

**Analysis of the most appropriate risk management option (RMOA)**

**Substance Name: Alkanes, C14-17, chloro**

**EC Number:** **287-477-0**

**CAS Number:** **85535-85-9**

**Authority: United Kingdom**

**Date: November 2019**

**Cover Note**

*MCCPs has been evaluated by the United Kingdom under the Community Rolling Action Plan (CoRAP). The UK has concluded that MCCPs is PBT/vPvB. The purpose of this RMO analysis is to summarise the available evidence relevant to implementing any additional regulatory actions that might be required to minimise MCCPs releases to the environment, and to discuss the form that further regulatory actions could take.*

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# identity of the substance

## Other identifiers of the substance

**Table 1:** **Other Substance identifiers**

|  |  |
| --- | --- |
| **EC name (public):** | Medium-chain chlorinated paraffins (MCCPs) |
| **IUPAC name (public):** | Alkanes, C14-17, chloro |
| **Index number in Annex VI of the CLP Regulation:** | 602-095-00-X |
| **Molecular formula:** | CxH(2x - y+2)Cly  where x = 14 - 17 and y = 1 - 17 |
| **Molecular weight or molecular weight range:** | 300 - 600 g/mole (approximately) |
| **Synonyms:** | The abbreviation MCCPs will be used for the substance throughout this dossier |

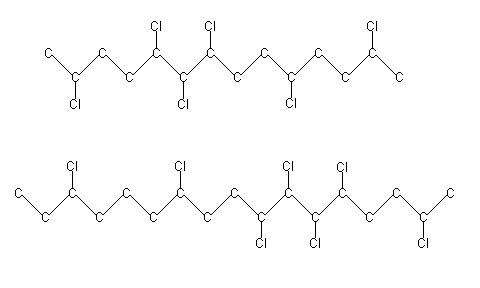
**Type of substance**  Mono-constituent  Multi-constituent  UVCB

**Structural formula**

Example structures (hydrogen atoms removed for simplicity) include:

C14H24Cl6

C17H29Cl7



**Other relevant information about substance composition**

**UVCB substance**

MCCPs is a substance of “unknown or variable composition, complex reaction products or biological materials” (hereinafter ‘UVCB’). It contains linear chloroalkanes predominantly in the range of C14-17 with chlorination levels in the range of 40-70% by weight. MCCPs therefore contains hundreds of constituents. The chain length distribution reflects the hydrocarbon feedstock that is used in its manufacture. In contrast, chlorinated paraffins produced in China are differentiated based on their chlorine content (or viscosity) rather than by the carbon chain lengths of their constituent congeners.

Around forty CAS numbers have been used to describe the whole chlorinated paraffin family. Some of these are now historical, and others may be in use for the sole purpose of compliance with national or regional chemical inventories. It is possible that some may contain chlorinated alkanes in the C14 to C17 range, and these are presented in the following table (Table 2; this is not necessarily exhaustive).

**Table 2**

|  |  |  |
| --- | --- | --- |
| **OTHER CAS NUMBERS ASSOCIATED WITH MCCPs** | | |
| **Substance** | **CAS number** | **EC number** |
| Alkanes, chloro | 61788-76-9 | 263-004-3 |
| Alkanes, C6-18, chloro | 68920-70-7 | 272-924-4 |
| Alkanes, C10-14, chloro | 85681-73-8 | 288-211-6 |
| Alkanes, C10-21, chloro | 84082-38-2 | 281-985-6 |
| Alkanes, C10-26, chloro | 97659-46-6 | 307-451-5 |
| Alkanes, C10-32, chloro | 84776-06-7 | 283-930-1 |
| Alkanes, C12-14, chloro | 85536-22-7 | 287-504-6 |
| Alkanes, C14-16, chloro | 1372804-76-6 | - |
| [Alkanes, C16-27, chloro](https://echa.europa.eu/substance-information/-/substanceinfo/100.076.273) | 84776-07-8 | 283-931-7 |
| [Alkanes, C16-35, chloro](https://echa.europa.eu/substance-information/-/substanceinfo/100.077.422) | 85049-26-9 | 285-195-2 |
| Reaction mass of Alkanes, C14-17, chloro and Paraffin waxes and Hydrocarbon waxes, chloro | 915-934-2 | - |
| Paraffin oils and hydrocarbon oils, chloro | 85422-92-0 | 287-196-3 |
| Paraffins (petroleum), normal C>10, chloro | 97553-43-0 | 307-202-0 |
| Slackwax (petroleum), chloro | 2097144-44-8 | - |
| Tetradecane, chloro derivatives | 198840-65-2 | - |

No registrations have been made for any of the CAS numbers in Table 2.

