers around a large e-waste area, highly industrialised and urbanised areas of a number of cities, and less industrialised areas upstream of these locations. Concentrations of "MCCPs" were between 0.880 and 38 mg/kg. At all locations the C_{14} chain length dominated followed by C_{15}, C_{16} and C_{17}.

130. "MCCPs" have been detected in a number of studies reviewing sediment cores as described in Section 2.2.2.2.3 (Iozza *et al.*, 2008; Yuan *et al.*, 2017; Chen *et al.*, 2011; Muir *et al.*, 2002; Zeng *et al.* 2017a; Zhang *et al.*, 2019). These vary in concentration depending on the core location (for example industrial locations are more contaminated). Analysis indicates the presence of "MCCPs" in the cores going back decades in some cases. Nearly all of the studies included chain length analysis, which showed that all of these could be detected.

2.3.1.4. Soil

131. Soil monitoring data is available for China, Switzerland and Germany. "MCCPs" concentrations in soil measured using GC-ECNI-HRMS show an increase from 1989 to 2014 from six sampling sites in Switzerland with "MCCPs" concentrations (up to 160 µg/kg) exceeding SCCPs in the most recent samples (Bogdal *et al.,* 2017). In Germany, the concentrations were up to 49 µg/kg dw (Yuan *et al.,* 2022). Levels in Chinese soil vary, but concentrations up to 2 mg/kg dw have been detected in agricultural soils based on a survey performed by Aamir *et al.* (2019). All chain lengths were detected in Chinese soil where this level of analysis was performed (Aamir *et al.*, 2019; Wang *et al.,* 2017; Xu *et al.*, 2016). Aamir *et al.* (2019) found that $C_{14\text{-}15}Cl_{5\text{-}7}$ were the predominant congeners. Concentrations in soil sampled around a non-ferrous metal recycling park in China detected concentrations of "MCCPs" up to 6 mg/kg, with the major "MCCPs" congener groups noted to be $C_{15–16}C_{l5}$ (Weng *et al.*, 2022). In the more remote agricultural Chinese soils sampled by Aamir *et al.* (2019), the authors also noted the possibility of a mountain cold-trapping effect for atmospheric CPs resulting in increasing levels of "MCCPs" compared to SCCPs in soils at higher elevation, which is similar to the suggestion of Zhang *et al.* (2019) regarding high altitude lake sediment.

2.3.1.5. Biota

2.3.1.5.1. Remote

132. Reth *et al.* (2006) detected "MCCPs" in liver and muscle samples from Arctic Char, Little Auk and Black-legged Kittiwake collected from the Arctic using HRGC-ECNI-LRMS. The highest concentration was 0.37 mg/kg (in auk liver tissue). The authors reported that the C14/C15 ratios detected in the study were similar to that found in commercially supplied "MCCPs" products. "MCCP" and SCCP concentrations in the bird muscle and liver tissue were also comparable. The very small sample size used in this study means that limited weight should be placed on the findings. Glüge *et al.* (2018) noted that the "MCCP" concentrations from the fish in the study were in the upper 50th percentile of the observed concentrations in fish sampled from Canada and Europe (principally Norway), and concentrations in the bird eggs were comparable between the Arctic and Norway.

133. Harju *et al.* (2013) detected "MCCPs" in the plasma of Ringed Seals and Polar Bears from the Arctic with concentrations of up to 74 and 600 µg/kg lw. Kittiwake eggs, Common Eider eggs, Glaucous Gull plasma and Atlantic Cod liver and whole Polar Cod were also sampled. These were in the same order of magnitude as SCCPs in the same samples, but at marginally lower values. This is described in more detail in Section 2.2.3.4.

134. Schlabach *et al.* (2018) detected "MCCPs" using GCMS in biota collected in 2017 from Svalbard and the Norwegian island of Røst. Tissue was sampled from Common Eider, European Shag, Kittiwake, Glaucous Gull and Polar Bear (n= 5 to 10). The detection frequency of "MCCPs" was 100% with the exception of Polar Bears (60%). "MCCPs" concentrations were generally lower than SCCPs but within the same order of magnitude apart from Polar Bears. The authors estimated the total measurement uncertainty to be 40-50%.

135. Green *et al.* (2018, 2019 & 2020) have analysed for SCCPs and "MCCPs" in remote biota as part of the *Contaminants in coastal waters of Norway* programme in Cod (liver) and the Common Eider (blood and egg) sampled from Svalbard in 2017, 2018 and 2019 (n=15 for all samples, except Eider blood in 2019). Analysis were performed using GC-MS, GC-HRMS or GC-QTOf-MS. In 2018 the median concentrations of "MCCPs" were 35 µg/kg ww and 14 µg/kg ww in Eider blood and egg, which were higher than the 2017 samples, but similar to those reported in Schlabach *et al.,* (2018). Green *et al.* (2019) notes that the median concentration of "MCCPs" detected in Cod liver samples originating from Svalbard (56 µg/kg ww) in 2018 were similar to those from urban areas of coastal Norway. "MCCPs" concentrations were broadly similar to SCCPs. In 2019, the median "MCCPs" concentration in Cod liver was slightly higher (110 µg/kg ww), with the levels in Eider eggs and blood slightly lower (31 and 9 µg/kg ww). SCCPs concentrations were slightly lower than 2018, although of a similar order of magnitude (Green *et al.*, 2020). The authors estimated the analytical uncertainty to be around 50%.

136. In addition to the biota above, a review article by Vorkamp *et al.* (2019) also noted the detection MCCPs in mussels in the Arctic.

137. Casa *et al.* (2019) detected "MCCPs" in blubber samples obtained from Humpback Whales stranded between 2007 and 2015 in western and eastern Australia. Genetic testing indicated that the whales were associated with two Antarctic Management Areas, and principally feed on Antarctic Krill. The authors expect the chemical profiles of this population to reflect their Krill diet. Unsatisfactory analytical recoveries were obtained for the "MCCP" congeners, but "MCCPs" were detected in three of the nine samples.

138. Wu *et al.* (2020a) detected SCCPs and "MCCPs" in soil, Pine needles, tree bark, lichen, and moss in four regions of the Tibetan plateau using GC-qTOF-NCI-MS. "MCCPs" were detected in all samples taken between 2010 and 2016. The mean concentration in soils was 2.4 mg/kg TOC, with levels in the biota around 2 mg/kg lw. The dominant congener profiles in samples were noted to be similar to those detected in soils at an e-waste dismantling site, and the Pearl River Delta. SCCPs were detected at marginally higher concentrations than "MCCPs", which was suggested to reflect a higher LRET of the substance, although there was a temporal difference in sampling which could also influence the findings. Different air currents and sources were thought to influence detection across the 700 000 km^2 sampling area.

2.3.1.5.2. Other

139. Huber *et al.* (2015) collected eggs of 3 species of seabird from two remote Norwegian coastal islands, and analysed for several contaminants including SCCPs and "MCCPs". Analyses were performed using GC/MS. Concentrations of "MCCPs" in bird eggs were <0.76─17.5 ng/g ww and found at a much higher frequency (80%) compared with SCCPs (40%). Concentrations of "MCCPs" in this study were in the same order of magnitude as the sea bird eggs sampled from Svalbard (Harju *et al.,* 2013).

140. Green *et al.* (2020) analysed for SCCPs and "MCCPs" in whole Blue Mussels and Cod liver at a number of monitoring stations along the Norwegian coast. This was part of the *Contaminants in coastal waters of Norway* programme which has been in place since 2012. The stations include areas with possible point and diffuse pollution sources (local airports were noted) and more remote areas. Analyses was performed using GC/MS. "MCCPs" were detected in all samples: median concentrations in blue mussel were 13 to 62 µg/kg ww and in Cod liver between 98 and 320 µg/kg ww. Earlier results from the programme are provided in Annex 6. Green *et al.* (2020) also assessed long-term trends in the monitoring for SCCPs and "MCCPs" at 8 of monitoring stations where there was sufficient data. No trend in levels was seen at any station for MCCPs, and only for one station for SCCPs (upwards at an "airport area").

141. Schlabach *et al.* (2018) detected "MCCPs" in all Common Gulls' eggs and Mink liver collected in 2017 from Tromsø, Norway. Analysis was performed by GC-MS. Concentrations of "MCCPs" in these urban eggs were comparable to the other bird species sampled from the remote Arctic in the same study.

142. Ruus *et al.* (2018 and 2019) and Grun *et al.* (2021) reported concentrations of "MCCPs" in Atlantic Cod liver, and Herring Gull blood and eggs in the Inner and Outer Oslo Fjord areas as part of the *Norwegian*

Environment Agency Urban Fjord Monitoring Programme. Analyses were performed using GC-MS with mean concentrations detected between 3.57 and 231.9 ng/g ww. Higher concentrations were seen in the Cod liver and Gull blood in the Inner Oslo Fjord in 2017 and 2018 compared to 2020, although the Gull egg concentrations were similar. Herring Gull samples from the Outer Oslo Fjord area were of the same order of magnitude as the Inner Fjord in 2017 (these were not sampled in 2018 and 2020. In a related study Knudtzon *et al.* (2021) analysed for a number of contaminants including C_{14-17} congeners (degree of chlorination not stated) in 30 paired whole blood and egg samples from female urban Herring Gulls from the inner and outer Oslofjord, Norway in May 2017. Measurements were performed using GC/MS, with C_{14-17} congeners detected above the LOD in all samples. Concentrations were between 6 and 200 ng/g ww in blood and 3 - 630 ng/g ww in eggs for the outer Oslofjord samples. The inner Oslofjord concentrations ranged from 8.0-76.0 ng/g ww in blood and 6.0-68.0 ng/g ww.

143. Herzke *et al.,* (2019) analysed liver samples from Herring Gulls collected in Skulsfjord in Troms, Northern Norway in 2017 for a number of plastic additives including "MCCPs" using GC/HRMS. CPs were noted to dominate the analytical results with mean concentrations in the livers of 210 ng/g ww for SCCPs and 87.8 ng/g ww for "MCCPs".

144. The *Environmental pollutants in the terrestrial and urban environment monitoring programme* in Norway has detected MCCPs in several terrestrial biota living in the Oslo area, including Tawny Owl eggs, Field Fare eggs and Red Fox liver from sampling performed in 2020. Concentrations in the Tawny Owl eggs were up to 26 ng/g dw or 544 ng/g lw, which were noted to be in a similar range to PFAS and PCBs (Heimstad *et al.,* 2020).

145. De Wit *et al.* (2020) reported the sampling and analysis of Blue Mussel and Viviparous Eelpout collected from several locations in the Baltic Sea in 2015 (which was additional to the sampling described in Section 2.2.3.4). CP analyses were performed using a modified method following Yuan *et al.* (2020). Average total "MCCPs" and SCCPs concentrations in the Mussels were 210 ng/g lw and 72 ng/g lw. Average total "MCCPs" and SCCPs concentrations in the fish muscle were 130 ng/g lw and 52 ng/g lw. The homologue and congener pattern of the Mussels (only) are graphically represented in the paper which indicates all MCCP chain lengths could be detected.

146. Yuan *et al.* (2021) analysed cetaceans, fish, and bivalves from marine waters around Greenland, Iceland, and the Swedish west coast between 2001 and 2020 for chlorinated paraffins using Ultra Performance Liquid Chromatography (UPLC)-APCI-Orbitrap-MS. "MCCPs" were quantified from the reconstruction of CP homologues, with congener specific analysis available. "MCCPs" were detected above their MDL in 54% of samples (see appendix for more details). These include mussel, scallop, Minke Whale muscle, Killer Whale muscle, Pilot whale muscle and blubber, Greenland Shark liver and Harbour Porpoise blubber (in most instances these were single samples). "MCCPs" concentrations were 14 – 270 ng/g lw. The homologue and congener pattern are graphically represented in the paper which indicates all MCCP chain lengths could be detected, with C_{14} dominating. The authors noted higher CPs concentrations in the cetacean muscle tissue compared to blubber (by a ratio of 3.6 for "MCCPs").

147. Yuan *et al.* (2022) determined the concentrations of CPs in 72 pooled biota samples from the German Environmental Specimen bank using UPLC-APCI-orbitrap-MS analysis. The samples were from multiple sites across coastal, terrestrial and freshwater ecosystems and collected in 2017 and 2018. "MCCPs" were detected in 99% of samples and noted to be the predominant CP in nearly all sample types. Additional Bream samples collected downstream from a CP production site were used to establish a temporal trend in CPs and indicated relatively steady "MCCPs" concentrations over the period 1995 – 2019 (with C_{14} and C_{15} chain lengths predominating, but all four detected).

148. Labadie *et al.* (2019) detected all four "MCCPs" chain lengths (with Cl_{7-9} congeners) in Common Barbel sampled from 4 rivers and a canal from the Rhone River basin in France in 2019. Using GC-ECNI-TOF HRMS analysis concentrations of "MCCPs" was up to 72.7 ng/g ww (11,300 ng/g lw).

149. Basconcillo *et al.* (2015) measured SCCPs and "MCCPs" in top predatory fish (Lake trout, Walleye, and Brook Trout) from nine freshwater bodies across Canada in 2010–2011 using GC-HRMS analysis. "MCCPs" were reported as a sum of detected congeners (chlorination at Cl_5 and above). SCCPs and "MCCPs" were detected in all fish that were sampled. The highest concentrations of "MCCPs" (11–12 ng/g ww) were found in Lake trout from industrialised and populated areas. Concentrations of "MCCPs" in fish in less populated locations ranged from 4 to 6 ng/g ww, while those in remote locations were 1 ng/g ww and similar to levels

reported by Harju *et al.* (2013) in Polar Cod from Svalbard. The C_{14} chain length was the most abundant in fish from all sites ranging from 60 to 85%, followed by C_{15} and C_{16}. C_{17} chain lengths were not detected. The authors also noted that concentrations of SCCPs in Lake Ontario Lake Trout collected in 2011 decreased 6.6-fold compared to 2001, but no significant differences were observed for "MCCPs". Furthermore, in Lake Trout from Lake Ontario the ratio of SCCPs/"MCCPs" decreased from 2001 to 2011 showing a shift towards "MCCPs".

150. Bennie *et al.* (2000) reported levels of "MCCPs" up to around 80 mg/kg wet weight (ww) in blubber samples from stranded Beluga Whales from the St. Lawrence River, Canada, although the analytical method may have been affected by the possible presence of co-eluting interfering organochlorine substances[21].

151. Choo *et al.* (2022) analysed for "MCCPs" congeners in egg samples from Black-Tailed gulls from two islands off the coast in South Korea, collected from 2012 to 2018. Analysed was performed using GC/MS and quantified based on correlation with known "MCCPs" mixtures. Pooled samples from both sites showed increasing "MCCPs" concentrations with time, ranging from 1287 - 4898 ng/g lw (380% increase) and 1263 - 2737 ng/g lw (217% increase) respectively. Individual egg samples from 2012 and 2016 showed the same trend and an increase in the congener molecular size over this time period. The predominant homologue grouping, irrespective of the chlorination degree was C_{14-15} (55%). The proportion of longer chain length (C_{16-17}) homologues increased at a rate of 5% over the time span of the study.

152. Du *et al.* (2018) investigated the occurrence of CPs in wildlife (2 fish, 3 reptiles, 1 mammal and 3 birds) from paddy fields in the Yangtze River Delta, China. The highest values were found in snakes, weasel and predatory birds (up to 33 mg/kg lw or 4.7 mg/kg dw). The authors found that the average concentrations were in the order "MCCPs" > SCCPs > LCCPs, except in birds where SCCPs were found to be more abundant. "MCCPs" appears to be widely dispersed in wildlife at the sampling locations.

153. In a related study to Du *et al.* (2018) by the same research group, Zhou *et al.* (2019) investigated the occurrence of CPs in aquatic wildlife (9 species: 7 fish, one snail and one clam) from Lake Dianshan in the Yangtze River Delta, China. "MCCPs" concentrations in fish were up to 3.1 mg/kg lw, which is similar to concentrations in the fish (up to 4 mg/kg lw) sampled in the paddy fields by Du *et al.* (2018). It should be noted that a limited number of fish were sampled in the lake (a single animal per species, aside from anchovy). Concentrations in clams and snails were at a similar order of magnitude to the fish.

154. As described in Section 2.2.3.4 two Chinese biomagnification studies detected "MCCPs" chain lengths in biota. Zeng *et al.* (2015) detected all four chain lengths (with Cl_{6-8} congeners) in the blubber samples of Finless Porpoises, and C_{14} and C_{15} chain lengths ((with Cl_{6-8} congeners) in Indo-Pacific Humpback Dolphins in Hong Kong waters from samples collected between 2004 and 2014. Statistically significant temporal increasing trends of both ΣSCCPs and Σ"MCCPs" were observed in both Porpoise and Dolphin samples from 2004 to 2014. Concentrations detected were between 0.32 and 23 mg/kg lw. Huang *et al.* (2017) detected all four "MCCPs" chain lengths in 12 species of fish, from the Liaodong Bay, North China in 2017. Mean concentrations in the fish ranged from 22.37±9.17 ng/g lw in Cod, to 5097±2242 ng/g lw in Turbot. Congener profiles indicated the C_{14} was the dominant homologue group in all the fish, accounting for 60.7–96.5% of total "MCCPs". The second most abundant group was C_{15}, accounting for 6.7–24.0%, followed by C_{16} and C_{17}. Cl_{7-9} congeners predominated.

155. Wang *et al.* (2021 ABSTR) collected 3 species of mollusc from the Chinese Bohai Sea between 2011 and 2018 and analysed these for SCCPs and "MCCPs". "MCCPs" concentrations ranged between not detected and 4.34 mg/kg dw. The authors noted no obvious temporal or spatial trends of CPs, but did record homologue profile changes which were thought to reflect compositional changes of CP industrial products. Oysters were reported to contain the highest CP concentrations of the species sampled.

[21] A gas-chromatography-low resolution negative ion mass spectrometry method was used. Although no comparison was carried out for "MCCPs", Bennie *et al.* (2000) compared their results for SCCPs with those obtained on Beluga Whale samples using a gas-chromatography-high resolution negative ion mass spectrometry method from another study. They found that the concentrations were one to two orders of magnitude *lower* using the high resolution method than the low resolution method.

156. Chen *et al.* (2021) determined the concentrations of SCCPs and "MCCPs" in 10 species of coastal coral at two locations in the South China sea. Using GC-QToFMS analysis, the median concentrations of "MCCPs" median (204 ng/g dw) were higher than SCCPs (103 ng/g dw). All 4 "MCCPs" chain lengths were detected, and the dominant chlorine pattern was noted to be similar to CP-52.

157. Niu *et al.* (2021) determined SCCPs and "MCCPs" concentrations in bark samples taken from Willow and Pine trees located on a transect between a CP production plant and Zhengzhou city in China. They used GC-LRMS analysis to investigate the congener fingerprint of the samples, which were taken 1.5m above the ground. In the sampling, the authors noted that the fingerprint of samples close to the CP plant reflected the CPs produced there, but nearer to the city the fingerprint was a mix of the CP plant and "city emissions" (a plastics and an electronics plant were located near to the city and cited as potential sources).

