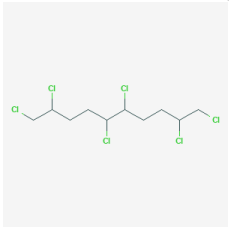
Draft EHS Summary
Short/Med/Long Chain Chlorinated Chloroparaffins
MA TURA Science Advisory Board Meeting – April 2024

CAS # 85535-84-8 (in MA FR Law)



Short chain paraffins are C10-C13
Medium-chain are C14-C17
Long-chain are C18-C20
40-70% chlorine content by weight (EPA 2015)

Chloroparaffins, short, medium and long chain

Chlorinated paraffins are complex mixtures that are expected to differ with respect to their chemical content between "batches" or "runs" and between manufacturers. Chlorinated paraffins may differ in the number of carbons in the chain, chlorine content, and trace contaminants. (National Academies Press 2000)

	C10-C13	C14-C17	C18-C20
Molecular Weight, g/mol (range)	~320-450	~330-600	~350-875
Molecular Formula	$C_{10}H_{16}Cl_6$ example	$C_{15}H_{26}Cl_6$ example	$C_{18}H_{27}Cl_3$ example

PHYSICAL CHARACTERISTICS	
Primary Use	Commonly used as flame retardants and plasticizers in plastics, and lubricants and coolants in metal forming.
Physical state, odor at room temperature & pressure	Amber liquid to waxy solid, faint odor
Melting point; Boiling point	<25C MP, >200C BP depending on the chlorine content and chain length (ECHA 2008, EPA 2015)
Solubility	Practically insoluble in water, 0.15-0.47 mg/L at 20C for SCCP, value for a 59% chlorine content product (ECHA 2008), estimated <0.03 and <0.005 mg/L for MCCP and LCCP (EPA 2015)
SAFETY/PHYSICAL HAZARDS	
Vapor Pressure	Very low, 0.021 Pa at 40C for SCCP for a 50% chlorine content product (ECHA 2008), <0.036 Pa for MCCP and <2.7E-4 Pa for LCCP (EPA 2015)
Other physical hazards associated with process: Heat, gases under pressure, noise, vibration, ergonomic hazard	When heated to decomposition, SCCP emit toxic fumes of hydrochloric acid and other chlorinated compounds. (NTP 2021)
HEALTH HAZARDS	
Acute Toxicity	
Oral LD_{50}	Low acute toxicity via the oral route.
Chronic or Sub-chronic Toxicity	
IARC rating	2B for average carbon chain length of 12 and 60% Cl
Carcinogenicity	*SCCP* There is sufficient evidence for the carcinogenicity of a commercial chlorinated paraffin product of average carbon-chain length C12 and average degree of chlorination 60% in experimental animals. No data were available from studies in humans on the carcinogenicity of chlorinated paraffins. Overall evaluation: **Chlorinated paraffins of average carbon-chain length C12 and average degree of chlorination approximately 60% are possibly carcinogenic to humans (Group 2B)**. (IARC 1990) Chlorinated Paraffins (C12, 60%): reasonably anticipated to be human carcinogens. (NTP 2021)

Oral exposure to chlorinated paraffins (C12, 60% chlorine) caused tumors at several different tissue sites in mice and rats. Administration of chlorinated paraffins by stomach tube increased the combined incidence of benign and malignant liver tumors (hepatocellular adenoma and carcinoma) in mice of both sexes, the thyroid gland (follicular-cell adenoma and carcinoma) in female mice and rats, and the kidney (tubular-cell adenoma and carcinoma) in male rats. It also caused benign liver tumors (hepatocellular adenoma) in rats of both sexes and possibly mononuclear-cell leukemia in male rats. (NTP 2021)

MCCP

No carcinogenicity studies have been conducted. MCCPs are 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 tumors 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 are not classified for this end point. (UK 2019)

LCCP+

2-year gavage studies showed no evidence of carcinogenicity of chlorinated paraffins (C23 43% chlorine) for male F344/N rats given 1,875 or 3,750 mg/kg per day. There was equivocal evidence of carcinogenicity of chlorinated paraffins (C23 43% chlorine) for female F344/N rats as shown by an increased incidence of adrenal gland medullary pheochromocytomas. There was clear evidence of carcinogenicity of chlorinated paraffins (C23, 43% chlorine) for male B6C3Fl mice as shown by an increase in the incidence of malignant lymphomas. There was equivocal evidence of carcinogenicity of chlorinated paraffins (C23, 43% chlorine) for female B6C3Ft mice as shown by a marginal increase in the incidence of hepatocellular neoplasms. (NTP 1986)