**1.2 Similar substances/grouping possibilities**

Short-chain chlorinated paraffins (SCCPs; CAS no. 85535-84-8, EC number 287‑476-5, containing C10-13 carbon chain lengths) and long-chain chlorinated paraffins (LCCPs, containing C18-30 carbon chain lengths[[1]](#footnote-1)) are structural analogues registered under REACH. SCCPs is a Substance of Very High Concern (SVHC) on the REACH candidate list for authorisation; it is persistent, bioaccumulative and toxic (PBT). It is also a Persistent Organic Pollutant (POP) under the UN Stockholm Convention and the UNECE Convention on Long-Range Transboundary Air Pollution[[2]](#footnote-2). MCCPs contains C10-13 constituents that may be analogous to SCCPs, at levels typically <1% w/w (often much lower), although the identity and actual concentration of the individual constituents is not known.

The transition Annex XV dossier (HSE, 2008) indicated that LCCPs based on a C18‑20 carbon chain length may contain up to 20% C17 chlorinated paraffins. The implications of this for the hazardous properties of LCCPs have not yet been fully evaluated, but should be taken into account in any further risk management of this substance group. No additional controls have been proposed for LCCPs to date.

# OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table 3: Completed or ongoing processes**

|  |  |  |  |
| --- | --- | --- | --- |
| RMOA |  | | Risk Management Option Analysis (RMOA) other than this RMOA |
| REACH Processes | Evaluation | | Compliance check, Final decision |
| Testing proposal |
| CoRAP and Substance Evaluation |
| Authorisation | | Candidate List |
| Annex XIV |
| Restri-ction | | Annex XVII |
| Harmonised C&L |  | | Annex VI (CLP) (see section 3.1) |
| Processes under other EU legislation | |  | Plant Protection Products Regulation  Regulation (EC) No 1107/2009 |
|  | Biocidal Product Regulation  Regulation (EU) 528/2012 and amendments |
| Previous legislation | |  | Dangerous substances Directive  Directive 67/548/EEC (NONS) |
|  | Existing Substances Regulation  Regulation 793/93/EEC (RAR/RRS) |
| (UNEP) Stockholm convention (POPs Protocol) | |  | Assessment |
|  | In relevant Annex |
| Other processes/ EU legislation | |  | Other (provide further details below)  Annex II dossier submitted by Sweden under the RoHS Directive (2011/65/EU) |

The United Kingdom Competent Authority (UK CA) was the rapporteur for MCCPs under the Existing Substances Regulation (EC) No. 793/93 (ESR), producing two environmental risk assessments (EC, 2005; EC, 2007), and a transitional Annex XV dossier once the REACH Regulation was introduced (HSE, 2008). The Annex XV dossier included an analysis of risk management options for scenarios that had been identified as posing an environmental risk in the earlier assessments. In particular, a restriction on the marketing and use of MCCPs in leather fat liquors was agreed at the 15th Risk Reduction Strategy meeting, and this was communicated to ECHA in the dossier. Subsequently, further data were provided by Industry in compliance with Commission Regulation (EC) No. 466/2008, and these were evaluated and reported to ECHA by the UK CA (EA, 2010). That evaluation identified further data needs but, as Industry was performing additional biodegradation studies and the REACH registration deadline was imminent, it was decided to leave it to Registrants to take the conclusions of the various UK CA reports into account and propose further testing or risk management measures as necessary.

MCCPs was subsequently included in the first Community Rolling Action Plan under the REACH Regulation, so that the Registrants’ treatment of the previous conclusions could be assessed. The UK CA has now completed its Substance Evaluation, and has concluded that MCCPs has PBT (and probably vPvB) properties. REACH calls for minimisation of emissions and exposures of PBT substances as far as technically and practically possible (recital 70). The purpose of this Risk Management Options Analysis (RMOA) is, therefore, to review the available evidence to determine what additional regulatory actions, if any, are required to minimise releases of MCCPs to the environment and the form that these measures could take. Since the transition dossier did not identify a need for further action to address human health risks, the RMOA does not consider measures to protect human health.

# HAZARD INFORMATION (INCLUDING CLASSIFICATION)

## Classification

### Harmonised Classification in Annex VI of the CLP

**Table 4** details the current harmonised classification for this substance.

**Table 4: Harmonised classification**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Index No** | **International Chemical Identification** | **EC No** | **CAS No** | **Classification** | | **Spec. Conc. Limits, M-factors** | **Notes** |
| **Hazard Class and Category Code(s)** | **Hazard statement code(s)** |
| 602-095-00-X | Alkanes, C14-17, chloro | 287-477-0 | 85535-85-9 | Lact.  Aquatic Acute 1  Aquatic Chronic 1 | H362  H400  H410 |  |  |

No multiplication factors (M-factors) for mixtures are given in this harmonised classification as it was introduced before the CLP Regulation was adopted.

### Self-classification

The self-classification given in the latest Lead Registration dossier includes M‑factors for acute and chronic aquatic hazards of 100 and 10, respectively, based on toxicity to aquatic invertebrates.

The self-classifications for human health hazards are not considered in this evaluation.