2.3.2. Humans

158. Greenpeace (1995) analysed human breast milk for "MCCP" content using pooled samples from six individuals (who ate fish at least once a week) and two non-fish-eaters (who ate fish a maximum of once a month). Similar results were obtained for both groups. The mean "MCCPs" concentration was 50.4 µg/kg lw in the fish-eating group, compared to 40.5 µg/kg lw in the non-fish-eaters; the low sample size meant that it was not possible to determine if any significant differences were apparent between the two groups.

159. Thomas and Jones (2002) detected "MCCPs" in 1 out of 22 samples of human breast milk from the UK, at 61 µg/kg lipid, although the analytical detection limit was relatively high. A follow-up study (Thomas *et al.*, 2006) detected "MCCPs" in all 25 samples of human breast milk at 6.2 to 320 µg/kg lw (median 21 µg/kg lw).

160. Darnerud *et al.* (2012) reported CP concentrations in human breast milk from samples collected between 1996 and 2010 in Uppsala County, Sweden. The mean "MCCP" concentration was 14.4 ng/g lw, although large variation between pools from different years was observed. The authors noted that their "MCCPs" concentrations were comparable to those from the UK measured by Thomas *et al.* (2006).

161. Xia *et al.* (2017a) found "MCCP" concentrations in pooled samples of human breast milk collected from rural China ranged from 9.05 to 139 µg/kg lw (median 35.7 µg/kg lw) in 2007, and between 9.51 and 146 µg/kg lw (median 45.4 µg/kg lw) for samples taken in 2011. Analysis was using GC-ECNI-HRToFMS, which indicated that the C14 homologues comprised 82% of the total "MCCP" content, with $Cl_{7\text{-}8}$ the most abundant congeners. In a further study of samples of human breast milk from urban locations in China at the same time points, Xia *et al.* (2017b) found "MCCP" concentrations ranged from 18.7 to 350 µg/kg lw (median 60.4 µg/kg lw) in 2007, and between 22.3 and 1501 µg/kg lw (median 137 µg/kg lw) for samples taken in 2011. Good correlation in the urban study was noted between areas with higher CP breast milk concentrations and areas of higher CP production (Xia *et al.*, 2017b).

162. Zhou *et al.* (2020) detected CPs using APCI-QToF-HRMS in human breast milk sampled from three cities in the Yangtze Delta of China, a city in Sweden and one in Norway. "MCCPs" were found in most samples, with concentrations ranging <l.o.d. – 1 260 µg/kg lw (median 78.8 µg/kg lw) for the Chinese samples, and <l.o.d. 311 µg/kg lw (median 29.6 µg/kg lw) for the Scandinavian samples.

163. Li *et al.* (2017) determined the concentration of CPs in all 50 human blood samples taken from the general population in Shenzhen, China. The "MCCP" concentrations were reported as being between 130 and 3 200 µg/kg lw. The relative exposure of the participants is unknown. "MCCPs" were also detected in human blood and human placenta samples from China by Wang *et al.* (2018), with concentrations ranging from 80.8 to 954 µg/kg lw.

164. The European Food Safety Authority recently summarised the available information on levels of CPs in human samples collected in Europe, Asia (mainly China) and Australia (EFSA, 2020). "MCCPs" have been detected in human milk samples, with levels generally being lower in the few European studies than in samples collected in Asia. EFSA (2020) quotes levels of "MCCPs" between < 5.5 to 112 µg/kg lw in human breast milk across 11 European countries.

165. The United Nations Environment Programme conducted a global survey of CPs in pooled human breast milk samples from individual countries collected from 2012–2019 (Krätschmer *et al.*, 2021). A total of 57 pooled milk samples were obtained from 53 countries on five continents (Africa, Central/South America, Asia,

Europe, and Australia/Oceania). Eligible donors were identified by application of standardised screening questionnaires. Analysis was conducted at the UNEP Reference Laboratories, Germany. MCCP's were present in all pooled samples, from 5.5 – 540 ng/g lw, with the highest ranges noted in Africa (47-370 ng/g lw) and Asia (38-540 ng/g lw). It is noted that individual levels (very high or very low) could not be taken into account.

166. Other more recent studies reporting the presence of CPs in human tissue and fluid samples are included in the Appendix 6.

2.3.3. Food

167. Numerous studies detecting "MCCPs" in food are summarised in EFSA (2020). That report notes that the majority of these are from China, where concentrations were in the order of tens of µg/kg, which was higher than in other Asian countries (a few ng/kg). Levels detected varied across different regions, the level of local contamination and food types. Higher concentrations were found in fish and marine mammals, and then fatty and liver tissues of terrestrial mammals. Only very limited data were available for detection of "MCCPs" in animal feed, and no general conclusions were drawn by EFSA (2020).

2.3.4. Synthesis

168. CPs with C_{14-17} chain lengths are not routinely included in many environmental monitoring programmes. However, the available data generally show widespread occurrence of "MCCPs" in water (at concentrations typically up to a few µg/L), sediment (at concentrations typically up to around 2 mg/kg dw, but up to 65 mg/kg dw near an industrial area) and soils (more limited information, but at concentrations up to around 2 mg/kg dw, and slightly higher near an industrial area). "MCCPs" is also found in sewage sludge up to 17 mg/kg dw, and in air at a few ng/m^3. Levels in dust were reported to be in the low mg/kg range.

169. Monitoring studies demonstrate widespread contamination of wildlife by CPs with C_{14-17} chain lengths at all trophic levels (including predatory species and sensitive life stages such as birds' eggs). Typically concentrations are below 1 mg/kg ww. Samples from relatively uncontaminated regions have maximum detected levels of 540 µg/kg lw (Grey Seal liver), 720 µg/kg lw (Eagle Owl muscle), 1 600 µg/kg lw (Moose muscle), 830 µg/kg lw (Grey Wolf muscle) and 5 390 µg/kg ww (Atlantic Cod liver). In cetaceans several studies record levels in blubber of up to 23 mg/kg lw (South China Sea), and up to 80 mg/kg ww (Canada). In more locally contaminated areas, biota tissue concentrations can exceed 1 mg/kg dw.

170. There are environmental monitoring data showing the detection of "MCCPs" in different matrices at locations in the following countries: Australia, Belgium, Canada, China, Czech Republic, Denmark, France, Germany, India, Ireland, Japan, Norway, Pakistan, Sweden, Switzerland, UK and USA, various marine locations such as the Baltic Sea, Irish Sea, North Sea in Europe and Chinese Bohai Sea, as well as remote locations such as the Arctic and Tibetan Plateau.

171. Human monitoring data shows that "MCCPs" are widely detected in breast milk, and in some instances maximum concentrations were 1 – 3 mg/kg lw. "MCCPs" can also be detected in other human tissue such as blood and placenta, and food for human consumption.

172. The most recent biota monitoring studies have usually provided chain length and congener level information. In these cases, all chain lengths of "MCCPs" are routinely detected.

173. Several studies provide information about increasing temporal trends in "MCCP" levels. These include both environmental matrices such as air and sediment, and biota including predators such as porpoise and dolphins. These increases in concentration are in good agreement with increasing use and production of "MCCPs". Increasing trends are also seen in "MCCPs" measured in air in all remote locations where data are available.

174. Overall the available monitoring data are consistent with the findings of the available measured laboratory for persistence and bioaccumulation, and modelling of long-range environmental transport potential. Extensive detection in wildlife, human tissue and food sources also indicate the bioavailability of "MCCPs".

2.4. Hazard assessment for endpoints of concern

2.4.1. Ecotoxicity

175. Since CPs with C_{14-17} chain lengths contain thousands of constituents, the reported toxicity end points effectively reflect an average of the contributions that individual constituents make. The influence of varying degrees of chlorination and chain length on toxicity is not known. It is therefore assumed that if toxicity is demonstrated for one type of product, it will be applicable for all, although this is an area of uncertainty.

176. The key data for the proposal are two aquatic toxicity studies performed with *Daphnia magna* using a C_{14-17} chlorinated n-alkane, 52% Cl wt. The first is an acute test performed according to OECD TG 202 and GLP that is considered to be reliable without restriction. This determined a 48-h EC_{50} value of 5.9 µg/L, based on (arithmetic) mean measured concentrations (Thompson *et al.*, 1996). The second is a long-term test performed according to OECD TG 202 (later superseded by OECD TG 211) and GLP that is also considered to be reliable without restriction (Thompson *et al.*, 1997a). The study met the validity criteria of the later test guideline as well as OECD TG 202. Based on the chemical analysis, results were calculated as time-weighted mean values, with the 21-day NOEC for reproduction and length being 8.7 µg/L. The lower EC_{50} value might be explained by the absence of food compared to the longer test (leading to greater availability of the substance and differences in elimination efficiency of the organisms).

177. The available acute and chronic data for fish and algae cited in EA (2019) and EC (2005) suggest that these taxa are less sensitive to "MCCPs" than *D. magna*. Long-term fish data are limited, but a GLP 60-d study using Rainbow Trout (*O. mykiss*) exposed to C_{14-17} CP, 52% Cl wt. found no effects on mortality, growth or behaviour at 4.5 mg/L (Madeley *et al.*, 1983). In a 72-h study performed with a C_{14-17} CP, 52% Cl wt. according to OECD TG 201 and GLP (Thompson *et al.*, 1997b), little or no toxic effect on the growth of the green alga *Selenastrum capricornutum* occurred at concentrations up to 3.2 mg/L.

178. A further long-term invertebrate toxicity study was summarised in EC (2005). This reported a 60-d NOEC of 0.22 mg/L for a C_{14-17}, 52% Cl wt. substance with Blue Mussel *Mytilus edulis* (Madeley and Thompson, 1983).

179. Reflecting the toxicity to *Daphnia magna*, "MCCPs" has a harmonised EU environmental classification of Aquatic Acute 1, Aquatic Chronic 1 (H400, H410) in accordance with the UN Globally Harmonised System. More recent self-classification by the lead EU REACH Registrants includes an M-factor for acute and chronic aquatic hazards of 100 and 10, respectively.

180. Three reliable prolonged sediment toxicity studies for "MCCPs" conducted in accordance with GLP using three taxa (*Hyalella azteca, Lumbriculus variegatus* and *Chironomus riparius*) are summarised in EC (2005 & 2007). These used sediment spiked with a C_{14-17}, 52% Cl wt. substance. The lowest NOEC was 130 mg/kg dw (~ 50 mg/kg ww), obtained in the study with *Lumbriculus variegatus* and also *Hyalella azteca.* EC (2005 & 2007) also reports three reliable long-term terrestrial toxicity studies conducted in accordance with GLP with the same chemical using earthworms (OECD TG 222), terrestrial plants (OECD TG 208) and soil microorganisms (OECD TG 216). Earthworms were the most sensitive species, with a 56-d NOEC of 280 mg/kg dw.

181. The acute oral 1-day LD50 values of "MCCPs" (Cereclor S52, C14–17, 52% Cl wt.) were reported to be > 24,606 mg/kg bw per day for ring-necked pheasants and > 10,280 mg/kg bw per day for mallard ducks. After 5-day dietary treatment, the LC50 values of "MCCPs" (C14–17, 52% chlorination) for ring-necked pheasants and also for mallard ducks were reported to be > 24,603 mg/kg diet (Madeley and Birtley, 1980). No long-term avian toxicity data are available.

2.4.2. Human health toxicity

182. The EU human health risk assessment report (HSE, 2008) provides a summary of the available laboratory mammalian testing, which used one commercial product type (a C_{14-17}, 52% Cl wt. substance) for the majority of regulatory studies. A more recent review performed by the European Food Safety Authority (EFSA, 2020) relies on the same key hazard data. The outline below summarises a more comprehensive assessment completed in 2021 and provided in Appendix 7. In addition, two more recent *in vitro* ED-studies and an epidemiology study are also briefly reported.

183. The potential of "MCCPs" to perturb thyroxine (T4) binding to the transport protein transthyretin (TTR) has been investigated using a non-standard *in vitro* assay (Sprengel *et al.,* 2021b). "MCCPs" and purified MCCP's demonstrated some capacity to interfere with T4 binding to TRR in this specific *in vitro* system. A second in vitro study (Zhou *et al.,* 2021) was conducted to determine if 17 technical CPs demonstrate aryl hydrocarbon receptor (AhR)-agonist activity. No information is available on chain length or percentage chlorination of the technical CP samples. Overall, it appears that in this assay system, "MCCPs" do not bind to the AhR.

184. The target organs for repeated oral dose toxicity are liver, thyroid and kidney. EFSA (2020) identified changes in kidney weights as the critical effect of "MCCPs" of relevance to humans. Eight relevant repeated dose toxicity studies were reviewed in HSE (2008). The assessment determined the lowest NOAEL of toxicological significance to be 23 mg/kg bw/day from a 90-d study with F344 rats *Rattus norvegicus* (CXR Biosciences Ltd, 2005b), based on increased relative kidney weights (HSE, 2008). A second 90-day study also using F344 rats *Rattus norvegicus* recorded a NOAEL of 10 mg/kg bw/day for the same endpoint (IRDC, 1984). EFSA (2020) has derived a $BMDL_{10}$[22] of 36 mg/kg bw/day from this second study (the BMDU/BMDL ratio of 6 indicates some uncertainty in the value). The $BMDL_{10}$ for CXR Biosciences Ltd (2005b) was 68 mg/kg bw/day (BMDU/BMDL ratio 2.7).

185. No carcinogenicity studies have been conducted. "MCCPs" is generally unreactive and not mutagenic. The carcinogenic potential of "MCCPs" is expected to be similar – at least in qualitative terms – to that of SCCPs, although direct read across is not appropriate. SCCPs induce liver and thyroid adenomas and carcinomas and kidney tubular cell adenomas and carcinomas in animal studies. The liver and thyroid tumours are considered to be of little or no relevance to human health. It cannot be completely ruled out that the kidney toxicity observed for "MCCPs" might lead to kidney cancer in rats through a non-genotoxic mode of action. However, "MCCPs" is not classified for this endpoint in Europe under Regulation (EC) No. 1272/2008.

186. "MCCPs" has no apparent effect upon fertility in rats up to approximately 400 mg/kg/day in the diet. No adverse developmental effects occurred during gestation in rats or rabbits in two conventional developmental studies using maternal doses up to 5 000 and 100 mg/kg/day, respectively. In contrast, exposure of Wistar rats *R. norvegicus* to $C_{14\text{-}17}$ CP, 52% Cl wt. at a maternal dietary dose of 74 mg/kg/day (1 000 ppm) up to approximately 400 mg/kg/day (6 250 ppm) produced internal haemorrhaging and deaths in the pups (IRDC, 1985). Follow-up studies with Sprague Dawley rats (CXR Biosciences Ltd, 2003, 2004 & 2006) demonstrated that "MCCPs" can perturb blood clotting. In adult females that had been treated for 7 to 8 weeks including pregnancy and lactation, decreased levels of vitamin K and of the clotting factors VII and X were found, and 5 out of 32 dams showed signs of haemorrhaging during parturition. However, these decreases did not affect their prothrombin times, indicating that the functional reserve in the majority of these adult animals was sufficient. The foetus *in utero* apparently receives sufficient vitamin K via the placenta, but after birth becomes severely deficient in vitamin K and related clotting factors and relies on the mothers' milk to receive them. Exposure to "MCCPs" in the milk may also further reduce their vitamin K levels. This in turn leads to a severe vitamin K deficiency in the neonates and consequently to haemorrhaging. This is the basis for the harmonised EU classification for effects via lactation (H362 – May cause harm to breast-fed children) according to Regulation (EC) No. 1272/2008.

187. From the studies available, an overall NOAEL of 47 mg/kg/day (600 ppm) as a maternal dose was identified for these effects mediated via lactation (EC, 2005). However, it should be noted that the effects (11% reduction in pup survival and related haemorrhaging) observed at the LOAEL (74 mg/kg/day; 1 000 ppm) were not statistically significant. Haemorrhaging was also seen in one study at the time of parturition in 16% of dams given 538 mg/kg/day (6 250 ppm), but not up to 100 mg/kg/day (1 200 ppm) in other studies. The NOAEL of 100 mg/kg/day (1 200 ppm) was therefore selected for the risk characterisation of haemorrhaging effects potentially occurring in pregnant women at the time of parturition. EFSA (2020) estimated the $BMDL_5$ values of 48.5 mg/kg bw/day (BMDU/BMDL ratio of 1.3) for the combined incidence of subcutaneous haematoma/haemorrhage in rats and 53 mg/kg bw/day (BMDU/BMDL ratio of 1.8) for rat pup deaths (EFSA, 2020).

[22] Benchmark Dose Level associated with a 10% response adjusted for background.

188. The potential association of kidney function with "MCCPs" exposure with was investigated in a cross-Sectional study (Zhao *et al.,* 2021). Information on educational attainment, smoking and drinking habits and history of kidney disease of the volunteers (n=387) was obtained by employing a standardised questionnaire. BMI (body mass index) blood glucose and blood pressure of volunteers were also recorded. After adjustment for multiple variables; in males only, elevated "MCCPs" levels (above median) were associated with an elevated odds ratio for glomerular hyperfiltration (eGFR of ≥ 135 mL/min/1.73 m2) ("MCCPs": OR = 3.25; 95% CI: 1.20–5.29; p = 0.009). It is possible that the elevated eGFR could reflect glomerular damage, indicative of early impaired kidney function. However, the study only noted an association between "MCCPs" and elevated eGFR in males, it is not possible to infer causation from this study.

189. "MCCPs" does not meet the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), toxic for reproduction (category 1A, 1B, or 2) or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) in Europe according to Regulation (EC) No. 1272/2008.

2.4.3. Adverse effects synthesis

190. A $C_{14\text{-}17}$ chlorinated n-alkane, 52% Cl wt. has a 48-h EC_{50} of 0.0059 mg/L for *Daphnia magna.* The 21-day NOEC for the same species and substance is 0.0087 mg/L. These two results, from reliable laboratory studies performed to recognised OECD test guidelines and to GLP, indicate that constituents of CPs with $C_{14\text{-}17}$ chain lengths are very toxic to aquatic invertebrates in the environment. Furthermore in the REACH registration and CLP inventory, these data are used by the companies involved to cover all "MCCPs" products supplied in the EU (the chlorine content of the commercially available product types is generally within the range 40% to 63% by weight). This indicates that all of the products were assessed to be equally toxic.

191. The concern for adverse effects is supported by the internal haemorrhaging and death observed in rodent offspring in the mammalian reproduction study resulting in a harmonised EU classification for "MCCPs" as H362 (May cause harm to breast-fed children). Potential adverse effects could therefore occur in mammalian wildlife.