With repeated dose, non-neoplastic, lymphohistiocytic inflammations in liver and in pancreatic and mesenteric lymph nodes were seen at the lowest dose tested, namely 100 mg/kg bw/day (female rats). According to EFSA (2020), there is evidence of carcinogenicity of LCCPs at very high doses (2500 and 5000 mg/kg bw/day) that exceed the limit dose. EFSA concluded that, since LCCPs do not appear to have mutagenic potential, 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. The EU REACH Registrants do not classify LCCPs for carcinogenicity, but note that IARC assigned LCCPs as Class 3 based on malignant lymphomas reported in male mice at very high (5000 mg/kg/day) doses. Furthermore, the registration

<table>
<tr><td></td><td>dossier assigns a Carc. 2 classification H351 (Suspected of causing cancer) under classification and labelling. (UK 2022)</td></tr>
<tr><td>Reproductive Effects</td><td>Exposure to MCCPs in the milk may also further reduce their vitamin K levels of neonates. This in turn leads to a severe vitamin K deficiency in the neonates and consequently to hemorrhaging. This is the basis for the harmonized classification for effects via lactation (H362 – May cause harm to breast-fed children) (UK 2019)</td></tr>
<tr><td colspan="2">ENVIRONMENTAL & ECO-SYSTEM HAZARDS</td></tr>
<tr><td>Persistence</td><td>SCCP
Chlorinated paraffins (SCCP) are lipophilic and persistent in the environment. The very low vapor pressure indicates that these compounds will not volatilize easily. (NTP 2021).

The results of a biodegradation simulation study with both freshwater and marine sediment are shown below. (ECHA 2008)
<table>
<tr><th></th><th>Half-life (days) in freshwater sediment aerobic</th><th>Half-life (days) in marine sediment aerobic</th></tr>
<tr><td>C10, 65% wt. Cl</td><td>1340</td><td>335</td></tr>
<tr><td>C13, 65% wt. Cl</td><td>1790</td><td>680</td></tr>
<tr><td>Mean (Assume for C10-C13, 65% wt. Cl)</td><td>1630</td><td>450</td></tr>
</table>
MCCP
An OECD TG 308 study performed on C14 chlorinated n-alkane, 50% Cl. wt. indicates that the total water-sediment DT50 values for the C14Cl3-14 congener groups of MCCP (equivalent to 35.32–72.98% Cl wt.) are greater than 120 days at 12°C (under aerobic conditions). The fact that there was no significant measurable degradation over 120 days suggests that it is unlikely that ≥50% mineralisation or primary degradation would occur over a subsequent 60-day period. Therefore, based on this study, it can be reasonably assumed that the C14Cl3-14 groups of congeners are very persistent in sediment (degradation half-lives >180 days). (ECHA 2021)