### Proposal for Harmonised Classification in Annex VI of the CLP

There are no intentions or proposals in the Registry of current or submitted Harmonised Classification and Labelling Intention because the harmonised classification was introduced before the CLP Regulation was adopted. Mixtures containing low concentrations of MCCPs (<2.5% w/w) are not intentionally produced, and the UK CA considers it a low priority to update the harmonized classification to include M-factors given the conclusion on PBT properties.

### CLP Notification Status

**Table 5: CLP Notifications**

|  |  |
| --- | --- |
|  | **CLP Notifications[[3]](#footnote-3)** |
| Number of aggregated notifications | 11 |
| Total number of notifiers | 378 |

From the total of 378 notifiers, 342 notifiers self-classify MCCPs as both Aquatic Acute 1 and Aquatic Chronic 1. Ten self-classify the substance as Aquatic Acute 1 only and one self-classifies it as Aquatic Chronic 1 only (contradicting the harmonised classification).

## Additional hazard information

Based on new data submitted in response to the Substance Evaluation decision, the UK CA considers that MCCPs contain constituents that meet the Annex XIII PBT criteria, with some constituents vPvB.

These findings were examined by the PBT Expert Group at its 22nd meeting in September 2019, and there was general support for the PBT conclusion.

The registered substance also contains constituents in the C10-13 range that are structural analogues of alkanes, C10-13, chloro (SCCPs). These are unintentional constituents present at up to 1% w/w. They are likely to have the same properties as SCCPs, including PBT properties for the higher chlorinated constituents. MCCPs containing them above 0.1% w/w could therefore be considered as PBT.

# Information on (aggregated) Tonnage and uses[[4]](#footnote-4)

## Tonnage and registration status

**Table 6: Tonnage and registration status**

|  |  |
| --- | --- |
| **From ECHA dissemination site** | |
| Registrations | Full registration(s)  (Art. 10)  Intermediate registration(s)  (Art. 17 and/or 18) |
| Total tonnage band for substance (excluding volume registered under Art 17 or Art 18, or directly exported) | 10,000-100,000 tpa |

Most MCCPs used in the EU is manufactured within the EU with only a small proportion (<10%) imported from outside the bloc. Based on confidential information in the REACH registration dossiers, the tonnage of MCCPs produced and used in the EU appears to have remained broadly unchanged since 2010.

There are six manufacturing sites (underlined in the list below) in the EU, in Germany, Italy, Spain, the Slovak Republic and the United Kingdom. There are ten active REACH registrations:

1. Altair Chimica S.P.A., Saline Di Volterra (PI), Italy
2. Caffaro Industrie S.P.A., Torviscosa (Udine), Italy
3. Fortischem a.s., Novaky, Slovakia
4. Inovyn Chlorvinyls Limited, Runcorn, United Kingdom
5. Kaustik Europe B.V., Barendrecht, The Netherlands
6. Prakash Chemicals Europe B.V., Rotterdam, The Netherlands
7. Leuna-Tenside GmbH, Leuna, Germany
8. Quimica Del Cinca S.L., Barcelona, Spain
9. REACHLaw Ltd (acting as OR for KLJ Organic Limited), Espoo, Finland
10. Sustainability Support Services (Europe) AB, Lund, Sweden

MCCPs may also be imported into the EU in finished or semi-finished articles (e.g. textiles, electrical items). Academic literature suggests a global production in excess of 600 000 tonnes/year, with the majority produced in China (Gluge *et al*., 2018). 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. The Swedish RoHS Annex II Dossier (KEMI, 2018) estimated that the EU imported approximately 2 100 tonnes of MCCPs in electrical cables in 2014.

## Overview of uses

MCCPs principally functions 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;
* a carrier solvent for colour formers in paper manufacture.