3. Synthesis of information

192. "MCCPs" is a widely used industrial chemical which is estimated to be supplied in the order of 750,000 tonnes per year globally. It has a broad range of uses, primarily as a flame retardant and plasticiser in polymers such as PVC, and in metal working fluids. The C_{14} constituents are a major congener group in commercial "MCCP" products currently being supplied in Europe and the US, with the $C_{15\text{-}17}$ constituents present in lower proportions. Chain lengths in CP products manufactured in China are broader, and the "MCCPs" appear to be more variable, although in a number of instances C_{14} is suggested to be dominant. CPs with these four chain lengths are strongly hydrophobic with a low water solubility (up to 27 µg/L) and high log K_{OW} values above 5.

193. CPs with $C_{14\text{-}17}$ chain lengths are shown to meet the persistence criteria of the Convention. The persistence screening information indicates that the concern is for all constituents with chlorination levels at or exceeding 45% chlorine by weight. The C_{14} chain length is considered to have a half-life exceeding 180 days in two types of aerobic sediment based on a laboratory test. Persistence in sediment is supported by sediment core monitoring data, where "MCCPs" can be detected at similar orders of magnitude across horizons spanning the last 8 years (and longer) in the same core. The persistence conclusion for the C_{14} chain length can be applied to the $C_{15\text{-}17}$ chain lengths because they will be more adsorptive based on the measured and predicted trends for water solubility and log K_{OW}. This is supported by the detection of these chain lengths in sediment, and notably, where data are available, the congener profile detected reflects that in commercial substances.

194. CPs with $C_{14\text{-}17}$ chain lengths are shown to meet the bioaccumulation criteria of the Convention. Two recent reliable laboratory fish bioaccumulation studies using C_{14} chain lengths show measured or estimated BCF values well above 5 000 L/kg. The available bioaccumulation laboratory studies for the C_{15}, C_{16} and C_{18} chain lengths were not performed to current test guidelines nor to such a high standard as the modern tests for C_{14}. Nevertheless, they indicate a high bioaccumulation potential for all three "MCCPs" chain lengths (although C_{17} was not tested, its bioaccumulation potential can be inferred to lie between that of C_{16} and C_{18}). Field monitoring studies indicate that all chain lengths are bioavailable and can be detected in biota, including in top predators as well as in sensitive life stages (such as birds' eggs). Where data are available, the congener profile in organisms is similar to the congener profile in environmental matrices such as soil and sediment, and wastewater treatment plant sludge, suggesting congener uptake reflects exposure. Overall,

the bioaccumulation behaviour of the longer chain lengths appears to be broadly similar to C_{14}. A number of field biomagnification studies are available. Each has limitations, but the data indicate that the possibility of biomagnification of "MCCPs" cannot be excluded.

195. CPs with C_{14-17} chain lengths are shown to meet the long-range environmental transport potential criteria of the Convention. The predicted atmospheric half-life values are between 37 and 140 hours, principally dependent on the degree of chlorination: more highly chlorinated constituents will be more photolytically stable and more adsorptive to particulates. There are uncertainties regarding both the model training set, and the effect of the fraction adsorbed to aerosols (which is reliant on the predicted log K_{OA}). Modelling using the OECD Screening tool indicates LRET comparable to, but slightly below, that for SCCPs, which is a listed POP. The "MCCPs" LRET also falls within the range of other listed POPs. The modelling is also affected by the fraction adsorbed to aerosols, which could be higher than the OECD tool predicts, and would result in greater LRET potential. Monitoring data support the modelling conclusion. Detection of "MCCPs" in air (gaseous and particulate) and water (dissolved and particulate) suggests a number of pathways exist to deliver "MCCPs" to remote locations. While "MCCPs" are rarely included in monitoring campaigns in remote regions, the available data indicate detection in air in the Arctic, Antarctic and Tibetan Plateau, sediment of the Arctic, and multiple detections in Arctic biota including predators. In some instances, the monitoring data indicate levels of "MCCPs" comparable to SCCPs and some other listed POPs in remote regions.

196. CPs with C_{14-17} chain lengths are shown to meet the adverse effects criteria of the Convention. A C_{14-17} chlorinated n-alkane, 52% Cl wt. is very toxic to *Daphnia magna* in both acute and long-term studies. This indicates significant toxicity to aquatic invertebrates which are an important part of aquatic food chains. Effects on organisms at this trophic level may reduce food availability at higher levels of the food chain with potential population-level effects. Regulatory testing is designed to protect all organisms living in the environment, and is limited in scope for practical and ethical reasons. High toxicity observed in one organism within a trophic level means that it cannot be excluded that others are equally or more affected. For chemicals that are also shown to be persistent and bioaccumulative, the concern is also for unpredictable effects within the food chain. Internal haemorrhaging and death has been observed in rodent offspring in a mammalian reproduction study. This suggests that potential adverse effects could occur in mammalian wildlife. As the (eco)toxicity tests used a substance containing C_{14-17} chain lengths, all chain lengths are considered to contribute to the observed effects. The tests are also used to support regulatory submissions by suppliers covering all "MCCPs" products on the market (not just 52% Cl wt.) indicating the applicability of the studies to a broad range of chlorination levels.

197. The available monitoring data generally show widespread occurrence of "MCCPs" in surface water, sediment, soil, biota, sludge and air, in multiple regions of the world. The substance can be widely detected in environmental biota including predators, as well as human tissues. In some instances concentrations up to xx have been detected Increasing local biota detection has been observed where trend information is available.

198. The most recent biota monitoring studies have usually provided chain length and congener level information, which indicates the bioavailability of all chain lengths. Where data are available, "MCCPs" chain length / congener profiles detected in biota are consistent with those detected in environmental matrices and wastewater treatment plant sludge.

199. Following national and international restrictions on the use of SCCPs, the supply of "MCCPs" has increased significantly as it appears to be the main drop-in replacement for SCCPs. The increase in supply is reflected in environmental monitoring trends: increasing levels of "MCCPs" are detected where multi-year sampling has been undertaken. Sediment core data also indicate a decline in SCCPs with a concurrent increase in "MCCPs" in more contemporaneous cores. As the switch from SCCPs to "MCCPs" has only occurred in recent years, "MCCPs" detection can be expected to increase in the absence of risk management.

200. The concentrations detected in biota in more contaminated areas shows that high levels can be attained by organisms. If environmental exposure of "MCCPs" is increasing in more remote areas as suggested by the limited trend data available, this indicates that increasing levels in remote biota can similarly be expected.

201. The concern for "MCCPs" is its demonstrated persistence, bioaccumulation and toxicity, together with similarities in the long-range environmental transport potential to SCCPs. The underlying concern is that "MCCPs" poses similar types of risk to SCCPs. While the two substances are not identical, they are

sufficiently similar to warrant action to address the potential risk from "MCCPs". The very high levels of estimated emission to the environment are reflected in widespread detection, together with indications that these levels are increasing, including in remote areas. Given the bioavailability and increasing trend in the detection of a known persistent, bioaccumulative and toxic substance, it can be expected that levels in remote environments will continue to increase, and levels in biota will also continue to increase with consequent risk of unpredictable impacts unless risk management measures are implemented.

4. Concluding statement

202. As a result of its persistence, bioaccumulative and toxic properties, "MCCPs" is of regulatory concern in the UK, EU, Switzerland, Australia and Canada. The different applications and ongoing use of CPs with $C_{14\text{-}17}$ chain lengths globally is conservatively estimated to result in around 2 800 to 28 000 tonnes being potentially emitted to the environment each year. Due to the hazard concerns for the substance, and the annual estimated level of environmental emissions, together with evidence of long-range transport potential, extensive environmental contamination and an indication that levels in the environment are increasing and spreading, global action is required to manage the risks to human health and the environment from carbon chain lengths in the range $C_{14\text{-}17}$ and chlorination levels ≥45% chlorine by weight.

203. [Based on evidence of its persistence, bioaccumulation and adverse effects, widespread occurrence in environmental compartments and frequent detection in biota in remote regions, it is concluded that carbon chain lengths in the range $C_{14\text{-}17}$ and chlorination levels ≥45% chlorine by weight are likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.]

Appendix 1: Abbreviations

AOPWIN	Atmospheric Oxidation Program
APCI-QToF-HRMS	Atmospheric-Pressure Chemical Ionization Quantitative Time of Flight High Resolution Mass Spectrometry
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BCFss	Steady State BCF
BMDL	Benchmark dose (lower confidence limit)
BMDU	Benchmark dose (upper confidence limit)
BMF	Biomagnification Factor
BMF_{KgL}	Growth-corrected and lipid-normalised kinetic biomagnification factor
BSAF	Biota-sediment accumulation factor
bw	Bodyweight
Ca.	Circa (“approximately”)
CAS number	Chemical Abstracts Service number
Cl wt.	Chlorine content by weight
CLP	Classification, Labelling and Packaging
CPs	Chlorinated paraffins
CTD	Characteristic Travel Distance
Cx	Carbon chain with x Carbon atoms
dw	Dry weight
EC_{50}	Half maximal effective concentration
EC number	European Community Number
EC (reg)	European Union council (regulation)
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
GC-ECNI-LRMS	Gas Chromatography Electron Capture Negative Ionisation Low Resolution Mass Spectrometry
GCxGC-ECD	Two Dimensional Gas Chromatography with Electron Capture Detector
GHS	Globally Harmonised System
GLP	Good Laboratory Practise
HCB	Hexachlorobenzene
HPLC	High Performance Liquid Chromatography
HRMS	High Resolution Mass Spectrometry
HSE	Health & Safety Executive
K_{AW}	Air/water partition coefficient
K_{OC}	Organic carbon-water partition coefficient
K_{OW}	Octanol/water partition coefficient
K_{OA}	Octanol/air partition coefficient
LCCP(s)	Long chain chlorinated paraffin(s)

LOD	Limit of detection
LOQ	Limit of Quantification
LRT	Long range transport
LRTP	Long range transport potential
lw	Lipid weight
MCCP(s)	Medium chain chlorinated paraffin(s)
M-factors	Multiplication Factors
MDL	Method Detection Limit
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OH-Radical	Hydroxyl radical
PBDEs	Polybromodiphenyl ethers
PBPK	Physiologically-based pharmacokinetic modelling
P_{OV}	Overall persistence
PBT	Persistent, Bioaccumulative and Toxic
PCBs	Polychlorinated biphenyls
POP	Persistent Organic Pollutant
PVC	Poly Vinyl Chloride
REACH	Registration, Evaluation and Authorisation of Chemicals
RMOA	Regulatory Management Option Analysis
RP-HPTLC	reversed-phase high performance thin layer chromatography
RSD	Relative Standard Deviation
SCCP(s)	Short chain chlorinated paraffin(s)
SMILES	Simplified Molecular Input Line Entry System
SVHC	Substance of very high concern
TE	Transfer Efficiency
TG	Test Guideline
ThOD	Theoretical Oxygen Demand
TMF	Trophic Magnification Factor
TOC	total organic carbon
UN	United Nations
UNEP	United Nations Environment Programme
UVCB	Unknown Variable Concentration or Biological
WHO	World Health Organisation
ww	Wet weight

Appendix 2: List of references (including for data in the appendices)

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Appendix 3: Further information on substance identity

Table 8: Constituents present in amounts <1% by weight in "MCCPs" on the EU market

Constituent	Typical concentration (w/w)	Concentration range	Remarks
Chlorinated alkanes with carbon chain lengths $<C_{14}$	<1%	Not specified	Based on information in EC (2005) and information in the REACH registration dossiers, assuming that the alkanes in the feedstock are chlorinated during manufacture of "MCCPs".
Chlorinated aromatics	<100 mg/kg	Not specified	Based on information in EC (2005) assuming that aromatics and isoparaffins in the feedstock are chlorinated during manufacture of "MCCPs".
Chlorinated isoparaffins	<1 - 2%	Not specified	

All constituents in commercial CPs are likely to be related to those present in the n-paraffin feedstock, in which the major non-paraffinic constituent is a small proportion of aromatics and isoparaffins. EU producers of "MCCPs" represented by EuroChlor have, since 1991, used paraffin feedstocks in the production process with a $C_{<14}$ content of <1% by weight and reported that the actual levels are often much lower than this (EC, 2005).

Various stabilisers can be added to commercial CPs at <1% by weight to improve thermal or light stability (EC, 2005). These include epoxidised soya oil and glycidyl ethers.

The details of substance identity for short chain chlorinated paraffins (SCCPs) and long chain chlorinated paraffins (LCCPs) from the EU REACH registrations can be found in Table 9 (ECHA 2021c and 2021d).

Table 9: Substance identity of relevant structural analogues

EC name	Alkanes, C_{10-13}, chloro	Paraffin waxes and hydrocarbon waxes, chloro
EC number	287-476-5	264-150-0
CAS number	85535-84-8	63449-39-8
Molecular formula	$C_xH_{(2x - y+2)}Cl_y$, where x = 10 - 13 and y = 1 - 13	$C_xH_{(2x - y+2)}Cl_y$, where x = 18 - 30 and y = 1 - 30
Molecular weight range	320 - 500 g/mole (approximately)	420 - 1 355 g/mole (approximately)
Synonyms	Short-chain chlorinated paraffins (SCCPs); alkanes, C_{10-13}, chloro; chlorinated paraffins, C_{10-13} (used in Annex VI of the CLP Regulation)	Long-chain chlorinated paraffins (LCCPs); alkanes, C_{18-30}, chloro; chlorinated paraffins, C_{18-30}

Around forty CAS numbers have been used to describe the whole CP family at one time or another. Some of these are now historical, and others may be in use for the sole purpose of compliance with national or regional chemical inventories. A list has been provided by representatives of the EU REACH LCCPs Consortium (Personal Communication, 2019). This is shown in Table 10, and is not necessarily exhaustive. Those CAS numbers that may be associated with C_{14-17} chain lengths are highlighted in bold.

Table 10: CAS numbers associated with CPs

CAS Number	CAS name	Note	Regulatory Regions
915-934-2	**Reaction mass of alkanes, C_{14-17}, chloro and paraffin waxes and hydrocarbon waxes, chloro**	-	-
61788-76-9[a]	**Alkanes, chloro; alkanes, chlorinated**	c	[1a], [1c], [2], [3], [4], [5a], [6a], [7], [8], [10], [11], [12]
63449-39-8[b]	Paraffin waxes and hydrocarbon waxes, chloro	b	[1a], [1b], [1c], [2], [3], [4], [5a], [6a], [6b], [7], [8], [9], [10], [11], [12]
68920-70-7	**Alkanes, C_{6-18}, chloro**	a	[1a], [1b], [1c], [2], [3], [4], [5a], [6a], [7], [8], [12]
71011-12-6	Alkanes, C_{12-13}, chloro	d	[2], [3], [5a]
84082-38-2	**Alkanes, C_{10-21}, chloro**	a	[1a], [1c], [3], [4], [5a], [7], [8], [9], [12]
84776-06-7	**Alkanes, C_{10-32}, chloro**	a	[1a], [1c], [3], [4], [5a], [7], [8], [9], [12]
84776-07-8	**Alkanes, C_{16-27}, chloro**	a	[1a]
85049-26-9	**Alkanes, C_{16-35}, chloro**	a	[1a], [4]
85422-92-0	**Paraffin oils and hydrocarbon oils, chloro**	c	[1a], [9]
85535-84-8	Alkanes, C_{10-13}, chloro	d	[1a], [1b][c], [1c], [3], [4], [5a], [6a], [7], [8], [12]
85535-85-9	**Alkanes, C_{14-17}, chloro**	b	[1a], [1b], [1c], [2], [3], [4], [5a], [5b], [7], [8], [9], [10], [12]
85535-86-0	Alkanes, C_{18-28}, chloro	a	[1a], [3], [4], [6a], [7], [9]
85536-22-7	**Alkanes, C_{12-14}, chloro**	a	[1a], [3], [4], [6a], [9], [12]
85681-73-8	**Alkanes, C_{10-14}, chloro**	a	[1a], [5a]
97553-43-0	**Paraffins (petroleum), normal $C_{>10}$, chloro**	a	[1a], [5a]
97659-46-6	**Alkanes, C_{10-26}, chloro**	a	[1a], [9]
106232-85-3	Alkanes, C_{18-20}, chloro	b	[2], [3], [4], [5a], [9], [10], [12]
106232-86-4	Alkanes, C_{22-40}, chloro	a	[1a], [4], [9]
108171-26-2	Alkanes, C_{10-12}, chloro	a	[1a], [7], [8], [9]
108171-27-3	Alkanes, C_{22-26}, chloro	a	[1a], [5a] [12]
288260-42-4	Alkanes, C_{22-30}, chloro	b	[2], [7]
198840-65-2	**Tetradecane, chloro derivatives**	b	[2]
1372804-76-6	**Alkanes, C_{14-16}, chloro**	b	[2]
2097144-48-2	Octadecane, chloro derivatives	b	[2]
2097144-45-9	Alkanes, C_{20-24}, chloro	b	[2]
2097144-43-7	Alkanes, C_{20-28}, chloro	b	[2]
2097144-44-8	**Slackwax (petroleum), chloro**	b	[2]
1417900-96-9	Alkanes, C_{21-34}-branched and linear, chloro	b	[2]
1401974-24-0	Alkanes, C_{22-30}-branched and linear, chloro	b	[2]
1402738-52-6	Alkanes, C_{24-28}, chloro	b	[2]
2097144-46-0	Hexacosane, chloro derivatives	b	[2]
2097144-47-1	Octacosane, chloro derivatives	b	[2]

[a]CAS 61788-76-9 replaces 11104-09-9, 12633-77-1, 51059-93-9, 53572-39-7 and 69430-53-1: [b]CAS 63449-39-8 replaces 8029-39-8, 11098-33-2, 37187-40-9, 39279-65-7, 39406-09-2, 39444-36-5, 50646-90-7, 51990-12-6, 52276-52-5, 52555-47-2, 52622-66-9, 52677-73-3, 52677-74-4, 52677-75-5, 53028-59-4, 53028-60-7, 53200-35-4, 54577-71-8, 55353-50-9, 56509-64-9, 56730-95-1, 58516-52-2, 60202-64-4, 66746-35-8 and 108688-63-7: [c]withdrawn

Note: a - Listed on at least one national inventory; b - Registered under legislation requiring dossier submission in 21st century; c - Broad scope with no carbon number definition (not favoured by some authorities); d - Subject to ban or restriction, substance of very high concern (EU) or Toxic Release Inventory requirement (USA).

Regulatory Regions: [1a] EU REACH pre-registered; [1b] EU REACH registered; [1c] EU CLP Inventory [2] USA TSCA (active list); [3] Canada DSL; [4] Australia (AICS); [5a] Korean Gazette No.; [5b] Korean REACH registered; [6a] Japan ENCS; [6b] Japan examined; [7] Philippines; [8] New Zealand; [9] Taiwan; [10] Turkey; [11] Switzerland (other CAS numbers in the table are also registered in Switzerland beyond the two indicated); [12] China.