MCCP and LCCP
EPA/OPPT's conclusions regarding environmental persistence of MCCPs and LCCPs are consistent with those provided by Canada and the EU. Canada's assessment states: "Information on physical properties of MCCPs, and especially LCCPs, is limited. Values used in this assessment are based on extrapolations mainly from SCCPs or QSARs. The analysis of SCCPs and MCCPs in sediment cores and associated calculations provide strong evidence for the persistence of these substances in the environment. Even though there are no data for persistence of LCCPs in sediment, based on biodegradation data</td></tr>
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	which indicate increasing stability with increasing carbon chain length, it is reasonable to **conclude that LCCPs are persistent in sediment**." The EU assessment on MCCPs states: "No standard ready or inherent biodegradation tests results are available for medium chain chlorinated paraffins. From the available information, **medium-chain chlorinated paraffins can be considered to be not biodegradable** in such test systems and so a biodegradation rate MCCPs of 0 day-1 is used in the risk assessment. There is evidence that some microorganisms may be capable of degrading MCCPs in the environment in acclimated or co-metabolic systems. The potential for biodegradation appears to increase with decreasing chlorine content. However, it is not possible from the available data to derive rate constants for biodegradation in soil, surface water and sediment systems. As a worst case approach, no biodegradation will be assumed in these media in the PEC calculations. Hydrolysis is not expected to be a significant degradation process for medium-chain chlorinated paraffins in the environment. An atmospheric half-life of 1-2 days is estimated for reaction with hydroxyl radicals. A value for the rate constant for the reaction (kOH) of 8 x 10-12 cm3 molecule-1 s-1 is used for the environmental modelling in the risk assessment." UK assessment on LCCPs concluded: "Based on the laboratory studies and other data available, **LCCPs are unlikely to be readily or inherently biodegradable**. Although there is some evidence that they may biodegrade in the environment, it is thought likely that this process will be sufficiently slow that LCCPs meet the P or vP (very persistent) criteria." EPA/OPPT generally concurs with these characterizations. **In the absence of information on specific congener groups and data for MCCP or LCCP products, EPA/OPPT concludes that at least some congener groups present in both MCCP and LCCP products are persistent to very persistent**; with estimated half-lives in air exceeding two days and estimated half-lives in water, sediment, and soil exceeding two months (60 days) (EPA 2015).
Bioaccumulation	*SCCP* Chlorinated paraffins potentially may bioaccumulate in some animal species; however, they do not biomagnify in the food chain. (NTP 2021) Short-chain chlorinated paraffins have a bioconcentration factor (BCF) of 7,273 l/kg for (freshwater) fish based on parent compound analysis and 7,816 l/kg based on 14C measurements (and so may represent accumulation of metabolites as well as short-chain chlorinated paraffins) (ECHA 2008) *MCCP* Based on the weight of evidence of the data available, it can be concluded that the C14Cl3–11 congener groups of MCCP (equivalent to 35.3–67.6% Cl wt.) have B/vB properties, C15Cl3–9 congener groups of MCCP (equivalent to 33.8–61.15% Cl wt.) have B and/or vB properties, C16Cl2–9 congener groups

	of MCCP (equivalent to 24.1–59.55% Cl wt.) have B and/or vB properties and C17Cl5–9 congener groups of MCCP (equivalent to 43–58% Cl wt.) have B properties in accordance with REACH Annex XIII. (ECHA 2021) *MCCP and LCCP* EPA/OPPT concludes that the bioconcentration varies with the chain lengths and degree of chlorination within the CP mixture and species evaluated. Shorter and less chlorinated chemicals are readily taken up by organisms but also may be excreted or degraded after absorption. Longer and more highly chlorinated chemicals are typically not absorbed across cellular membranes and are not accumulated in tissues. Some MCCP chemicals with intermediate chain length and chlorination may be absorbed and retained. **The available evidence for MCCP and LCCP congener groups with intermediate chain lengths and chlorination suggests that some may have bioconcentration factors (BCFs) or bioaccumulation factors (BAFs) greater than 1000 or 50000**. This suggests that some congener groups in MCCP and LCCP products may be bioaccumulative or very bioaccumulative. The Canadian assessment (2008) on MCCPs and LCCPs states: "On the basis of the available information, and in particular the field BAF estimates, it is concluded that **MCCPs are bioaccumulative substances**…" "On the basis of the available information, and in particular the BAF model and empirical BMF estimates, it is concluded that C18–20 liquid LCCPs are bioaccumulative substances…" and "…While there is a lack of empirical bioaccumulation data for LCCPs, the modelling results provided by the Modified Gobas BAF Model - which suggest that of all the LCCPs congeners only liquid C18-20 LCCPs have significant bioaccumulation potential -- are considered credible." The UK assessment (2009) on LCCPs states: "The available data for LCCPs do show that uptake into fish from food occurs in the laboratory, and that this uptake can be significant in some cases. The degree of uptake appears to be highest for the C18–20 liquid chlorinated paraffins, but uptake of C>20 liquid chlorinated paraffins has also been demonstrated. The uptake of the highly chlorinated C>20 solid chlorinated paraffins from food appears to be minimal." EPA/OPPT generally concurs with these characterizations**. In the absence of information on specific congener groups and data for MCCP or LCCP products, EPA/OPPT concludes that at least some congener groups present in both MCCP and LCCP products are bioaccumulative to very bioaccumulative based on multiple lines of evidence** including: Log KOW values, modeled BCFs, laboratory-measured BCFs, field-measured BAFs, field-measured biomagnification factors (BMFs), laboratory-measured biota-sediment