**Table 7: MCCPs uses identified on ECHA’s dissemination site**

|  |  |
| --- | --- |
|  | **Use(s)** |
| **Formulation** | This substance is used in the following products: polymers, coating products, fillers, putties, plasters, modelling clay, adhesives and sealants and lubricants and greases.  This substance is used in the following activities or processes at the workplace: transfer of chemicals, mixing in open batch processes, transfer of substance into small containers, closed batch processing in synthesis or formulation, calendering operations and roller or brushing applications.  Release to the environment of this substance can occur from industrial use: formulation of mixtures, formulation in materials, in the production of articles and for thermoplastic manufacture.  The lead applicant’s CSR identifies formulation of the following products:  PVC and rubber  Metalworking fluids and lubricants  Adhesives and sealants  Paints and coatings |
| **Uses at industrial sites** | This substance is used in the following products: polymers, adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, metal working fluids and textile treatment products and dyes.  This substance is used in the following areas: formulation of mixtures and/or re-packaging and mining. This substance is used for the manufacture of: plastic products, rubber products, textile, leather or fur, fabricated metal products, pulp, paper and paper products and furniture.  This substance is used in the following activities or processes at the workplace: transfer of chemicals, mixing in open batch processes, transfer of substance into small containers, roller or brushing applications, calendering operations, hand mixing with intimate contact only with personal protective equipment available, industrial spraying and treatment of articles by dipping and pouring.  Release to the environment of this substance can occur from industrial use: in the production of articles, in processing aids at industrial sites, for thermoplastic manufacture, of substances in closed systems with minimal release, as processing aid, as an intermediate step in further manufacturing of another substance (use of intermediates) and formulation of mixtures.  The lead applicant’s CSR identifies the following industrial uses:  PVC and rubber processing  Treatment of textiles  Paper manufacturing and recycling  Use of metalworking fluids and lubricants – neat oils  Use of metalworking fluids and lubricants - emulsions |
| **Uses by professional workers** | This substance is used in the following products: coating products, adhesives and sealants and fillers, putties, plasters, modelling clay.  This substance is used in the following areas: building and construction work and printing and recorded media reproduction. This substance is used for the manufacture of: plastic products, furniture, textile, leather or fur, chemicals, rubber products, fabricated metal products and machinery and vehicles.  This substance is used in the following activities or processes at the workplace: hand mixing with intimate contact only with personal protective equipment available, roller or brushing applications, non-industrial spraying, transfer of chemicals and transfer of substance into small containers.  Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners) and outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives).  The lead applicant’s CSR identifies the following uses by professional workers:  Use of paints and coatings  Use of adhesives and sealants |
| **Consumer Uses** | This substance is used in the following products: polymers, adhesives and sealants, coating products and textile treatment products and dyes.  Other release to the environment of this substance is likely to occur from: indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment) and outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials).  The lead applicant’s CSR does not identify any consumer uses. |
| **Article service life** | This substance is used in the following activities or processes at the workplace: high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding), the low energy manipulation of substances bound in materials or articles, production of mixtures or articles by tabletting, compression, extrusion or pelletisation and open transfer and processing with minerals/metals at elevated temperature.  Release to the environment of this substance can occur from industrial use: in processing aids at industrial sites, formulation of mixtures and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment), outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners).  This substance can be found in products with material based on: rubber (e.g. tyres, shoes, toys), plastic (e.g. food packaging and storage, toys, mobile phones), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper), plastic used for large surface area articles (e.g. construction and building materials for flooring, insulation), leather (e.g. gloves, shoes, purses, furniture) and fabrics, textiles and apparel (e.g. clothing, mattress, curtains or carpets, textile toys).  The lead applicant’s CSR identifies the following uses:  PVC and rubber articles (indoors)  Textiles (indoors and outdoors)  Adhesives and sealants (indoors and outdoors)  Paints and coatings (indoors and outdoors) |

Since the transition dossier was issued in 2008, use in leather fat-liquors and carbon copy paper appears to have ceased in the EU as they are not mentioned in the REACH registrations. It is not known whether imported leather goods or carbon copy paper contain MCCP residues. The CSR does not, however, explicitly advise against any uses.

## Additional information

### Emissions and exposure

The lead Registrant included an exposure assessment in their Chemical Safety Report (CSR) in the REACH registration dossier and calculated the local releases to wastewater, air and soil from all relevant exposure scenarios. Environmental releases via emissions to solid waste streams were not explicitly considered, even though this may be a significant route for some uses such as waste paper recycling (sludge to land).

The release estimates presented in **Table 8** and **Table 9** have been calculated from the estimated EU tonnages applicable to manufacturing, formulation, industrial use, professional use and article service life, multiplied by the emission factors provided in the CSR. The total estimated release to surface water in Table 10 was calculated by multiplying the total release to wastewater (153 tonnes/year) by (1-0.971) to reflect the removal of MCCPs from aqueous waste streams by treatment plants. That does imply, however, that approximately 149 tonnes/year of MCCPs are diverted to sludges for which the environmental fate has not been assessed (via landfill, agricultural use or incineration). Overall, a comparison with information presented in the transitional dossier indicates a ten-fold reduction in estimated emissions to the environment, from approximately 3,000 tonnes/year to approximately 300 tonnes/year. This reflects a reduction in the value of emission factors rather than a substantial reduction in tonnage used.

**Table 8: Estimated total releases of MCCPs to the environment per year by use (from all lifecycle stages except waste, such as sludges)**

|  |  |
| --- | --- |
| 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** |

**Table 9: Estimated total releases of MCCPs to the environment per year from all lifecycle stages (except waste, such as sludges)**

|  |  |
| --- | --- |
| Release route | Total releases per year (tonnes) |
| Water | 4 |
| Air | 89 |
| Soil | 61 |

Note: Release to soil is likely to be an underestimate as it excludes inputs from wastewater treatment sludges (149 tonnes/year) and sludges from paper recycling.

### Environmental monitoring data

MCCPs is not routinely included in environmental monitoring programmes. Due to the complex nature of this UVCB substance, chemical analysis in environmental samples is challenging. In an inter-laboratory comparison, the most commonly used analytical technique for SCCPs analysis – GC-ECNI-LRMS – showed the largest variation. 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. A large proportion of measured values reported in the academic literature may therefore not be accurate.