Appendix 4 – screening biodegradation data

Table 11: Summary of modified and enhanced ready biodegradation test results

Substance tested	Inoculum	Administration method		Pass/fail		Reference
				Modified (28-d)	Modified & Enhanced (60-d)	
C_{14}, 41.3% Cl wt.	Activated sludge	Suspension using alkylphenol polyalkoxylate (PAAP)	Series 1	Pass	Pass	Unpublished (2010e)
			Series 2	Pass	Pass	Unpublished (2010e)
	River water	Suspension using PAAP		Pass	Pass	Unpublished (2010e)
C_{14}, 45.5% Cl wt.	Activated sludge	Suspension using PAAP	Series 1	Fail	Pass	Unpublished (2010e)
			Series 2	Pass	Pass	Unpublished (2010e)
	Activated sludge	Suspension using PAAP		Pass	Pass	Unpublished (2010a)
	River water	Suspension using PAAP		Fail	Pass	Unpublished (2010e)
C_{14}, 50% Cl wt.	Activated sludge	Suspension using PAAP	Series 1	Fail	Pass	Unpublished (2010e)
			Series 2	Fail	Pass	Unpublished (2010e)
	Activated sludge	Suspension using PAAP		Fail	Pass	Unpublished (2018a)
	River water	Suspension using PAAP		Fail	Pass	Unpublished (2010e)
C_{14}, 55% Cl wt.	Activated sludge	Suspension using PAAP	Series 1	Fail	Fail	Unpublished (2010e)
			Series 2	Fail	Fail	Unpublished (2010e)
	Activated sludge	Suspension using PAAP		Fail	Fail	Unpublished (2018b)
	River water	Suspension using PAAP		Fail	Fail	Unpublished (2010e)
C_{14}, 60% Cl wt.	Activated sludge	Suspension using PAAP	Series 1	Fail	Fail	Unpublished (2010e)
			Series 2	Fail	Fail	Unpublished (2010e)
	Activated sludge	Suspension using PAAP		Fail	Fail	Unpublished (2018c)
	River water	Suspension using PAAP		Fail	Fail	Unpublished (2010e)
	Activated sludge	Suspension using PAAP		Fail	Fail	Unpublished (2018d)

Substance tested	Inoculum	Administration method	Pass/fail		Reference
			Modified (28-d)	Modified & Enhanced (60-d)	
C_{15}, 51% Cl wt.	Activated sludge	Suspension using PAAP	Fail	Pass	Unpublished (2014a)
	River water	Unspecified solubilising agent	Fail	Fail	Unpublished (2014b)
$C_{14\text{-}17}$, 45.6% Cl wt.	Activated sludge	Suspension using PAAP	Fail	Pass	Unpublished (2010b)
$C_{14\text{-}17}$, 51.7% Cl	Activated sludge	Suspension using PAAP	Fail	Fail	Unpublished (2010d)
$C_{14\text{-}17}$, 63.2% Cl wt.	Activated sludge	Suspension using PAAP	Fail	Fail	Unpublished (2010c)

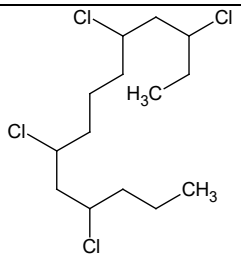
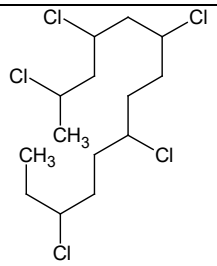
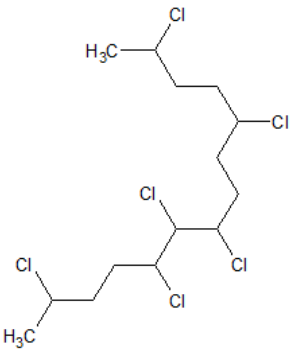
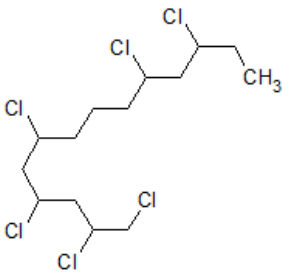
Note: 'Modified' means use of solubiliser. 'Enhanced' means extended timescale. Light brown shading indicates that although the pass level was achieved after 28 days, the inoculum was not considered appropriate for regulatory purposes. 'Series 1' and 'Series 2' indicate that a duplicate set of test vessels were assessed in parallel. Studies that more closely resemble inherent biodegradability assessments have not been included.

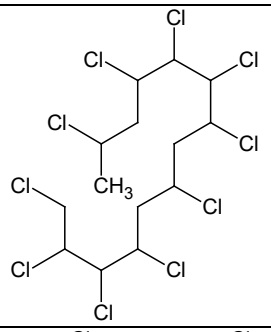
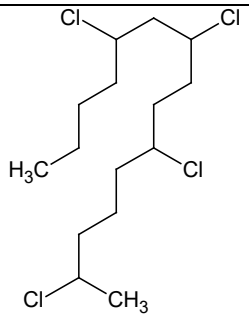
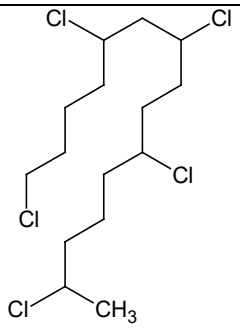
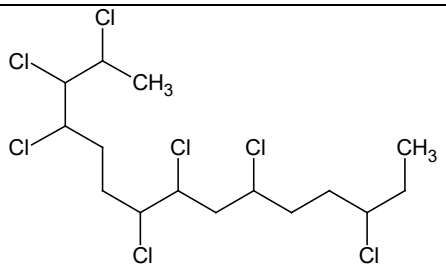
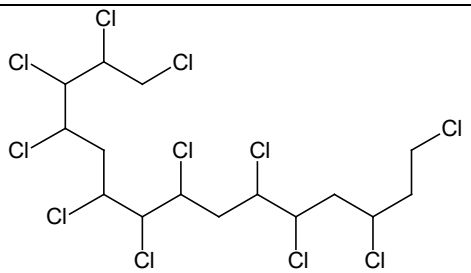
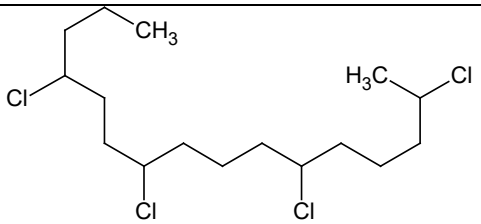
Appendix 5: Further information for LRET modelling

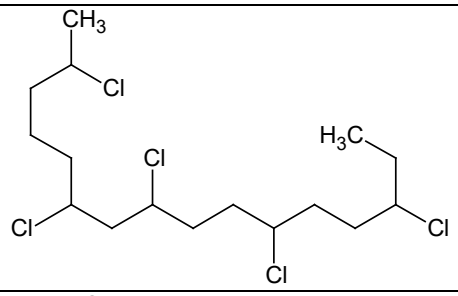
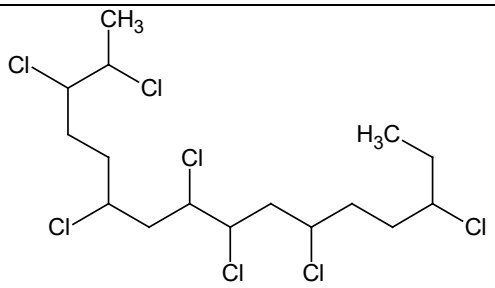
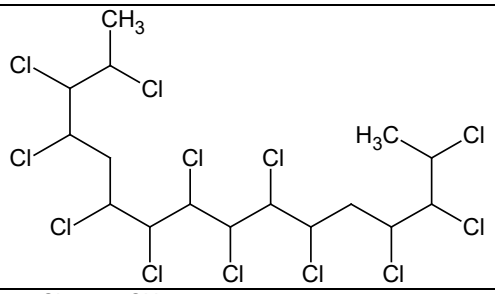
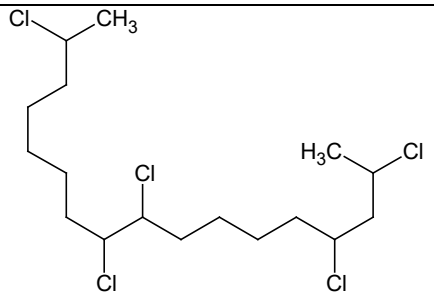
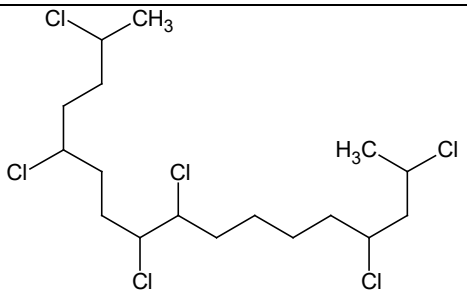
Structures used for modelling of MCCP congeners

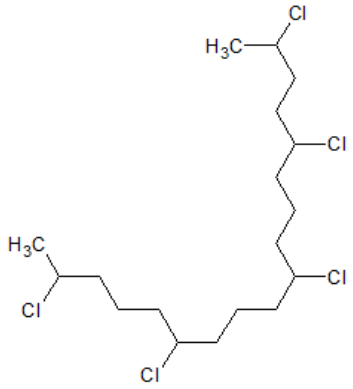
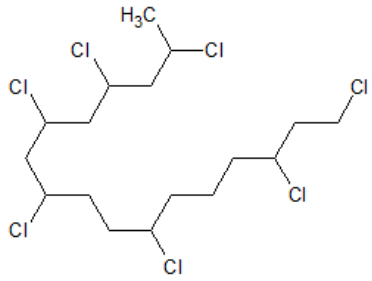
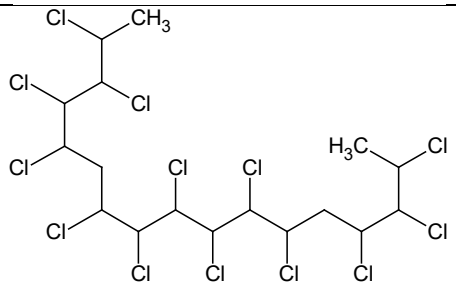
The OECD P_{OV} & LRTP Screening Tool has been used to estimate the long-range transport potential (LRTP) of a fourteen C_{14}, C_{15}, C_{16} and C_{17} constituents of the substance proposed for listing. A further 4 constituents outside the scope of the listing proposal have been included to help illustrate the trends in the data at chlorination <45%. All eighteen constituents are listed in Table 12 below.

Table 12: Example structures of "MCCP" constituents representing C_{14}, C_{15}, C_{16} and C_{17} used for the LRET modelling

Example structure	Chemical formula	% Cl	Structure
MCCP-5	*$C_{14}H_{26}Cl_4$*	*42*	
MCCP-6	$C_{14}H_{25}Cl_5$	48	
MCCP-1	$C_{14}H_{24}Cl_6$	53	
MCCP-2	$C_{14}H_{24}Cl_6$	53	

Example structure	Chemical formula	% Cl	Structure
MCCP-7	$C_{14}H_{20}Cl_{10}$	65	
MCCP-8	*$C_{15}H_{26}Cl_4$*	*41*	
MCCP-9	$C_{15}H_{27}Cl_5$	46	
MCCP-10	$C_{15}H_{25}Cl_7$	55	
MCCP-11	$C_{15}H_{21}Cl_{11}$	66	
MCCP-12	*$C_{16}H_{30}Cl_4$*	*39*	

Example structure	Chemical formula	% Cl	Structure
MCCP-13	$C_{16}H_{29}Cl_5$	45	
MCCP-14	$C_{16}H_{27}Cl_7$	53	
MCCP-15	$C_{16}H_{22}Cl_{12}$	67	
MCCP-16	*$C_{17}H_{31}Cl_5$*	*43*	
MCCP-17	$C_{17}H_{30}Cl_6$	48	

Example structure	Chemical formula	% Cl	Structure
MCCP-3	$C_{17}H_{29}Cl_7$	52	
MCCP-4	$C_{17}H_{29}Cl_7$	52	
MCCP-18	$C_{17}H_{23}Cl_{13}$	67	

Constituents in italics are not within the scope of the proposal, but included to provide an illustration of the trend in properties and LRET

Results of LRET predicted by the OECD Screening tool

The input parameters for the 18 constituents. These use physico-chemical values predicted by COSMOtherm (Glüge, Pers. Comm., 2021). Atmospheric half-lives values were predicted using EPISuite™. These data and the results from the OECD Screening Tool are shown in Table 13.

Table 13: LRTP predictions using Log K_{AW} and Log K_{OW} predicted using COSMOtherm

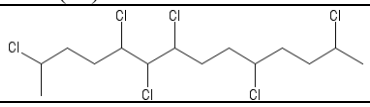
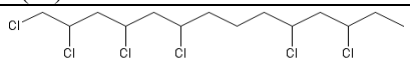
Example structure	Chemical formula	% Cl	Inputs				Predictions		
			Log K_{AW}	Log K_{OW}	Log K_{OA}	Half-life in air (hours)*	P_{OV} (days)	Transfer Efficiency (%)	Characteristic Travel Distance (km)
MCCP-5	*$C_{14}H_{26}Cl_4$*	*42*	*-2.89*	*6.854*	*9.74*	*42.0*	*172.8*	*0.38*	*834.4*
MCCP-6	$C_{14}H_{25}Cl_5$	48	-3.82	6.679	10.50	49.3	517.9	1.12	1004.0
MCCP-1	$C_{14}H_{24}Cl_6$	53	-4.93	6.397	11.33	61.5	518.1	3.95	1603.5
MCCP-2	$C_{14}H_{24}Cl_6$	53	-4.56	6.766	11.32	48.0	518.3	3.10	1465.5
MCCP-7	$C_{14}H_{20}Cl_{10}$	65	-6.57	7.32	13.89	98.1	518.7	12.40	2805.1
MCCP-8	*$C_{15}H_{26}Cl_4$*	*41*	*-3.21*	*7.352*	*10.57*	*36.2*	*173.0*	*0.62*	*829.5*
MCCP-9	$C_{15}H_{27}Cl_5$	46	-4.9	6.911	11.81	37.9	518.5	5.20	1839.2
MCCP-10	$C_{15}H_{25}Cl_7$	55	-5.96	7.06	13.02	65.3	518.6	11.8	2717.1
MCCP-11	$C_{15}H_{21}Cl_{11}$	66	-7.49	7.558	15.04	94.3	518.8	12.53	2830.6
MCCP-12	*$C_{16}H_{30}Cl_4$*	*39*	*-3.57*	*7.67*	*11.24*	*34.0*	*518.7*	*1.75*	*1168.7*
MCCP-13	$C_{16}H_{29}Cl_5$	45	-4.35	7.35	11.70	38.7	518.7	4.57	1759.6
MCCP-14	$C_{16}H_{27}Cl_7$	53	-5.37	7.574	12.94	54.7	518.8	11.80	2753.2
MCCP-15	$C_{16}H_{22}Cl_{12}$	67	-5.79	9.117	14.91	140.0	519.0	12.66	2859.8
MCCP-16	*$C_{17}H_{31}Cl_5$*	*43*	*-4.19*	*8.262*	*12.46*	*30.8*	*518.9*	*9.23*	*2455.4*
MCCP-17	$C_{17}H_{30}Cl_6$	48	-5.36	8.064	13.42	37.7	518.9	12.24	2809.8
MCCP-3	$C_{17}H_{29}Cl_7$	52	-5.73	7.935	13.66	40.2	518.9	12.41	2825.9
MCCP-4	$C_{17}H_{29}Cl_7$	52	-5.92	7.79	13.71	36.6	518.9	12.39	2821.1
MCCP-18	$C_{17}H_{23}Cl_{13}$	67	-6.28	9.16	15.45	135.3	518.9	12.70	2860.0

*AOPWIN v1.92 has been used to make predictions of the hydroxyl radical rate constant (kOH) to estimate atmospheric half-lives
Constituents in italics are not within the scope of the proposal, but included to provide an illustration of the trend in properties and LRET

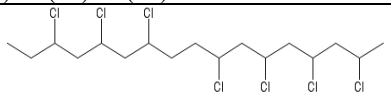
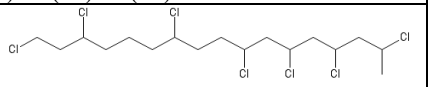
In-depth consideration of LRET modelling of MCCPs

Four of the constituents[23] modelled were selected to compare and investigate the sensitivity of LRET modelling of MCCPs. At a congener level, these four constituents also provide a good illustration of the lower and higher ends of the LRET range of the substance proposed for listing.

Table 14: Input (predicted) values for the four representative $C_{14\text{-}17}$ constituents ("MCCPs")

Parameters	C_{14} constituent (52.6% Cl wt.)	
OECD LRTP ID	**MCCP-1 (non-terminal chlorine)**	**MCCP-2 (terminal chlorine)**
SMILES	CC(Cl)CCC(Cl)CCC(Cl)C(Cl)C(Cl)CCC(Cl)C	ClCC(Cl)CC(Cl)CC(Cl)CCCC(Cl)CC(Cl)CC
Structure		
Molecular mass (g/mol)	405.07	405.07
Molecular formula	$C_{14}H_{24}Cl_6$	$C_{14}H_{24}Cl_6$
Log K_{AW}	-4.93 (-2.0)[#]	-4.56 (-2.0)[#]
Log K_{OW}	6.40 (6.58)[#]	6.77 (6.58)[#]

[23] Two representative "MCCPs" congeners ($C_{14}H_{24}Cl_6$ (52.6% Cl wt.) and $C_{17}H_{29}Cl_7$ (51.6% Cl wt.)) have been modelled. The C_{14} congener was selected based on the available laboratory data for persistence and bioaccumulation, and a C_{17} congener with an equivalent chlorination level was chosen for comparison. For each congener, 2 constituents were modelled, one with a chlorine atom on a terminal carbon atom and the other with no chlorines on the terminal carbon atom. This was designed to investigate the variation of degradation with the relative position of chlorine atoms in the chain.