	accumulation factors (BSAFs) and the presence of MCCPs and LCCPs in human and wildlife biota. (EPA 2015) The relevance of aquatic bioaccumulation appears to decline with increasing CP molecular weight, with accumulation in terrestrial predators becoming more important. LCCPs with chain lengths between C18 and C25 and chlorination levels in the range 40 to 50% appear to have the greatest capacity to bioaccumulate. The available evidence provides a suitable, though incomplete, indication that a high level of bioaccumulation cannot be ruled out for some constituents of LCCPs. However, a definitive B/vB conclusion is not possible given the limitations of the data available. The EU REACH registration concludes that LCCPs are not B/vB (UK 2022).
Ecological Toxicity	
Aquatic Toxicity: LC_{50}, EC_{50}, ErC_{50}, NOAEC/NOEC	*SCCP* The lowest NOEC was from a 21-day multi-generation study on Daphnia magna using a 58% chlorinated short chain paraffin (C10-12). The study was considered valid. The **21-day NOEC was 0.005 mg/l**. In addition to the freshwater toxicity data, several marine/estuarine data are also available. There are NOECs available for fish (sheepshead minnow Cyprinodon variegatus), invertebrate (mysid shrimp Mysidopsis bahia) and algae. The lowest **NOEC was found for Mysidopsis bahia at 0.007 mg/l**. In addition to this there are indications of effects on growth (as assessed by increase in shell length and tissue weight) in mussels (Mytilus edulis) at 0.0093 mg/l. Thus the marine data is similar to the freshwater data in that invertebrates appear to be the most sensitive species. (ECHA 2008) *SCCP and MCCP* Generally, SCCPs have a high ecotoxicity and bioaccumulation potential in aquatic environment but lower toxicity in soils where ecotoxicity values are hundreds to thousands mg/kg of dry soil. MCCPs have lower acute toxic potential thanks to their higher molecular size but even higher bioaccumulation rate than SCCPs. (Kobeticova 2018) *MCCP* 48h EC50 results from acute Daphnia magna studies fall in the range < 6.5 – 2200 µg/L. The most reliable result is 48h EC50 5.9 µg/L for the C14-17, 52% Cl wt. Substance. For chronic toxicity of MCCP to Daphnia magna, 21d NOEC (reproduction) values range from ~ 4 - 15.6 µg/L. The most reliable result is 21d NOEC 8.7 µg/L for the C14-17, 52% Cl wt. (ECHA 2021) *MCCP and LCCP* Using estimated environmental concentrations, MCCP and LCCP may present an unreasonable risk following acute and chronic exposures to aquatic

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<tr><td></td><td>organisms. (EPA 2015). See Table 4 (from EPA 2015) at the end of this document.

See also Table 26/27 (page 126) at UK 2022 reference for Fish Toxicity table and Table 28/29 (page 131) for Invertebrates Toxicity table.</td></tr>
<tr><td>Log Kow</td><td>Depends on chain length and chlorine content (ECHA 2008, EPA 2015, UN 2016)
<table>
<tr><td></td><td>C10-C13</td><td>C14-C17</td><td>C18-C20</td></tr>
<tr><td>Log Kow range</td><td>4.48-7.38</td><td>5.56-8.38</td><td>7.5-11.5</td></tr>
<tr><td>Log Kow typical</td><td>6</td><td>7</td><td>8</td></tr>
</table></td></tr>
<tr><td>Transport Issues</td><td>Chlorinated paraffins (SCCP) have low water solubility and a high log Kow. Therefore, if released to water, they will not volatilize from water or remain in solution, but will adsorb to sediment or suspended solid material. If released to soil, chlorinated paraffins are bound to the soil. (NTP 2021)</td></tr>
<tr><td colspan="2">Special Reports</td></tr>
<tr><td>EU</td><td>Alkanes, C10-13, chloro are PBT, vPvB and SVCH.

MCCPs are PBT, vPvB and SVHC. This conclusion is assumed to apply to all MCCP product types because they will contain shared constituents with PBT/vPvB properties above 0.1% w/w. Longer chain length constituents appear to be significantly bioaccumulative in invertebrates even if bioaccumulation in fish is reduced. It is possible that lower chlorine content MCCP products (≤45% Cl wt.) might not be persistent within the meaning of the Annex XIII criteria, but definitive data to confirm this are not available. In addition, the registered substance contains unintentional C10-13 constituents that are structural analogues of SCCPs in the range 0.1-1% w/w. SCCPs is on the ECHA Candidate List of Substances of Very High Concern due to its PBT properties, and is also listed as a persistent organic pollutant under the United Nations Stockholm Convention on Persistent Organic Pollutants. The C10-13 constituents of MCCPs are likely to have the same PBT properties as SCCPs. As they are present above 0.1% w/w, MCCPs is therefore also a “PBT-containing substance”. (UK Environment Agency 2019)