The available European monitoring data generally show widespread occurrence of MCCPs in water (at concentrations typically up to a few µg/L), sediment (at concentrations typically up to a ca. 2 mg/kg dry weight) and biota (typically below 1 mg/kg wet weight but higher concentrations up to around 80 mg/kg have been reported in some studies). MCCPs is also found in sewage sludge up to 9,700 mg/kg dry weight. Low levels of chlorinated paraffins (determined as the sum of SCCPs and MCCPs) were present in an indoor air sample from apartments in Stockholm, Sweden (<5 – 210 ng/m3, dominated by the more volatile SCCPs). Levels in dust were reported to be in the low mg/kg range. MCCPs was present at concentrations of <0.81 to 14.5 ng/m3 (mean 3.0 ng/m3) in air samples from the Hazelrigg field station near Lancaster, UK in 2005.

Further information can be found in the Substance Evaluation report.

### Alternatives to MCCPs

Potential alternatives to MCCPs are identified and summarised in **Table 10** below, reproduced from the transitional dossier. Since the data are now approximately ten years old, a more comprehensive survey of industry would be beneficial.

**Table 10. Alternatives to MCCPs**

| **Use** | **Alternatives** | | |
| --- | --- | --- | --- |
| **Available substances** | **Identified hazards** | **Technical and economic feasibility[[5]](#footnote-5)** |
| **Polyvinyl chloride (PVC)** | | | |
| MCCPs is used as a secondary plasticiser/ flame retardant in various PVC products including: coatings, floorings, garden hose, shoe compounds, calendared flooring, cable sheathing/ insulation and general purpose PVC. MCCPs imparts both plasticising effects and fire retardancy. A move away from MCCPs may require the use of separate plasticisers and fire retardants. | LCCPs | Environment risk assessment by the Environment Agency in the UK on LCCPs identified PEC/PNEC ratios above 1 for some uses (EA 2009). LCCPs with carbon chain length C18-20 may contain up to 20% C17 chlorinated paraffins. The implication of this for the hazardous properties of LCCPs has not yet been evaluated. | LCCPs suitable for some applications – subject to viscosity considerations - but have a higher purchase price than MCCPs. |
| Phthalates e.g. di-isononyl phthalate have been identified as potential alternatives for the manufacture of wall coverings and cable compounds. Additional flame retardancy may be required for some cable applications. | EU risk assessment for DINP concluded that there is no need to limit the risks. Concerns were identified for potential hepatotoxicity in newborns and infants due to the presence of DIDP in toys. Another phthalate, DEHP, is a SVHC on Annex XIV of REACH and subject to Authorisation and Restriction. | Phthalates are effective plasticisers and have equivalent or superior properties to MCCPs but are more expensive and are not suitable where high fire resistance is required. In the case of standard wallcoverings, relevant flammability tests can be passed without the need for MCCPs or other fire retardants. However, this may not be the case for heavy duty wall coverings (conforming to EN259). It may be necessary to add an alternative flame retardant such as antimony trioxide or aluminium trihydrate to cable compounds for use in some applications. |
| Inorganic compounds (e.g. aluminium hydroxide, aluminium polyphosphate) | Although a detailed assessment has not been performed for this analysis, inorganic compounds are expected to pose lower risks than MCCPs. | Inorganic compounds provide flame retardancy but do not impart any plasticising effects. More information is needed to determine whether there are any technical barriers (e.g. viscosity constraints) to the use of inorganic compounds as substitutes for MCCPs and the range of applications in which these compounds may be used. |
| Phosphate esters (tri-alkyl phosphates and aryl phosphates e.g. tricresyl phosphate) have been identified as potential alternatives for flooring, cables and coated fabrics. May be used in combination with solid flame retardants such as borates. | The UK CA has assessed environmental risks from a number of aryl phosphates, and screened the environmental hazards of a number of tri-alkyl phosphates. Although some aryl phosphate esters may possess PBT properties, in general, these types of substance do not appear to have PBT properties (though some are, like MCCPs, very toxic to aquatic organisms). A more detailed evaluation is necessary to make side by side comparisons with MCCPs. | Phosphate esters can be used where there is a need for fire retardancy. This would require modification of the formulation but would also improve processing and compatibility of composition. Some may have inferior performance in use or may cause discolouration to finished product.  The transition dossier states that phosphate esters are around 4 times the cost of MCCPs. |
| **Metalworking/cutting** | | | |
| MCCPs may be present in oil based and water based metalworking fluid formulations for use in cutting, grinding and forming operations.  Replacement of chlorinated paraffins in metal working lubricants for cutting processes of ordinary steel, copper, brass and less demanding metal forming operations has generally been successful. However, it is reportedly difficult to find substitutes for MCCPs in certain arduous applications such as chip-less processing of stainless steel and titanium and applications requiring the use of extreme temperatures and pressures e.g. pilgering and deep drawing.  Substitution may have significant costs attached (including R&D).  Replacement of chlorinated paraffins will require extensive reformulation of the lubricant system. Alternatives to MCCPs may lead to increased energy consumption. Without MCCPs there is a high risk of cracks and other instabilities in the end product. | Polysulfides (e.g. di-(tert-nonyl) and di-(tert dodecyl) polysulfides) and synthetic sulfurised esters.  Sulfur based additives. Includes esters, fatty compounds and polysulfides. | This group includes substances that may have adverse health and environmental properties. A preliminary assessment by the Environment Agency in the UK identified high PEC/PNEC ratios and possible PBT properties for polysulfides (EA, 2008).  The UK CA does not have any information on the human health and environmental hazards of synthetic sulfurised esters. | Suitability for high temperature applications may be an issue. Other technical limitations include the aggressiveness of these substances on yellow metals, the intense odour and dark colour. These issues may be addressed with synthetic sulfurised esters which are being developed but the UK does not have any specific information on sulfurised esters that could be used as substitutes at present. |