Log K_{OA}	11.33 (8.58)#	11.32 (8.58)#
OH rate constant at 25 °C (cm^3/molecule-sec)	6.26 x 10^{-12}	8.02 x 10^{-12}
Half-life in air (h)*	61.5	48
Half-life in water (h)	4 320	4 320
Half-life in soil (h)	8 640	8 640
Parameters	**C_{17} constituent (51.6% Cl wt.)**	
OECD LRTP ID	**MCCP-3 (non-terminal chlorine)**	**MCCP-4 (terminal chlorine)**
SMILES	CC(Cl)CC(Cl)CC(Cl)CC(Cl)CCC(Cl)CC(Cl)CC(Cl)CC	ClCCC(Cl)CCCC(Cl)CCC(Cl)CC(Cl)CC(Cl)CC(Cl)C
Structure		
Molecular mass (g/mol)	481.5	481.5
Molecular formula	$C_{17}H_{29}Cl_7$	$C_{17}H_{29}Cl_7$
Log K_{AW}	-5.73	-5.92
Log K_{OW}	7.93	7.79
Log K_{OA}	13.66	13.71
OH rate constant at 25 °C (cm^3/molecule-sec)	9.58 x 10^{-12}	1.05 x 10^{-11}
Half-life in air (h)*	40.2	36.7
Half-life in water (h)	4 320	4 320
Half-life in soil (h)	8 640	8 640

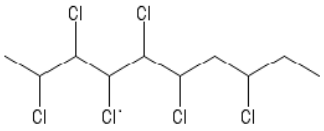
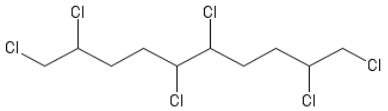
Note: # Measured values (used in sensitivity analysis).

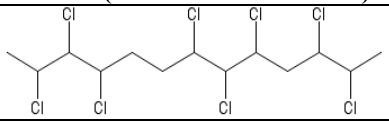
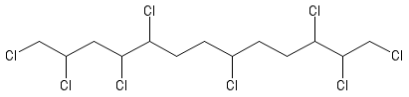
* Derived using a global annual average hydroxyl radical concentration of 5 x 10^5 molecule/cm^3.

Data for modelling of SCCP congeners

Table 15 provides information on the four (of the five) representative SCCP structures used to provide comparison to the "MCCPs" LRET modelling. The input parameters for these constituents rely on physico-chemical and atmospheric half-life values predicted by EPISuite™.

Table 15: Input (predicted) values for two C_{10-13} constituents (SCCPs) used to predict their LRET

Parameters	**C_{10} constituent (61% Cl wt.)**	
OECD LRTP ID	**SCCP-1 (non-terminal chlorine)**	**SCCP-2 (terminal chlorine)**
SMILES	ClC(CC(Cl)CC)C(Cl)C(Cl)C(Cl)C(C)Cl	C(CC(C(CCC(CCl)Cl)Cl)Cl)C(CCl)Cl
Structure		
Molecular mass (g/mol)	348.9	348.9
Molecular formula	$C_{10}H_{16}Cl_6$	$C_{10}H_{16}Cl_6$
Log K_{AW}	-1.133	-1.133
Log K_{OW}	6.34	6.48
Log K_{OA}	7.47	7.61
OH rate constant at 25 °C (cm^3/molecule-sec)	2.67 x 10^{-12}	3.22 x 10^{-12}
Half-life in air (h)*	144.3	119.7
Half-life in water (h)	4 320	4 320
Half-life in soil (h)	8 640	8 640
Parameters	**C_{13} constituent (61% Cl wt.)**	
OECD LRTP ID	**SCCP-3 (non-terminal chlorine)**	**SCCP-4 (terminal chlorine)**
SMILES	CC(Cl)C(Cl)CC(Cl)C(Cl)C(Cl)CCC(Cl)C(Cl)C(C)Cl	C(Cl)(C(Cl)CCC(Cl)CCC(C(Cl)CC(CCl)Cl)Cl)CCl

Parameters	C_{10} constituent (61% Cl wt.)	
OECD LRTP ID	**SCCP-1 (non-terminal chlorine)**	**SCCP-2 (terminal chlorine)**
Structure		
Molecular mass (g/mol)	459.9	459.9
Molecular formula	$C_{13}H_{20}Cl_8$	$C_{13}H_{20}Cl_8$
Log K_{AW}	-1.67	-1.67
Log K_{OW}	8.17	8.32
Log K_{OA}	9.84	9.99
OH rate constant at 25 °C (cm^3/molecule-sec)	3.07×10^{-12}	4.55×10^{-11}
Half-life in air (h)*	125.3	84.7
Half-life in water (h)	4 320	4 320
Half-life in soil (h)	8 640	8 640

Note: * Derived using a global annual average hydroxyl radical concentration of 5×10^5 molecule/cm^3 in REACH Guidance R.16 (ECHA, 2016)

Predictions of log K_{OW}, log K_{AW} and log K_{OA} values using COSMOtherm for "MCCPs" and their relationship with chain length and degree of chlorination

Endo (2021) investigated variability of predicted values for physico-chemical properties of CPs. They calculated log K_{OW}, log K_{AW} and log K_{OA} values for 193 "MCCPs" congener groups using COSMOtherm for (C_{10-20}, Cl_{0-21}). Overall, 1,070 congeners for training and 420 congeners for validation were used in the study and the predicted values were compared to the experimental data from Hilger *et al.*, (2011a). A summary of the results for C_{14} to C_{17} congeners are presented in Table 16 and Figure 4, Figure 5, Figure 6 and Figure 7. The structures of the congeners modelled is not specified in the paper or supplementary information.

Similar to Gluge *et al.,* (2013), Endo (2021) reported that good agreement was obtained between the calculated data for COSMOtherm and measured data. The results summarised in Table 16 show that there is a general positive correlation between increasing K_{OA} and increasing % chlorination and increasing chain length for constituents from C_{14} to C_{17} which indicates an increasing binding potential to particles and overall long rang-transport potential via the atmosphere; in particular for the most chlorinated longer chain length constituents.

Table 16: Log K_{AW} , Log K_{OA} and Log K_{OW} from COSMOtherm predictions for all "MCCPs" constituents" from Endo (2021)

Congener	% Cl	log K_{OW}	log K_{OA}	log K_{AW}
$C_{14}H_{30}Cl_0$	*0.0*	*8.26*	*6.19*	*2.37*
$C_{14}H_{29}Cl_1$	*15.23*	*7.93*	*7.56*	*0.86*
$C_{14}H_{28}Cl_2$	*26.53*	*7.64*	*8.55*	*-0.09*
$C_{14}H_{27}Cl_3$	*35.25*	*7.49*	*9.55*	*-0.93*
$C_{14}H_{26}Cl_4$	*42.18*	*7.35*	*10.51*	*-1.88*
$C_{14}H_{25}Cl_5$	47.83	7.35	11.36	-2.61
$C_{14}H_{24}Cl_6$	52.52	7.33	12.11	-3.25
$C_{14}H_{23}Cl_7$	56.47	7.38	12.76	-3.85
$C_{14}H_{22}Cl_8$	59.84	7.58	13.37	-4.19
$C_{14}H_{21}Cl_9$	62.76	7.81	13.78	-4.49
$C_{14}H_{20}Cl_{10}$	65.31	8.09	14.20	-4.67
$C_{14}H_{19}Cl_{11}$	67.56	8.44	14.58	-4.77
$C_{14}H_{18}Cl_{12}$	69.55	8.83	14.92	-4.73
$C_{14}H_{17}Cl_{13}$	71.33	9.20	15.33	-4.86
$C_{14}H_{16}Cl_{14}$	72.92	9.62	15.73	-4.97
$C_{14}H_{15}Cl_{15}$	74.37	9.96	16.14	-5.07

Congener	% Cl	log K_{OW}	log K_{OA}	log K_{AW}
$C_{14}H_{14}Cl_{16}$	75.68	10.21	16.42	-5.23
$C_{15}H_{32}Cl_{0}$	*0.0*	*8.82*	*6.68*	*2.45*
$C_{15}H_{31}Cl_{1}$	*14.36*	*8.49*	*8.05*	*0.95*
$C_{15}H_{30}Cl_{2}$	*25.21*	*8.19*	*9.04*	*0.00*
$C_{15}H_{29}Cl_{3}$	*33.68*	*8.03*	*10.05*	*-0.90*
$C_{15}H_{28}Cl_{4}$	*40.50*	*7.89*	*11.00*	*-1.87*
$C_{15}H_{27}Cl_{5}$	46.09	7.80	11.88	-2.65
$C_{15}H_{26}Cl_{6}$	50.76	7.78	12.61	-3.32
$C_{15}H_{25}Cl_{7}$	54.72	7.83	13.27	-3.86
$C_{15}H_{24}Cl_{8}$	58.12	7.92	13.91	-4.38
$C_{15}H_{23}Cl_{9}$	61.08	8.13	14.42	-4.69
$C_{15}H_{22}Cl_{10}$	63.67	8.43	14.87	-4.88
$C_{15}H_{21}Cl_{11}$	65.95	8.70	$_{15}$.21	-5.11
$C_{15}H_{20}Cl_{12}$	67.99	9.07	15.58	-5.16
$C_{15}H_{19}Cl_{13}$	69.81	9.49	15.97	-5.13
$C_{15}H_{18}Cl_{14}$	71.45	9.86	16.36	-5.20
$C_{15}H_{17}Cl_{15}$	72.94	10.22	16.79	-5.31
$C_{15}H_{16}Cl_{16}$	74.29	10.63	17.17	-5.50
$C_{15}H_{21}Cl_{17}$	74.96	10.91	17.56	-5.73
$C_{16}H_{34}Cl_{0}$	*0.0*	*9.37*	*7.17*	*2.54*
$C_{16}H_{33}Cl_{1}$	*13.59*	*9.04*	*8.54*	*1.03*
$C_{16}H_{32}Cl_{2}$	*24.01*	*8.75*	*9.50*	*0.09*
$C_{16}H_{31}Cl_{3}$	*32.25*	*8.58*	*10.52*	*-0.84*
$C_{16}H_{30}Cl_{4}$	*38.94*	*8.43*	*11.48*	*-1.81*
$C_{16}H_{29}Cl_{5}$	*44.46*	*8.30*	*12.36*	*-2.62*
$C_{16}H_{28}Cl_{6}$	49.11	8.24	13.17	-3.40
$C_{16}H_{27}Cl_{7}$	53.08	8.25	13.89	-3.96
$C_{16}H_{26}Cl_{8}$	56.50	8.34	14.47	-4.52
$C_{16}H_{25}Cl_{9}$	59.48	8.50	15.04	-4.86
$C_{16}H_{24}Cl_{10}$	62.10	8.70	15.53	-5.15
$C_{16}H_{23}Cl_{11}$	64.42	9.02	15.96	-5.35
$C_{16}H_{22}Cl_{12}$	66.50	9.36	16.30	-5.48
$C_{16}H_{21}Cl_{13}$	68.36	9.71	16.62	-5.49
$C_{16}H_{20}Cl_{14}$	70.04	10.11	17.01	-5.53
$C_{16}H_{19}Cl_{15}$	71.56	10.49	17.42	-5.60
$C_{16}H_{18}Cl_{16}$	72.95	10.90	17.79	-5.59
$C_{16}H_{17}Cl_{17}$	74.22	11.16	18.21	-5.82
$C_{17}H_{36}Cl_{0}$	*0.0*	*9.93*	*7.66*	*2.63*
$C_{17}H_{35}Cl_{1}$	*12.90*	*9.60*	*9.03*	*1.12*
$C_{17}H_{34}Cl_{2}$	*22.92*	*9.30*	*9.99*	*0.17*
$C_{17}H_{33}Cl_{3}$	*30.94*	*9.11*	*11.01*	*-0.79*
$C_{17}H_{32}Cl_{4}$	*37.49*	*8.94*	*11.97*	*-1.81*
$C_{17}H_{31}Cl_{5}$	*42.95*	*8.77*	*12.86*	*-2.68*
$C_{17}H_{30}Cl_{6}$	47.57	8.73	13.70	-3.47
$C_{17}H_{29}Cl_{7}$	51.53	8.74	14.42	-4.05
$C_{17}H_{28}Cl_{8}$	54.96	8.75	15.06	-4.62
$C_{17}H_{27}Cl_{9}$	57.96	8.83	15.63	-5.11
$C_{17}H_{26}Cl_{10}$	60.61	9.07	16.18	-5.39
$C_{17}H_{25}Cl_{11}$	62.97	9.35	16.63	-5.63
$C_{17}H_{24}Cl_{12}$	65.07	9.58	16.98	-5.90
$C_{17}H_{23}Cl_{13}$	66.97	9.97	17.34	-5.90
$C_{17}H_{22}Cl_{14}$	68.68	10.32	17.68	-5.87
$C_{17}H_{21}Cl_{15}$	70.24	10.75	18.07	-5.88

Congener	% Cl	log K_{OW}	log K_{OA}	log K_{AW}
$C_{17}H_{20}Cl_{16}$	71.66	11.11	18.45	-6.01
$C_{17}H_{19}Cl_{17}$	72.96	11.46	18.86	-6.03
$C_{17}H_{18}Cl_{18}$	74.16	11.84	19.17	-6.25

Constituents in italics are not within the scope of the proposal, but included to provide an illustration of the trend in properties

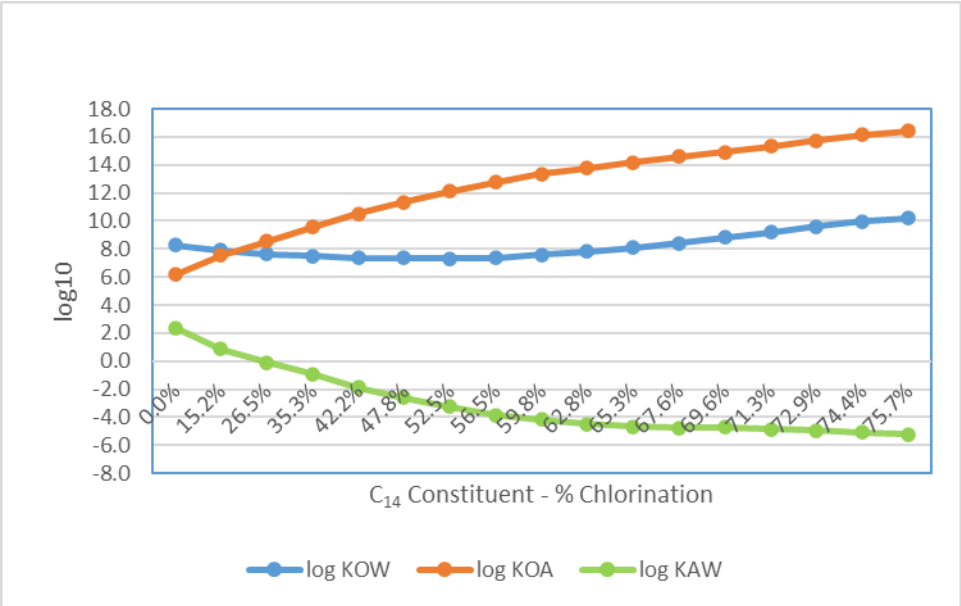


Figure 5: Plots of K_{OA}, K_{OW} and K_{AW} for CPs - C_{14} constituents (Endo, 2021)

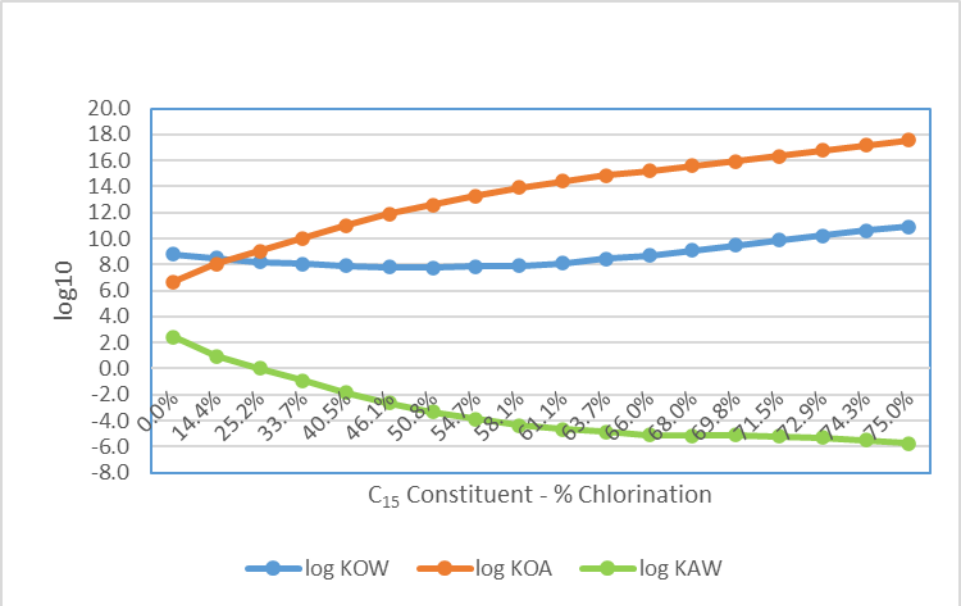


Figure 6: Plots of K_{OA}, K_{OW} and K_{AW} for CPs - C_{15} constituents (Endo, 2021)

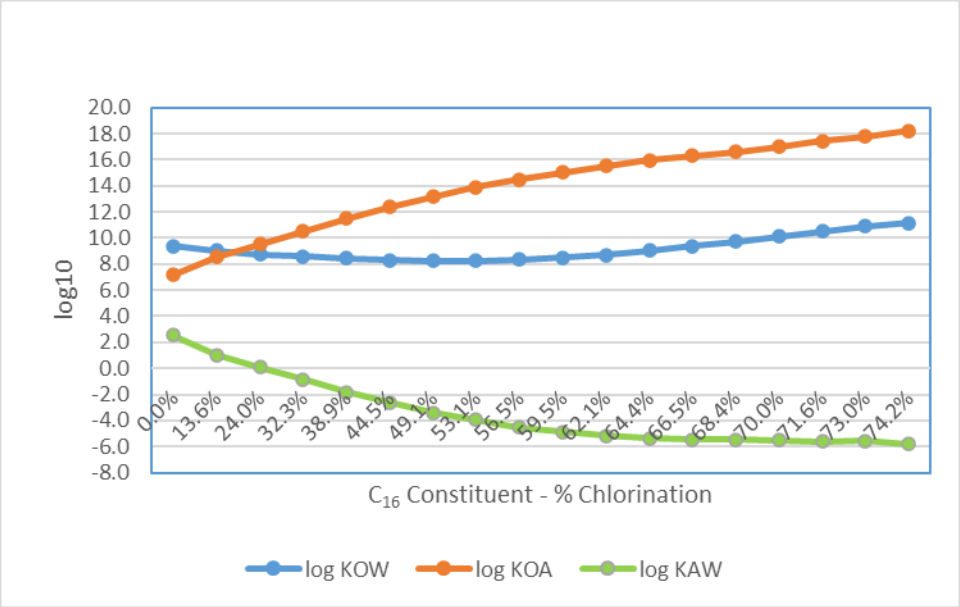


Figure 7: Plots of K_{OA}, K_{OW} and K_{AW} for CPs - C_{16} constituents (Endo, 2021)