Medium-chain chlorinated paraffins have been recommended by the Persistent Organic Pollutant Review Committee for inclusion in the Stockholm Convention list so countries can eliminate or restrict their production and use, and manage their wastes. (Stockholm Convention 2023)</td></tr>
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Table 4: Summary of Aquatic, Sediment and Terrestrial Ecotoxicity Data for MCCPs and LCCPs

Test Substance	Test Organism (Species)	Test Guideline; Study type	End-point	Value[a]	Reference
Aquatic Invertebrates					
Cereclor S-52 (52 wt% Cl, C_{14-17})	Water flea (*Daphnia magna*)	OECD 202, 1984; Acute immobilization test	EC_{50}	0.0059	CPA (1996)
Cereclor S-52 (52 wt% Cl, C_{14-17})	Water flea (*Daphnia magna*)	OECD 202- Part II, 1984; Reproduction test	NOEC LOEC MATC	0.01 0.018 0.013	Thompson, Williams et al. (1997)
Sediment-Dwelling Invertebrates					
Cereclor S-52 (52 wt% Cl, C_{14-17})	Amphipod (*Hyalella azteca*)	OECD 218- Draft, 2001; 28-day prolonged sediment toxicity study	NOEC LOEC MATC	130 270 187	Thompson et al. (2002)
Terrestrial Invertebrates					
Cereclor S-52 (52 wt% Cl, C_{14-17})	Earthworm (*Eisenia fetida*)	OECD Guideline-Draft, 2000; 28-day reproductive toxicity test	NOEC LOEC MATC	79 280 149	Thompson et al. (2001d)
Terrestrial Vertebrates					
Commercial CP (58 wt% Cl, C_{10-12})	Mallard duck (*Anas platyrhynchos*)	EPA 560/6-82-002; 22-week reproduction test	NOEC LOEC	168 1000	ECB (2000)

[a]Units are mg/L for aquatic invertebrates, mg/kg dry weight (dw) sediment for sediment-dwelling invertebrates; mg/kg dw soil for earthworm study; and mg/kg diet for the duck study.

(EPA 2015)

References:

ECHA 2008: Support Document for Identification of Alkanes, c10-13, Chloro as a Substance of Very High Concern, https://echa.europa.eu/documents/10162/2edcfedb-ec53-4754-8598-e787a8ff7a58

ECHA 2021: Support Document for Identification of Medium-chain Chlorinated Paraffins as Substances of Very High Concern, https://echa.europa.eu/documents/10162/98611952-49d5-b0be-d4b9-3df6579315c9

EPA 2015: TSCA New Chemicals Review Program Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins and Long-Chain Chlorinated Paraffins, 2015

National Academies Press 2000: Toxicological Risks of Selected Flame-Retardant Chemicals.

IARC1990: Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972/PRESENT. (Multivolume work). Available at: https://monographs.iarc.fr/ENG/Classification/index.php, p. 48 69 (1990)

Kobetičová 2018: Ecotoxicity assessment of short- and medium-chain chlorinated paraffins used in polyvinyl-chloride products for construction industry. Sci Total Environ. 2018 Nov 1;640-641:523-528. doi: 10.1016/j.scitotenv.2018.05.300. Epub 2018 Jun 1. PMID: 29864666.

National Toxicology Program, Report on Carcinogens, Fifteenth Edition (2021), Chlorinated Paraffins (c12, 60% chlorine), https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/chlorinatedparaffins.pdf (First listed in the Fifth Annual Report on Carcinogens, 1989)

National Toxicology Program (NTP) 1986: Technical Report 305, Toxicology and Carcinogenesis Studies of Chlorinated Paraffins (C23, 43% CHLORINE) in F344/N Rats and B6C3Ft Mice

United Nations 2016: Stockholm Convention Report of the Persistent Organic Pollutants Review Committee on the work of its twelfth meeting. https://guides.turi.org/ld.php?content_id=74235533

United Nations 2023: Stockholm Convention Nineteenth Meeting of the Persistent Organic Pollutants Review Committee.https://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC19/Overview/tabid/9548/Default.aspx

United Kingdom (UK) Environment Agency 2019: Substance Evaluation Conclusion as Required by REACH Article 48 and Evaluation Report for Medium-chain Chlorinated Paraffins.

United Kingdom (UK) Environment Agency 2022: Persistent, Bioaccumulative and Toxic (PBT) properties of Long Chain Chlorinated Paraffins (LCCPs)