| Phosphorus based compounds. Includes phosphate esters (mono-, di- and tri-ester compounds) also phosphates and phosphonates. | The UK CA has assessed environmental risks from a number of aryl phosphates, and screened the environmental hazards of a number of tri-alkyl phosphates. Although some aryl phosphate esters may possess PBT properties, in general, these types of substance do not appear to have PBT properties (though some are, like MCCPs, very toxic to aquatic organisms). A more detailed evaluation is necessary to make side by side comparisons with MCCPs. | Phosphonates are considered to have excellent performance under high temperature conditions because of their greater thermal stability.  The organic radicals in the phosphorus additives can be either aliphatic or aromatic with the alkyl phosphates considered to be better than the aryl derivatives. Acid alkyl phosphates have good extreme pressure performance but are more difficult to formulate due to their high acidity or are less economically viable. Neutral alkyl phosphates can work synergistically with sulfurised additives to achieve a performance level similar to chlorinated paraffins in a cost-effective manner.  The transition dossier states that tri-butyl phosphate is not suitable for use under extreme temperature and pressure. |
| Overbased sulfonates | The UK CA does not have sufficient information on the human health and environmental hazards and risks associated with the use of these potential substitutes to carry out a side by side evaluation with MCCPs. | Overbased calcium and sodium sulfonates have been suggested as possible extreme pressure agents when used in combination with sulfurised esters. The technical limitations identified above for sulfur based additives apply to overbased sulfonates. |
| Zinc-dialkyl dithiophosphate (ZDDP) | The UK CA does not have sufficient information on the human health and environmental hazards and risks associated with the use of this substitute to carry out a side by side evaluation with MCCPs. | The effectiveness of ZDDP is limited because when burnt, ZDDP leaves a residue. Burning is unavoidable with extreme temperature and pressure. This could only be an effective substitute where temperature and pressure do not reach extreme levels. |
| **Rubber / polymers (non-PVC)** | | | |
| Used as a plasticiser/flame retardant in rubbers for conveyor belts and automotive applications.  Used in non PVC polymers as a plasticiser/flame retardant. | LCCPs | Environmental risk assessment by the Environment Agency in the UK on LCCPs identified PEC/PNEC ratios above 1 for some uses (EA 2009). LCCPs with carbon chain length C18-20 may contain up to 20% C17 chlorinated paraffins. The implication of this for the hazardous properties of LCCPs has not yet been evaluated. | Industry estimates a €375k per year increase in raw materials costs. Rubbers formulated with LCCPs may be too brittle to use for certain conveyor belts e.g. use in mines. Also rubbers may be too brittle for use in bellows on buses and trains. The suitability of other flame retardants and non fire-resistant formulations has not been assessed. |
| **Paints and adhesives** | | | |
| Used in chlorinated rubber based paints for aggressive marine and industrial environments and vinyl copolymer-based paints for protection of exterior masonry. | LCCPs may be suitable for anticorrosive primers/topcoats for metals based on PVC-related copolymer also outdoor wall paints and acrylics. | Environment risk assessment by the Environment Agency in the UK on LCCPs identified PEC/PNEC ratios above 1 for some uses (EA 2009). LCCPs with carbon chain length C18-20 may contain up to 20% C17 chlorinated paraffins. The implication of this for the hazardous properties of LCCPs has not yet been evaluated. | The UK CA does not have information on the technical implications of this potential substitution. |
| Chlorine-free polymer | The UK CA does not have any information on the human health and environmental hazards and risks associated with the use of this alternative. |
| Polybutenes may be used in acrylic topcoats; some antifouling paints and some acrylic and epoxy underwater primers. | The UK CA does not have any information on the human health and environmental hazards and risks associated with the use of this alternative. |
| **Sealants** | | | |
| Used as plasticiser/flame retardant in e.g. polysulfide, polyurethane, acrylic and butyl sealants. | Terphenyls | Terphenyl contains “o-terphenyl”, which has been identified as vPvB (cf. support document of “Terphenyl, hydrogenated”). | The transition dossier states that terphenyls have inferior technical properties. No further information is available. |

**Use in PVC**

MCCPs is used in PVC formulation as a secondary plasticiser with flame-retardant properties. It is a partial replacement for the more expensive primary plasticisers such as phthalates (e.g. di-isononyl phthalate (DINP) and di-isodecyl phthalate) and phosphate esters. In addition to cost-effectiveness, PVC properties such as fire retardancy, chemical and water resistance, low temperature performance and viscosity and ageing stability may all be enhanced through incorporation of MCCPs. It can be used in a wider variety of PVC formulations and in combination with a broader range of other plasticisers than any other plasticiser type. This leads to reduced formulation costs. PVC containing MCCPs can be recycled, with the MCCPs remaining in the PVC matrix for multiple product lifecycles.