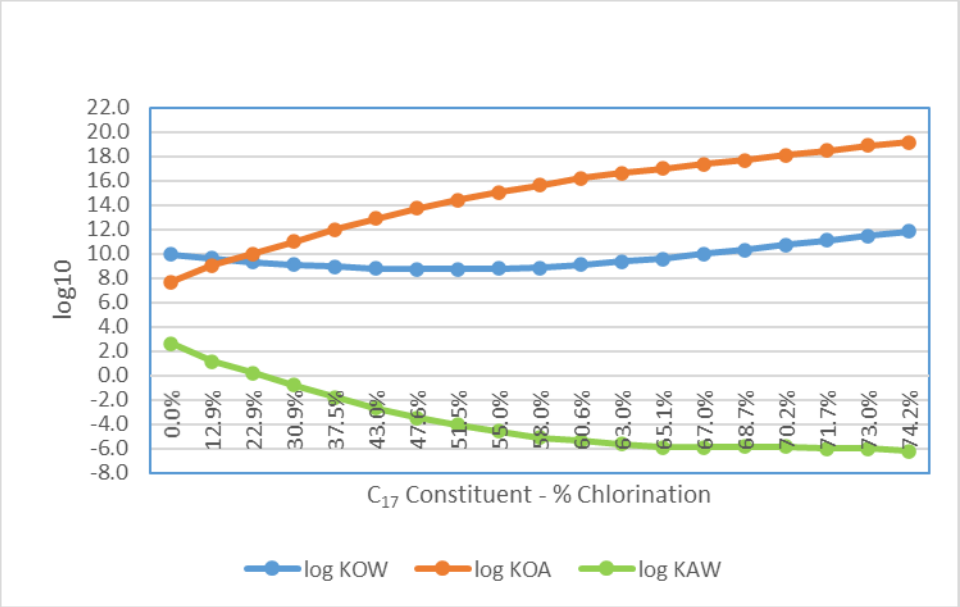


Figure 8: Plots of K_{OA}, K_{OW} and K_{AW} for CPs - C_{17} constituents (Endo, 2021)

Sensitivity of using log K_{OW}, log K_{AW} and log K_{OA} values predicted using EPISuite™ for LRET modelling

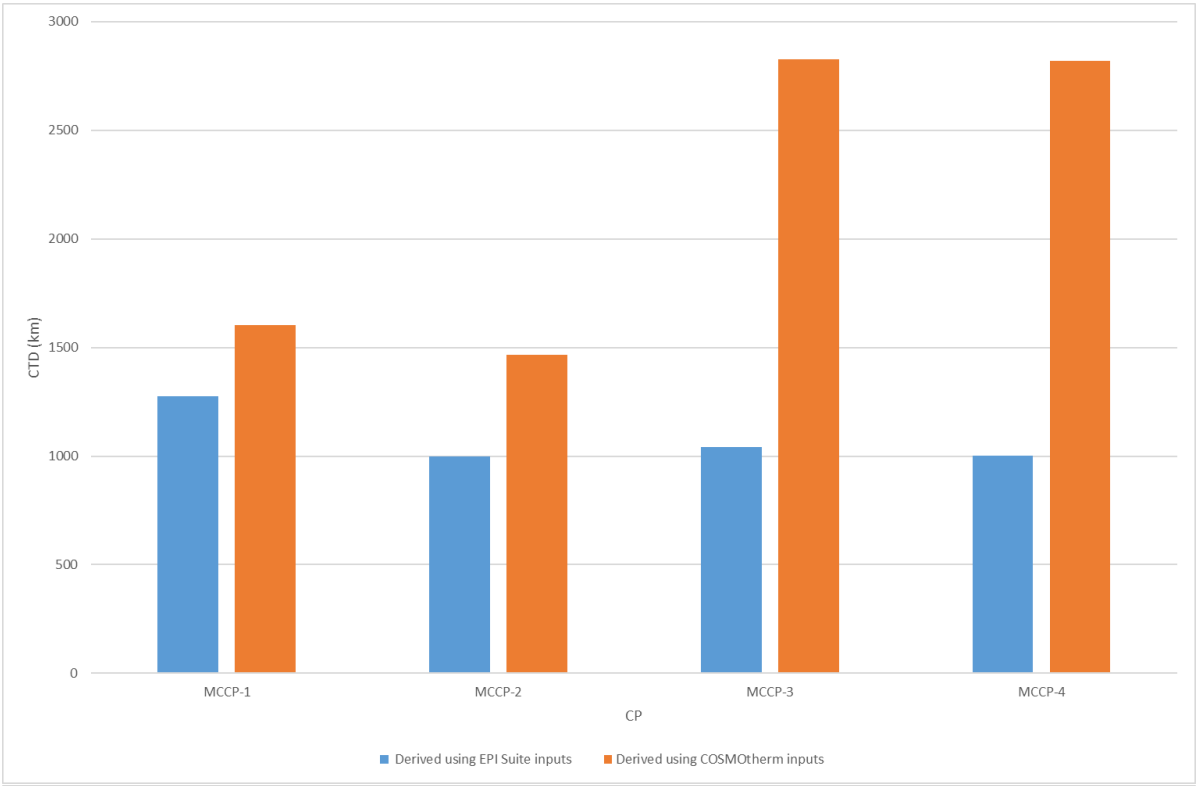
Glüge *et al.* (2013) reported that EPISuite™ showed the largest discrepancies for all physico-chemical properties when compared to the measured data, and therefore is potentially less reliable. To check the sensitivity of the LRET predictions, the physico-chemical input parameters (i.e. K_{AW} and K_{OW}) have been predicted using EPISuite™ for 18 congeners whilst retaining the other values as Table 13. The results are presented in Table 17 below.

It can be seen that there is a large decrease in the TE for the 18 constituents and a more modest decrease in the CTD for the C_{14} and C_{15} constituents but a large decrease in the CTD for the C_{16} and C_{17} constituents when using EPISuite™ compared to COSMOtherm. This is illustrated in Figure 8 below.

Table 17: LRTP predictions using predicted Log K_{AW} and Log K_{OW} from EPISuite™

Example structure	Chemical formula	% Cl	Inputs				Predictions		
			Log K_{AW}	Log K_{OW}	Log K_{OA}	Half-life in air (hours)*	P_{OV} (days)	Transfer Efficiency (%)	Characteristic Travel Distance (km)
MCCP-5	*$C_{14}H_{26}Cl_4$*	*42*	*0.266*	*7.94*	*7.67*	*42.0*	*168.1*	*0.004*	*870.5*
MCCP-6	$C_{14}H_{25}Cl_5$	48	-0.187	8.12	8.31	49.3	496.7	0.01	1021.2
MCCP-1	$C_{14}H_{24}Cl_6$	53	-0.64	8.3	8.94	61.5	511.4	0.05	1276.2
MCCP-2	$C_{14}H_{24}Cl_6$	53	-0.64	8.37	9.01	48.0	512.3	0.03	998.0
MCCP-7	$C_{14}H_{20}Cl_{10}$	65	-2.453	9.1	11.55	98.1	519.0	7.73	2512.4
MCCP-8	*$C_{15}H_{26}Cl_4$*	*41*	*0.389*	*8.43*	*8.04*	*36.2*	*169.5*	*0.005*	*751.4*
MCCP-9	$C_{15}H_{27}Cl_5$	46	-0.064	8.68	8.74	37.9	508.0	0.01	787.1
MCCP-10	$C_{15}H_{25}Cl_7$	55	-0.97	8.97	9.94	65.3	518.1	0.25	1395.3
MCCP-11	$C_{15}H_{21}Cl_{11}$	66	-2.783	9.84	12.62	94.3	519.0	11.94	2805.8
MCCP-12	*$C_{16}H_{30}Cl_4$*	*39*	*0.512*	*8.92*	*8.41*	*34.0*	*499.8*	*0.007*	*705.1*
MCCP-13	$C_{16}H_{29}Cl_5$	45	0.059	9.1	9.04	38.7	512.8	0.02	807.8
MCCP-14	$C_{16}H_{27}Cl_7$	53	-0.848	9.46	10.31	54.7	518.6	0.38	1238.3
MCCP-15	$C_{16}H_{22}Cl_{12}$	67	-3.114	10.36	13.47	140.0	519.0	12.60	2856.9
MCCP-16	*$C_{17}H_{31}Cl_5$*	*43*	*0.182*	*9.59*	*9.41*	*30.8*	*516.1*	*0.02*	*647.8*
MCCP-17	$C_{17}H_{30}Cl_6$	48	-0.271	9.77	10.04	37.7	518.3	0.10	830.7
MCCP-3	$C_{17}H_{29}Cl_7$	52	-0.725	9.95	10.68	40.2	518.8	0.49	1041.0
MCCP-4	$C_{17}H_{29}Cl_7$	52	-0.725	10.05	10.78	36.6	518.9	0.53	1003.3
MCCP-18	$C_{17}H_{23}Cl_{13}$	67	-3.443	11.04	14.48	135.3	519.0	12.66	2860.4

*AOPWIN v1.92 has been used to make predictions of the hydroxyl radical rate constant (kOH) to estimate atmospheric half-lives
Constituents in italics are not within the scope of the proposal, but included to provide an illustration of the trend in properties and LRET



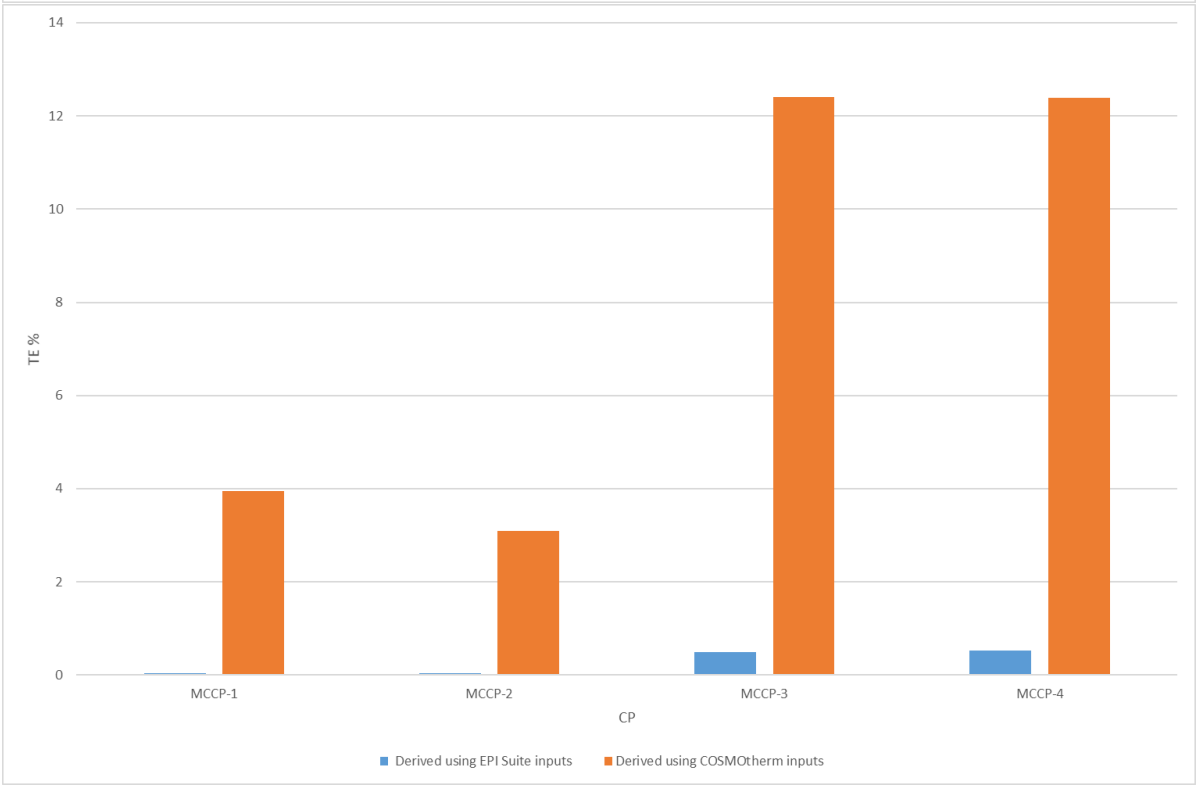


Figure 9: Plots of CTD and TE for 4 MCCP constituents (derived using inputs from EPISuite™ and COSMOtherm)

Sensitivity using log K_{OW} values predicted using ACD Percepta

ECHA (2021) used the ACD Percepta program to predict log K_{OW} for "MCCPs" congener groups including structural isomers. For $C_{14}H_{24}Cl_6$ and $C_{17}H_{29}Cl_7$, the predicted log K_{OW} ranged from 6.36 to 7.01 and 7.33 to 8.67. These are broadly comparable to the predicted values in Table 13 and the predicted LRET results are expected to be similar to those using COSMOtherm.

Further consideration of the relationship of log K_{AW} and log K_{OA} values based on Gawor & Wania (2013)

ECHA (2021a) summarised work by Gawor and Wania (2013) in predicting log K_{AW} and log K_{OA} values for "MCCPs" with ranges of -7.66 to 1.13 and 5.96 to 16.08 respectively. As the carbon chain length of CP increases, the K_{OA} values increase, i.e. the constituents are getting less volatile. However, the K_{AW} is relatively unchanged by an increasing carbon chain length, indicating that the water solubility and the vapour pressure of CP changes to a similar extent. The K_{AW} decreases and K_{OA} increases with increasing degree of halogenation. Gawor and Wania (2013) predicted that "MCCPs" with ~5–6 and ~6–7 chlorines, respectively, were identified to have the highest LRTP.

Sensitivity of using measured physico-chemical values for the LRET modelling

Experimental values for log K_{OW} (6.58) and a log K_{AW} of -2.0 were used as input values for the C_{14} constituent (see Table 14). The log K_{AW} of -2.0 is calculated from experimental values for vapour pressure (2.7×10^{-4} Pa at 20 °C) and water solubility (6.1 µg/L at 20 °C). Using these values but with the same degradation half-lives predicts a P_{OV} of 503 days, a CTD of 1 258 km and a TE of 0.18% for MCCP-1. For MCCP-2, a P_{OV} of 503 days, a CTD of 985 km and a TE of 0.11% was predicted. Therefore overall, the use of the measured data makes little difference to the modelled outcome when using the EPISuite™ input predictions (Table 17) but the CTD and TE are lower than the values derived when using the COSMOtherm input predictions (Table 13). The predicted CTD and TE are heavily influenced by partitioning to the particle phase. A lower input value of log K_{AW} results in an increase in the log K_{OA} and in the predicted CTD and TE as the predicted proportion of CPs with $C_{14\text{-}17}$ chain lengths in the particle phase increases.

Sensitivity using Environment Canada (2008) atmospheric half-lives for the LRET modelling

Environment Canada (2008) reported atmospheric half-lives for vapour phase "MCCPs" ranging from 2.7 to 7.1 days (64.8 to 170.4 hours). The sensitivity of the OECD tool to this range of half-lives is shown in Table 18. Other parameters were as per Table 14.

Table 18: Sensitivity of the LRTP predictions to different atmospheric half-lives from Environment Canada (2008)

Predictions	**C_{14} constituent (52.6% Cl wt.)[a]**			
	MCCP-1 (non-terminal chlorine)		**MCCP-2 (terminal chlorine)**	
Atmospheric half-life (h)	**64.8**	**170.4**	**64.8**	**170.4**
CTD (km)	1 344	3 479	1 344	3 477
TE (%)	0.052	0.35	0.056	0.37
P_{OV} (days)	512	513	512	513
Predictions	**C_{17} constituent (51.6% Cl wt.)[a]**			
	MCCP-3 (non-terminal chlorine)		**MCCP-4 (terminal chlorine)**	
Atmospheric half-life (h)	**64.8**	**170.4**	**64.8**	**170.4**
CTD (km)	1 575	3 275	1 625	3 243
TE (%)	1.13	4.88	1.4	5.57
P_{OV} (days)	519	519	519	519

Note: a – For explanations about the actual structures selected, see Section 2.2.4.2.

Consideration of the degree of adsorption to particles predicted by different models on the LRET modelling

Physical removal of a chemical substance from the atmosphere can occur by wet and/or dry deposition of a gaseous or particulate substance. The distribution of the chemical between gas and particulate phases affects deposition rates and chemical reactivity that alters the long-range transport and distribution properties of a chemical (Boethling *et al.*, 2004).

The OECD Tool estimates the fraction of substance sorbed to atmospheric particulates which is used to estimate the atmospheric transport potential. The AEROWIN v1.0 Program estimates the fraction of substance sorbed to atmospheric particulates, which is also known as the parameter *phi*, by three methods:

- Junge-Pankow Adsorption Model;
- Mackay Adsorption Model; and
- Octanol-Air Partition Coefficient Model.

Estimates for the predicted fraction of "MCCPs" and SCCPs sorbed to atmospheric particulates is presented in Table 19 and Figure 9. As AEROWIN v1.0 is an EPISuite™, model, the input parameters for these constituents rely on physico-chemical and atmospheric half-life values predicted by EPISuite™ as summarised in Table **17** and Table 15.

For the majority of CP congeners presented in Table 19 and Figure 9 and Figure 10, the fraction sorbed to particulates predicted by the OECD Tool is typically significantly lower than the three methods from AEROWIN v1.0 when using the same physico-chemical and atmospheric half-life values predicted by EPISuite™ as inputs for all models (Table 17). The predicted sorption to particles increases with the % chlorination and carbon chain length of the constituent(s) as K_{OA} increases generally for all 4 methods. At ~65% chlorination, all 4 methods show similar outcomes and predict between 70% and 100% sorption to particles for all carbon chain lengths (see Figure 10). In contrast, at ~42% chlorination, the range of predicted sorption to particles range is between 0.04% and 10.2% and at ~52% chlorination, it is between 0.73% and 48.2% with the heavily chlorinated, longer carbon chain constituents having the greatest sorption to particles predicted.

When using physico-chemical input values derived by COSMOtherm (Table 13) the OECD LRTP tool predicts a much greater sorption to particles for all carbon chain lengths when compared to using physico-chemical inputs derived by EPISuite™ (see Figure 11) due to the larger predicted K_{OA} by COSMOtherm. At ~65% chlorination, the tool predicts between 99% and 100% sorption to particles for all carbon chain lengths (see Figure 11). In contrast, at ~42% chlorination, the range of predicted sorption to particles range is between 4.5% and 96.0% and at ~52% chlorination, it is between 64.2% and 99.7% with the heavily chlorinated, longer carbon chain constituents having the greatest sorption to particles predicted.

Table 19: Comparison of fraction of sorption of chlorinated paraffins to atmospheric particulates

Example structure	Chemical formula	% Cl	Fraction bound to atmospheric particulates (phi)*			
			Junge-Pankow method	Mackay method	K_{OA} method	OECD LRTP Tool
"MCCPs"						
MCCP-5	*$C_{14}H_{26}Cl_4$*	*42*	*0.003*	*0.006*	*0.001*	*0.000*
MCCP-6	$C_{14}H_{25}Cl_5$	48	0.007	0.016	0.004	0.002
MCCP-1	$C_{14}H_{24}Cl_6$	53	0.019	0.042	0.017	0.007
MCCP-2	$C_{14}H_{24}Cl_6$	53	0.040	0.084	0.020	0.009
MCCP-7	$C_{14}H_{20}Cl_{10}$	65	0.695	0.835	0.875	0.750
MCCP-8	*$C_{15}H_{26}Cl_4$*	*41*	*0.005*	*0.012*	*0.002*	*0.001*
MCCP-9	$C_{15}H_{27}Cl_5$	46	0.029	0.061	0.010	0.005
MCCP-10	$C_{15}H_{25}Cl_7$	55	0.092	0.183	0.146	0.068
MCCP-11	$C_{15}H_{21}Cl_{11}$	66	0.964	0.983	0.988	0.972
MCCP-12	*$C_{16}H_{30}Cl_4$*	*39*	*0.010*	*0.022*	*0.005*	*0.002*
MCCP-13	$C_{16}H_{29}Cl_5$	45	0.026	0.056	0.021	0.009
MCCP-14	$C_{16}H_{27}Cl_7$	53	0.163	0.301	0.285	0.146

Example structure	Chemical formula	% Cl	Fraction bound to atmospheric particulates (phi)*			
			Junge-Pankow method	Mackay method	K_{OA} method	OECD LRTP Tool
MCCP-15	$C_{16}H_{22}Cl_{12}$	67	0.969	0.986	0.998	0.996
MCCP-16	*$C_{17}H_{31}Cl_5$*	*43*	*0.049*	*0.102*	*0.048*	*0.021*
MCCP-17	$C_{17}H_{30}Cl_6$	48	0.121	0.234	0.178	0.085
MCCP-3	$C_{17}H_{29}Cl_7$	52	0.272	0.453	0.482	0.284
MCCP-4	$C_{17}H_{29}Cl_7$	52	0.443	0.638	0.528	0.334
MCCP-18	$C_{17}H_{23}Cl_{13}$	67	0.994	0.997	1.000	1.000
SCCPs						
SCCP-1	$C_{10}H_{16}Cl_6$	61	0.0015	0.0032	0.0006	0.0002
SCCP-2	$C_{10}H_{16}Cl_6$	61	0.0067	0.0147	0.0008	0.0003
SCCP-3	$C_{13}H_{20}Cl_8$	61	0.069	0.142	0.120	0.055
SCCP-4	$C_{13}H_{20}Cl_8$	61	0.251	0.426	0.161	0.076

Constituents in italics are not within the scope of the proposal, but included to provide an illustration of the trend in properties and LRET

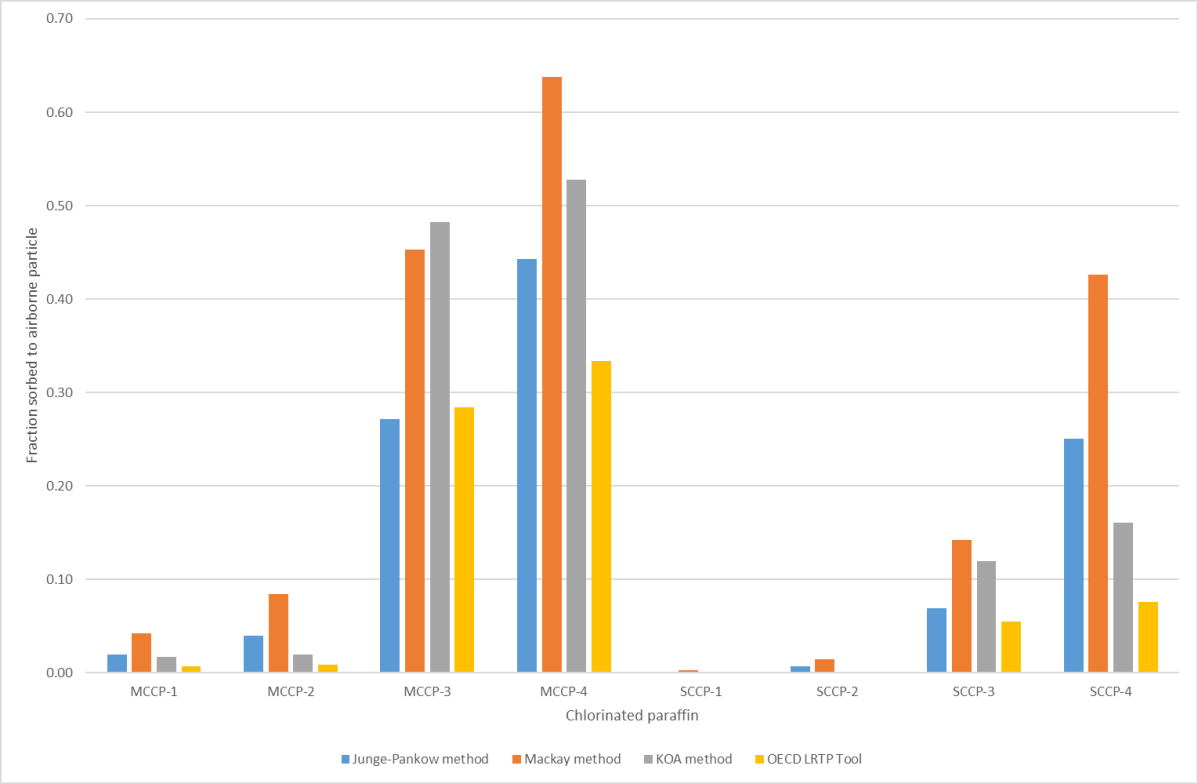


Figure 10: Comparison of fraction of sorption of selected "MCCPs" and SCCPs to atmospheric particulates (derived using EPISuite™ inputs)

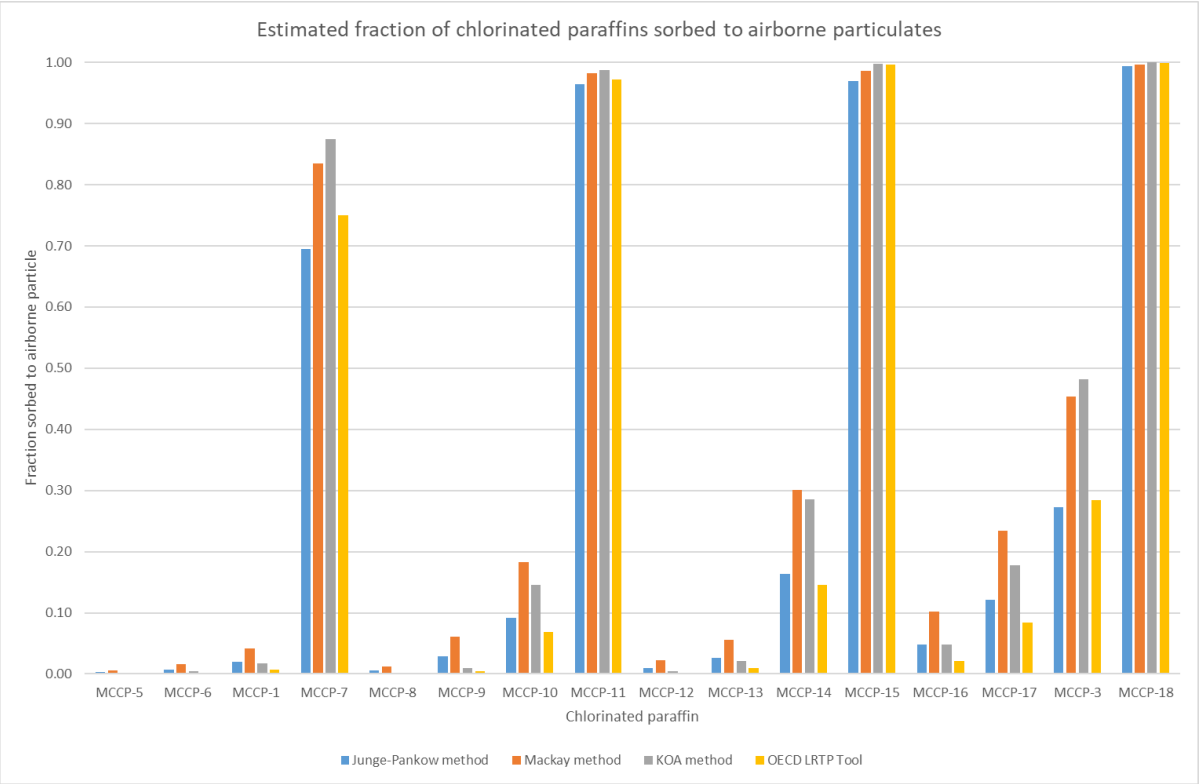


Figure 11: Comparison of fraction of sorption of "MCCPs" (with variable % chlorination) to atmospheric particulates (derived using EPISuite™ inputs)

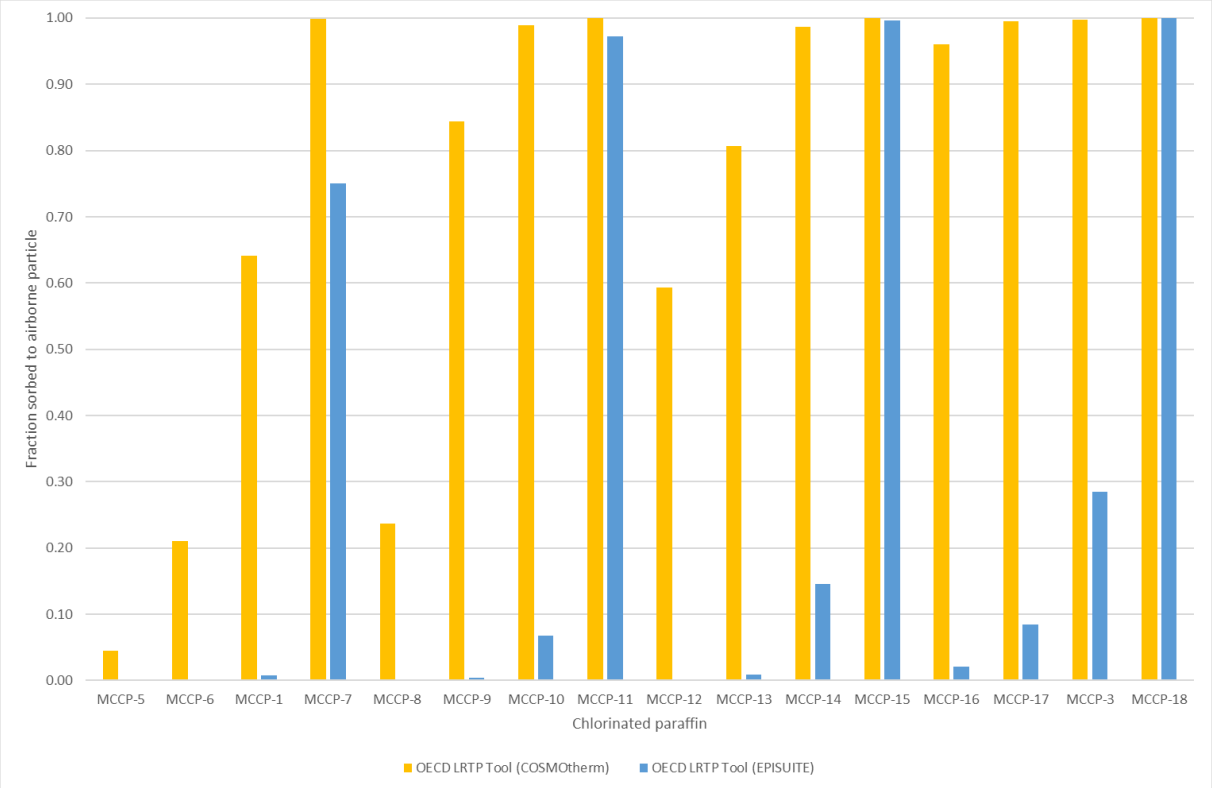


Figure 12: Comparison of predicted fraction of sorption of "MCCPs" (with variable % chlorination) to atmospheric particulates derived using EPISuite™ and COSMOtherm inputs

Appendix 6: monitoring data

Please see separate document.

Appendix 7: Human health toxicity assessment prepared by HSE April 2021

Summary

Alkanes, C_{14-17}, chloro (chlorinated paraffins, C_{14-17}), CAS number 85535-85-9 have a harmonised classification on Annex VI to CLP that includes Lact. H362: May cause harm to breast-fed children. No other human health effects are listed in this entry. The review by EFSA (2020) and other recently published information does not indicate that MCCPs meet the criteria for classifications for other human-health end-points.

Background

According to Annex XIII of (UK) REACH, the following CLP classifications lead to a substance fulfilling the 'T' criterion for PBT status: Carc 1A or 1B; Mut 1A or 1B; Repr 1A or 1B; other evidence of chronic toxicity, such as STOT RE category 1 or 2.

Current classification on CLP Annex VI (human health):	Effects on or via lactation (Lact.)
Other notified classifications (human health):	Skin irrit. 2; Eye irrit. 2; STOT SE 3 (respiratory irritation)
Registrants' proposed classification (human health):	Effects on or via lactation (Lact.)

This report supplements the consultation document '*Proposal to list "Chlorinated paraffins with carbon chain lengths in the range C_{14-17} and chlorination levels ≥ chlorine by weight" in Annex A, B or C to the Stockholm Convention on Persistant Organic Pollutants'* (published by Defra on the gov.uk website February 2021) with additional relevant information contained in the EFSA Scientific Opinion on the *Risk assessment of chlorinated paraffins in feed and food* (2020) and identified during the commenting phase. Additionally, in March 2021 HSE conducted a literature search to identify any more-recently published information relevant to the human-health assessment.

Previous UK assessments of the human-health effects of MCCPs have been reported in the draft EU Risk Assessment Report (HSE, 2008) and REACH Annex XV transitional dossier (derived no-effect levels (DNELs) calculated and risk characterisation ratios (RCR) presented) (2008). The conclusions of the following regulatory or international reviews of the human-health effects of MCCPs are also incorporated into this update.

- World Health Organisation (WHO, 1996)
- Canadian Environmental Protection Act (CEPA, 2008)
- Scientific opinion on the risk assessment report on C_{14-17}, chloro, human health part of the Scientific Committee on Health and Environmental Risks (SCHER, 2008)
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT, 2009)
- Federal Institute for Occupational Safety and Health (BAuA, 2011) (in German: not referred to further in this assessment)
- Danish Ministry of the Environment (DEPA, 2013)
- United States Environmental Protection Agency (EPA, 2015)

Additionally, the German REACH CA has recently published an RMOA conclusion document (BAuA, 2020). The publicly-available document does not contain any study or measured data but identified two potential concerns in relation to human exposure to MCCPs: a preliminary RCR > 1 for the use of hand blenders for food preparation for infants; and, from the use of oil-based metal-working fluids that contain > 3% MCCPs, risks that are not adequately controlled for workers, as the UK previously concluded in its REACH Annex XV transitional dossier. The German CA proposed that a targeted restriction would address the latter risk; however, since an unacceptable risk must be demonstrated for a restriction proposal to proceed, it suggested that standard data on reproductive toxicity and mutagenicity be requested through a compliance check. The German CA also suggested that a compliance check could be followed by substance evaluation, to further explore the first concern in relation to infant exposure via food preparation. The German concerns were explained in more detail in a published letter (Zellmer *et al.*, 2020), in which the following areas were highlighted as needing more data:

- validated analytical methods for the detection of chlorinated paraffins (CP) (in food and food contact materials)
- data on the occurrence in food and monitoring of CP in food

- data on the occurrence in consumer products and exposure scenarios
- health effects of different congeners of CP in potential target organs of humans.

1 Acute toxicity

The reviews and registration dossier refer to the same data on the acute toxicity of MCCPs.

MCCPs (40-60% chlorination; with or without 0.2-1% epoxy stabiliser) administered orally to rats had low acute toxicity, with reportedly no deaths or other severe adverse effects at doses up to 15 g/kg bw reported. No acute inhalation or dermal toxicity studies are available for MCCPs, but from animal data on SCCPs via these routes, and the low oral toxicity of MCCPs, reviewers have predicted that MCCPs are likely to have low acute inhalation and dermal toxicity.

The REACH registration dossier refers to the irritation studies included in the EU Risk Assessment Report (HSE, 2008), which concluded that MCCPs (40 to 60% chlorination) have only a slight skin irritation potential and a low eye irritation potential. Likewise, the registrants referred to the skin sensitisation studies assessed by HSE (2008), which comprised guinea-pig tests. These indicated that the MCCPs tested (40 or 45% chlorination) were not skin sensitisers. There are no data on their respiratory sensitisation potential, but since MCCPs are generally unreactive, and given their lack of skin sensitisation potential, it is reasonable to conclude that they would not be respiratory sensitisers.

2 Repeated-dose toxicity

Short summary of toxicological information

4.1. Human data

EFSA (2020) did not identify any data on the repeated-dose toxicity of MCCPs following exposure in humans.

A recent cross-Sectional study has investigated associations between serum SCCP and MCCP concentrations (i.e., mixed exposures) and six liver enzymes in 197 residents of Jinan, China (Liu *et al.*, 2021). Higher than median levels of serum MCCPs were associated with decreased levels of one liver enzyme, pre-albumin, in males only. A change in an isolated liver enzyme, only in males, was not convincing evidence of liver damage. Furthermore, the causality of MCCPs exposure and effects on liver enzymes could not be established because of the cross-Sectional nature of the study; additionally, only a single measure of MCCPs was made.

4.2. Animal data

Repeated-dose toxicity studies in laboratory animals (rats and dogs) have been conducted by the oral route. There are no data from inhalation or dermal exposure.

As reported in the previous assessments, the main target organs of MCCPs (40% or 52% chlorination) upon repeated oral exposure are the liver, thyroid and kidney. Additional studies in rats, mice and guinea pigs have explored the mechanisms of toxicity on these organs. HSE (2008) concluded that liver changes in rats and dogs (liver weight increases from 100 mg/kg bw/d in rats; enzyme induction and histopathological changes from 222 mg/kg bw/d in rats and 30 mg/kg bw/d in a limited dog study) likely represented an adaptive response, with possibly peroxisome proliferation in the rat at higher doses (not relevant to humans). Liver toxicity of potential relevance to humans (single cell necrosis) was observed in rats only at higher doses (approx. 360 mg/kg bw/d). Thyroid pathology and changes in thyroid hormones occurred from 312 mg/kg bw/d in rats; HSE (2008) concluded these effects most likely resulted from increased thyroid hormone clearance caused by the liver-enzyme induction and were not relevant to humans. HSE (2008) considered kidney weight increases and histopathological changes ('chronic nephritis' and tubular pigmentation) in male and female rats at doses from 222 mg/kg bw/d in a 90-day study to be potentially relevant to humans. Whilst there was some evidence of the male-rat-specific α2-urinary globulin mode of action, this protein was only detected at dose levels above those at which the renal effects described above occurred. The overall NOAEL for repeated exposure was 23 mg/kg bw/d from this rat 90-day study, with increased kidney weight occurring at the next dose of 222 mg/kg bw/d and histopathology changes ('chronic nephritis' and tubular pigmentation) at 625 mg/kg bw/d.