MCCPs with varying degrees of chlorination is used in most applications. The majority comprises around 45% w/w Cl or 50-52% w/w Cl, with only very small amounts (<1% of total sales) with higher (e.g. 56-58% w/w Cl) or lower (e.g. ~40% w/w Cl) chlorine content. The properties and compatibility of the chlorinated paraffin with both PVC and the primary plasticiser vary with both the carbon chain length and the degree of chlorination. Generally, as the chain length of the chlorinated paraffin is increased, its volatility decreases and so the potential for migration from the finished PVC is reduced. At the same time, however, the compatibility with PVC and the primary plasticiser is reduced. On the other hand, the compatibility of chlorinated paraffins with PVC and the primary plasticiser increases with increasing chlorination, and so the potential for migration is reduced, but the flexibility of the final product is also reduced.

For soft PVC products that require a high flexibility at normal and low temperatures, MCCPs comprising around 40-45% w/w Cl is used as a secondary plasticiser. Examples of applications for this type of PVC include coatings, some types of flooring, garden hose and shoe compounds. The secondary plasticiser is added at 10-15% by weight of the total plastic.

MCCPs with higher degrees of chlorination (typically around 50-52% w/w Cl) is used as a secondary plasticiser in calendered flooring, cable sheathing and insulation and in general purpose PVC compounds. In heavily filled products, such as some types of calendered flooring, they can be used as the sole plasticiser at levels of around 10% in the finished product.

The more highly chlorinated MCCPs (e.g. 56-58% w/w Cl) is used for softening plastics that are subject to higher temperatures during processing.

Typical applications for PVC products containing MCCPs include cables, flooring, wall coverings and other uses (e.g. general extruded and injection moulded articles). A single substitute cannot replace all applications in PVC but a combination of known alternatives could adequately and effectively replace MCCPs. According to the transition dossier, possible alternatives for use in PVC include LCCPs, phthalates (e.g. DINP - these are effective plasticisers but do not provide flame retardant properties) and phosphate esters. Inorganic flame retardants (e.g. aluminium hydroxide, magnesium hydroxide, aluminium polyphosphate, zinc borate and red phosphorus) may perform well at low concentrations, but would need to be used with plasticisers.

**Use in paints**

MCCPs comprising typically around 50-60% w/w Cl (though 40% w/w Cl to 70% w/w Cl are used) is used in paints and other coatings. They are based on various resin types, but most commonly chlorinated rubber or vinyl copolymers. They act as viscosity modifiers, adhesion promoters and maintain flexibility of the coating in addition to their flame retardant properties. They are generally retained within the paint over its lifetime and primarily have a plasticising effect, reducing cracking and detachment of paints with good colour retention compared to some alternatives. Typical applications are for corrosion- or weather-resistant coatings: chlorinated rubber-based paints are used in marine and industrial environments, whilst vinyl copolymer-based paints tend to be used on exterior masonry. Other applications include sealers and coatings for concrete; general purpose primers and undercoats for structural steel; roof coatings; swimming pool paints; chemical resistant coatings; high humidity resistant coatings; security fencing paints; damp-proof paints; flame retardant coatings for wood and paper; road markings; and industrial floor coatings.

The typical level of MCCPs in formulated paint is 4-15% w/w. After drying (evaporation of solvent) the content increases to around 5-20% w/w.

Around 30 sites in the UK manufactured paints and coatings containing MCCPs in 1999. The MCCPs-containing paint made up only a very small proportion of the total paint manufactured at each site (typically <1-2% of the total, up to 5% in some cases). The major users are professional painters and specialist applicators, but some ‘do-it-yourself’ (DIY) paints containing MCCPs may be used by the general public. Based on information gathered in a survey by the British Coatings Federation in 1999, it was estimated that for the UK there would be around 40 000 users of coatings containing MCCPs for water proofing of walls, with around 1 000-1 500 users of paints and coatings for other uses. It is not known how many of these would be professional and how many DIY users. The quantity of paint produced using MCCPs represents ~1% of EU paint sales.

Possible alternatives to MCCPs for paint applications include LCCPs and polybutenes.