The EPA (2015) and SCHER (2008) reached the same conclusions as HSE (2008). WHO (1996) and COT (2009) proposed a lower NOAEL, of 4 mg/kg bw/d from a different 90-day rat study, one which HSE considered to be unrepresentative of the repeated-dose toxicity profile of MCCPs (and on which EFSA (2020) was not able to reach a conclusion). No or very limited data were presented in DEPA (2013) and CEPA (2008).

EFSA (2020) reviewed the same studies as HSE (2008) and assessed the human relevance of the effects on the target organs of liver, thyroid and kidney.

The EFSA report incorporated some recent *in vivo* and *in vitro* studies to supplement the mode-of-action information on the liver toxicity induced by chlorinated paraffins (primarily SCCPs and MCCPs investigated) (Geng *et al.*, 2015; Wang *et al.*, 2018; Geng *et al.*, 2019; Gong *et al.*, 2019; US EPA, 2019; Ren *et al.*, 2019). EFSA concluded that enzyme induction and proliferation of smooth endoplasmic reticulum in hepatocytes, which leads to hypertrophy and consequently increases in liver size, is an adaptive physiological response and hence not adverse. The proliferation of rodent peroxisomes was mediated by a mode of action that is not relevant to humans.

Regarding kidney toxicity, no more recent data to inform on the mode of action of MCCPs were available. EFSA concluded the kidney effects were potentially of relevance to humans.

No new studies were available to further elucidate the mode of action for thyroid effects induced by MCCPs. However, EFSA (2020) referred to recent data that challenges the long-established assumption that thyroid effects (particularly tumours) in rodents resulting from liver-enzyme induction are quantitatively not relevant to humans. Consequently, EFSA concluded that thyroid tumours in female rats following SCCP administration were potentially relevant to humans (see carcinogenicity Section). In terms of the repeated-dose toxicity of MCCPs, EFSA considered the changes in thyroid hormones in rats to be too inconsistent for the setting of a reference point. The panel set a reference point on thyroid histopathology, whilst recognising the uncertainties regarding the extrapolation of liver-mediated effects from rats to humans. The panel concluded that an endocrine-mediated mode of action was not implicated in the thyroid effects. No studies to investigate other potential endocrine-mediated effects of MCCPs were available.

The EFSA panel identified changes in kidney weights as the critical effect of MCCPS of relevance to humans. A BMD analysis, with an effect level (BMR) of 10% change in kidney weight, resulted in a $BMDL_{10}$ of 36 mg/kg bw/d for increased relative kidney weight from a 90-day rat study (IRDC, 1984, unpublished report; the BMDL/BMDU ratio of 6 indicated some uncertainty in this value). This was consistent with the previously-identified NOAEL for the same effect, of 23 mg/kg bw/d from a different 90-day rat study (CXR, 2005, unpublished report); the $BMDL_{10}$ for this study was 68 mg/kg bw/d (BMDU/BMDL ratio 2.7).

EFSA (2020) considered neurotoxicity and immunotoxicity as end-points separate from repeated-dose toxicity. An old study investigating the effects of MCCP (C16, chlorination level unknown) on muscarinic receptors and sodium-dependent choline uptake in the nervous system of immature mice was cited (Eriksson and Nordberg, 1986). Seven days after a single oral dose (dose not clear to the CONTAM panel) to 10-day-old mice, there were no changes between treated and control mice, and the panel concluded that MCCPs was not neurotoxic in this test. No studies that investigated the immunotoxicity of MCCPs were identified.

Key data for consideration of repeated-dose toxicity classification

The available repeated-dose toxicity studies on MCCPS comprise six in rats, one in mice (to investigate liver effects) and one in dogs. The products tested had chlorination levels of 40% or 52%. There are no carcinogenicity studies to inform on the non-neoplastic adverse effects of MCCPs after chronic exposure, nor are there human data to reliably inform on this end-point. The observed effects in these studies at doses relevant for classification for STOT RE are summarised in the table below.

Table 1. Repeated-dose toxicity studies on MCCP C_{14-17} in rats, mice and dogs (all oral administration)

Study	CLP guidance value for classification	Effects below guidance value
Rat, 14 days, 52% chlorination (IRDC, 1981)	Cat 1 = 30 Cat 2 = 300	Category 1 No effects (lowest dose was 17.3 mg/kg bw/d) Category 2 Statistically significantly increased liver weight (19%) in females at 180 mg/kg bw/d (NOAEL 58 mg/kg bw/d)
Rat, 14 days, 40% chlorination (Wyatt *et al.*, 1993)	Cat 1 = 30 Cat 2 = 300	Category 1 No effects (lowest tested dose was 10 mg/kg bw/d) Category 2 Statistically significant increase (18/19% M/F) in absolute liver weight at 100 mg/kg bw/d but irregular dose response (NOAEL 50 mg/kg bw/d)
Rat, 90 days, 52% chlorination (CXR, 2005)	Cat 1 = 10 Cat 2 = 100	Category 1 No effects (lowest dose was 2.4/2.5 mg/kg bw/d) Category 2 Changes in thyroid hormones from 23/24.6 mg/kg bw/d (NOEL 9.3/9.7 mg/kg bw/d in M/F)
Rat, 90 days, 52% chlorination (Poon *et al.*, 1995)	Cat 1 = 10 Cat 2 = 100	EFSA was not able to interpret the histopathological findings and did not assign a NOAEL
Rat, 90 days, 52% chlorination (IRDC, 1984)	Cat 1 = 10 Cat 2 = 100	Category 1 'Chronic nephritis' in 3/15 males at 10 mg/kg bw/d Category 2 'Chronic nephritis' at 100 mg/kg bw/d, compared with 1/15 control males Increase in liver (by 28%) and kidney (by 11%) weights from 100 mg/kg bw/d (NOAEL 10 mg/kg bw/d)
Rat, 90 days, 52% chlorination + 0.2% epoxidized vegetable oil (Birtley *et al.*, 1980)	Cat 1 = 10 Cat 2 = 100	Category 1 Lowest dose was 33/32 mg/kg bw/d in M/F Category 2 Increase in relative liver weight (by 11%) in females at 32 mg/kg bw/d, with proliferation of smooth endoplasmic reticulum
Mouse, 14 days, 40% chlorination (Wyatt *et al.*, 1993)	Cat 1 = 30 Cat 2 = 300	Category 1 No effects (lowest dose was 10 mg/kg bw/d) Category 2 No effects (NOAEL was 250 mg/kg bw/d)
Dog, 90 days, 52% chlorination + 0.2% epoxidized vegetable oil (Birtley *et al.*, 1980)	Cat 1 = 10 Cat 2 = 100	Category 1 No effects (lowest dose was 10 mg/kg bw/d) Category 2 Increase in smooth endoplasmic reticulum of hepatocytes in males at 30 and 100 mg/kg bw/d (NOEL 10 mg/kg bw/d)

No effects were observed at doses relevant for classification in STOT RE category 1.

At doses relevant for classification in STOT RE category 2, some effects occurred in the main target organs: liver, thyroid and kidney. The liver effects at relevant doses comprised increases in organ weight and increases in smooth endoplasmic reticulum that EFSA and others concluded to be an adaptive physiological response. As such, they do not meet the criteria for being severe or significant toxicity and do not warrant classification. Similarly, the only finding relevant to the thyroid at a dose below the guidance cut-off value for category 2 was a change in some thyroid hormone levels, which EFSA concluded to be inconsistent. In the absence of associated pathology to indicate thyroid toxicity, these do not support classification for repeated-dose toxicity.

In the kidney, 'chronic nephritis' was noted at 10 and 100 mg/kg bw/d in one study (in 3/15 and 4/15 males respectively, compared with 1/15 control males). HSE (2008) reported that the 'chronic nephritis' was mild in the high-dose group (625 mg/kg bw/d) and trace at 10 and 100 mg/kg bw/d. Given the low incidence at these doses and mildness of the effect, HSE concluded that this finding was only toxicologically relevant at 625 mg/kg bw/d. Increased (by 11%) kidney weight was recorded at 100 mg/kg bw/d in the same study. In accordance with the CLP criteria, changes in organ weight with no evidence of organ dysfunction do not justify classification.

The use of BMD by EFSA (2020) leads to a refined, more scientifically robust risk assessment but does not impact hazard identification.

Classification opinion of CRD

Based on several repeated-dose toxicity studies in which MCCP products (40% or 52% chlorination) were administered orally to rats, mice and dogs for 14 or 90 days, we conclude that MCCPs do not meet the criteria for classification for as STOT RE.

Classification opinion of registrant

The REACH registrants concluded that MCCPs are not classified for repeated specific target-organ toxicity (STOT RE) because the observed kidney effects in the 90-day oral studies in rats occurred at doses higher than 100 mg/kg bw/d.

3 Mutagenicity

Short summary of toxicological information

Previous assessments have concluded that MCCPs are not mutagenic (WHO, 1996; CEPA, 2008; HSE, 2008; SCHER, 2008; COT, 2009, US EPA, 2015).

The EFSA CONTAM panel (2020) referred to the same information as previous reviews and the REACH registrants. The four *in vitro* mutagenicity tests in bacterial cells (Ames reverse mutation) each used MCCPs with different levels of chlorination: 40%, 42%, 45%, 52%, all of which were negative. A product with 52% chlorination level was tested in an *in vivo* bone marrow chromosomal aberration test, whilst two products (42% and 45% chlorination) were assessed in *in vivo* micronucleus tests, all of which were negative.

Key data for consideration of mutagenicity classification

No new data on the potential of MCCPs to induce mutations are available in the EFSA review or published literature.

Classification opinion of CRD

MCCPs do not meet the criteria for classification for mutagenicity.

Classification opinion of registrant

The REACH registration dossier refers to tests on *in vitro* bacterial mutation and *in vivo* cytogenicity (a bone marrow chromosome aberration test and two micronucleus tests). There are no tests on gene mutation in mammalian cells (either *in vitro* or *in vivo*), but the result of an *in vitro* mammalian cell mutation test is read across from SCCPs.

The REACH registrants concluded that MCCPs do not meet the criteria for classification for mutagenicity.

4 Carcinogenicity

Short summary of toxicological information

4.3. Human data

No human data on the carcinogenic potential of MCCPs are available.

4.4. Animal data

The carcinogenic potential of MCCPs has not been investigated in laboratory animals. SCCPs have a harmonised classification for carcinogenicity in Category 2 because they induce kidney tumours of uncertain relevance to humans (i.e., relevance could not be excluded; the modes-of-action of liver and thyroid tumours were concluded by the TC C&L not to be relevant to humans). The kidney is a target organ of MCCPs in repeated-dose toxicity studies so it is feasible that they could also induce kidney tumours. The one LCCP investigated in experimental animals was carcinogenic (malignant lymphoma in male mice, hepatocellular carcinomas in female mice), but only at very high exposure levels (5000 mg/kg bw/d). Because the chlorinated paraffins do not appear to have mutagenic potential, this carcinogenic activity is likely to be the result of a non-genotoxic mode of action and it can be assumed that the carcinogenicity will have a threshold exposure level. This was also the conclusion presented by EFSA (2020).

HSE (2008) cited investigations into the mode of action underlying the formation of kidney tumours following SCCP exposure, to inform on hazard identification for MCCPs. Some of these investigations were conducted after the EU harmonised classification for carcinogenicity was originally adopted, and strengthened but did not fully elucidate the mode of action to be binding of SCCPs to the male rat-specific protein, α2-urinary globulin. Remaining uncertainties about this mode of action led to referral of the issue to the EC Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity in 2004. Owing to some data gaps in the evidence, the Specialised Experts recommended that the classification in Category 2 (translated to CLP) for SCCPs be retained. However, the Specialised Experts agreed that a read-across to MCCPs was not justified for carcinogenicity, and hence MCCPs should not be classified for carcinogenicity.

EFSA (2020) considered that liver tumours induced by high doses of SCCPs were not relevant to humans, whereas the human relevance of kidney tumours in male rats and thyroid tumours in female rats could not be excluded. EFSA made no comment on the carcinogenic potential of MCCPs and used values from the 90-day rat studies to derive health-based guidance values.

Key data for consideration of carcinogenicity classification

There are no human or animal data to inform on the carcinogenicity of MCCPs. MCCPs were not mutagenic in the available *in vitro* and *in vivo* genotoxicity studies.

Although SCCPs are classified for carcinogenicity Category 2 because of kidney tumour induction, it is not appropriate to classify MCCPs for carcinogenicity, considering the lack of tumour data in experimental animals, the toxicological differences between SCCPs and MCCPs and the heterogenous nature of the substances. Nevertheless, it is noted that MCCPs caused kidney toxicity in male and female rats at doses below which key events related to α2-urinary globulin mode of action were recorded; consequently, these effects are potentially relevant to humans.

Classification opinion of CRD

MCCPs do not meet the criteria for classification for carcinogenicity (no data available).

Classification opinion of registrant

The REACH registrants referred to studies on SCCPs and, noting the similar physico-chemical properties, considered that neither SCCPs nor MCCPs were carcinogenic to humans (i.e., they concluded that the tumours induced by SCCP were not relevant to humans and disregarded the harmonised classification for carcinogenicity).

5 Reproductive toxicity

short summary of toxicological information

4.5. Fertility

4.5.1. Human data

No data are available.

4.5.2. Animal data

Previous reviews refer to a one-generation study and a range-finding study prior to a two-generation reproduction study that was never conducted (HSE, 2008; WHO, 1999; COT, 2009; US EPA, 2015; SCHER, 2008). In both studies a 52% chlorination product was administered orally to rats.

In the two studies there was no impact upon sexual function or fertility at doses up to approximately 400 mg/kg bw/d in the dose-range-finding study and 100 mg/kg bw/d in the one-generation study; the latter followed the general principles of OECD test guideline 421 (reproduction / developmental toxicity screening test) but with larger group sizes and longer treatment duration before pairing and during lactation. In the first study, however, post-natal effects indicative of haemorrhaging were observed in pups before weaning from doses of 74 mg/kg bw/d, with all pups dying before weaning in the high-dose group. This is further discussed in the Section on *effects on or via lactation*.

EFSA reported the same studies but gave the highest dose in the dose-range-finding study to be 560 mg/kg bw/d. EFSA concluded that there were no effects on fertility at the highest doses tested in each study. BMD values for pup deaths and haematoma/haemorrhage are reported in *effects on or via lactation*.

4.6. Developmental toxicity

4.6.1. Human data

No data are available.

4.6.2. Animal data

Two standard oral developmental toxicity studies on MCCP (52% chlorination) are available and have previously been reviewed, one in rats and one in rabbits (HSE, 2008; WHO, 1999; COT, 2009; US EPA, 2015; SCHER, 2008). In these studies no developmental toxicity was observed at doses up to 5000 mg/kg bw/d in rats and 100 mg/kg bw/d in rabbits (but it was noted that this dose was not maternally toxic, and hence the highest dose could have been increased).

EFSA (2020) reviewed the same two studies and reached the same conclusion. Because it did not identify any adverse developmental effects, EFSA did not perform BMD analysis on this data.

Classification opinion of CRD

4.7. Fertility

The effects of MCCPs on sexual function and fertility has not been investigated in a two-generation reproduction study or extended one-generation reproduction study. A study that was nominally a reproduction / developmental toxicity screening study was extended in terms of animal numbers and exposure duration, although from the available information the extent of investigations isn't clear. Nevertheless, there were no indications of adverse effects on reproduction in this or a dose-range-finding study.

MCCPs do not meet the criteria for classification for effects on sexual function or fertility.

4.8. Developmental toxicity

MCCP products have been tested in two standard developmental toxicity studies, one in rats up to the very high dose of 5000 mg/kg bw/d and one in rabbits up to a dose that was, arguably, not high enough, since there was no evidence of maternal toxicity. There was no indication of developmental toxicity in either of these studies; hence, MCCPs do not meet the criteria for classification for developmental toxicity.

Classification opinion of registrant

4.9. Fertility

The REACH registration dossier contains information on the dose-range finding study for a two-generation study and a one-generation study (the same data as discussed above). There would seem to be a data-gap for an extended one-generation reproductive toxicity study. The registrants stated that, since MCCPs do not elicit adverse effects on fertility or development in the available studies, they would be unlikely to commission a multi-generation study and did not self-classify for this end-point.

4.10. Developmental toxicity

The REACH registration dossier contains information on the two developmental toxicity studies, one in rats and one in rabbits. Therefore, the information requirements are met. The registrants concluded that self-classification for developmental toxicity was not required.

Effects on or via lactation

CLP Annex VI contains an entry for alkanes, C_{14-17}, chloro (chlorinated paraffins, C_{14-17}), CAS number 85535-85-9 that includes Lact. H362: May cause harm to breast-fed children. No new information is available and EFSA (2020) reaffirmed the assumption that MCCPs perturb the clotting system in lactating pups of exposed mothers, leading to internal haemorrhaging and deaths. The likely explanation is that the foetus *in utero* receives enough vitamin K via the placenta, but after birth it becomes deficient in vitamin K and related clotting factors when reliant on these via the mother's milk. Exposure to pups of MCCPs via the milk might also contribute to the reduction of vitamin K. Haemorrhaging appears to be a consequence of the vitamin K deficiency. This effect is potentially relevant to humans.

EFSA applied BMD analysis to estimate $BMDL_5$ values of 48.5 (BMDU/BMDL ratio of 1.3) for the combined incidence of subcutaneous haematoma/haemorrhage in rats and 53 (BMDU/BMDL ratio of 1.8) for rat pup deaths.

EFSA (2020) summarised the available information on levels of CPs in human samples collected in Europe, Asia (mainly China) and Australia. MCCPs have been detected in human milk samples, with levels generally being lower in the few European studies than in samples collected in Asia, and lower than the detected levels of SCCPs; a recent study of sample in China has indicated that congeners with high carbon and chlorine atoms tend to accumulate in breast milk (Xu, 2021). A comparison of volumes of distribution and half-lives of the CPs, from extrapolation of rat PBPK (physiologically-based pharmacokinetic modelling) to a human PBPK model, predicted that the CPs accumulate in the liver and fat and that SCCPs have a substantially longer half-life than MCCPs and LCCPs. The body burdens of MCCPs and LCCPs were predicted to be 5-10 times lower than those of SCCPs because of higher biliary elimination of the longer-chain CPs (Dong *et al.*, 2020).

Mother-foetus distribution of SCCPs and MCCPs has been investigated in a recent study that measured levels in matched maternal serum, umbilical cord serum and placenta (Aamir *et al.*, 2019). Whereas foetal exposure to SCCPs was positively correlated with that in the umbilical cord, indicating foetal exposure, this was not the case for MCCPs and the indication was that MCCPs were retained in placenta tissue rather than being transported to the foetus. This would support there not being a direct effect of MCCPs on the foetus via *in utero* exposure.

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