**Use in adhesives and sealants**

MCCPs is used in polysulfide, polyurethane, acrylic and butyl sealants for use in building and construction, including double and triple glazed windows. They are typically added at amounts of 10-14% w/w of the final sealant but could be added at amounts up to 20% w/w in exceptional cases. The MCCPs used in these applications generally has a chlorine content of 50-58% w/w Cl. They are primarily used for their plasticising and flame retardant properties although their low water solubility also imparts benefits for use in aggressive biological environments.

Terphenyls have been identified as alternatives for polysulfide sealants, but they apparently have inferior technical characteristics and hydrogenated terphenyls are SVHCs (vPvB).

**Use in metalworking/cutting fluids**

Metalworking fluids remove deformation heat and friction heat arising during metal cutting, grinding and forming operations and additionally flush away chips and prevent dusting. MCCPs can be used in neat (oil-based) and water-emulsifiable metalworking fluids (water emulsions tend to be used for cooling), as well as greases and gear oils for industrial and automotive applications. It enhances lubrication and surface finish in metalworking and forming applications requiring the use of extreme pressures. MCCPs can be used across a wider temperature range than many alternatives and is particularly suitable for low temperature applications.

The MCCPs used generally has a chlorine content of between 40 and 55% w/w Cl. The amount present in a given fluid depends on the final application:

* the content in oil-based fluids ranges from about 5% w/w for light machining to up to 70% w/w for heavy drawing processes (metal forming fluids);
* MCCPs content in water-based cooling lubricant concentrate is up to 8% w/w (the concentration in the final water-based fluid is around 0.4% w/w; this emulsion is used in grinding, rough machining and sawing applications).

Whilst companies of all sizes are understood to use either neat or emulsifiable metalworking fluids (or both), machines at smaller companies generally have smaller sumps and hence require only small quantities of metalworking fluid (of the order of a few litres). Smaller companies will often undertake less arduous machining and hence will more often use water miscible fluids (this also helps to keep down costs). Large machines may have sumps of several hundred or even several thousand litres.

During preparation of the transition dossier, reviews by the UK, Denmark, the Netherlands and Sweden on the replacement of chlorinated paraffins in metalworking fluids and the metalworking fluids case study in the OMNITOX project were consulted. The transition dossier indicated that LCCPs, phosphorus-based additives (e.g. aryl phosphates, alkyl phosphates and phosphites, complex phosphate esters), sulfur-based additives (e.g. sulfurised esters, polysulfides), overbased sulfonates and zinc dialkyl dithiophosphate are possible alternatives for some uses of MCCPs in oil-based metal working fluids. However, it appears that no suitable alternative currently exists for some specific applications (e.g. extreme temperature and pressure activities such as the sheet metal forming processes of deep drawing and punching, extrusion, the cold rolling process of pilgering and the metal cutting process of broaching), and some pose problems with staining, odour, etc.

**Use in rubber and polymers (other than PVC)**

MCCPs with a ‘high’ chlorine content is a cost-effective softener (or process oil) additive with flame retardant properties used in nitrile, natural and styrene-butadiene rubbers in applications such as conveyor belts and tubes for compressed air in the mining industry, bellows for buses and trains, and profiles for fireproof doors. The ESR Risk Assessment Report (Part 1) indicates that MCCPs can be present at up to 15% w/w of the total rubber.

MCCPs with chlorine content >50% by weight acts as a secondary flame retardant plasticiser in non-PVC plastics. It is also used as a physical property modifier, such as for modification of viscosity in polyurethane, especially rigid foams and one-component foams.

LCCPs has been identified as an alternative for several rubber applications, although there is no up to date information about its effects on product performance (e.g. flexibility) or fire safety approvals (e.g. for use on public transport).

**Availability of alternative materials and techniques**

Some information on alternative materials and techniques was presented in the transition dossier. For most situations where MCCPs is used it was possible to identify alternative materials. The impacts of the use of alternative technologies on human health and the environment were not assessed in the transition dossier so it is not clear whether such moves would provide an overall reduction in risks to human health and/or the environment. A move to alternative materials and techniques would result in shifts from one supply chain to another. It is likely that many companies would need to replace existing manufacturing machinery with different types of machinery. For this reason, it is likely that many companies using products containing MCCPs would prefer to seek alternative substances.

The transition dossier stated that alternative technologies were not available for some metalworking applications requiring the use of MCCPs, but no further details were available. Also no suitable alternative materials or technologies were identified for the manufacture of conveyor belts for use in mines, bellows for buses/trains and fireproof doors.

**Table 11: Overview of non-substance alternatives for main MCCPs uses of concern**

| **Use** | **Potential substitutes** | **Implications of switch** |
| --- | --- | --- |
| PVC wallcoverings | Non-vinyl wallpaper  Painted walls | No use of MCCPs (in coating)  Cost implications for PVC and wallcoverings industry.  Reduced consumer choice.  Hygiene issues (if non-washable). |
| PVC flooring | Linoleum, wood, stone/slate tiles | Although renewable, possible implications for other environmental impacts (e.g. higher energy use) would need to be considered.  Potentially higher cost implications for end users/consumers. |
| PVC cables | Polyethylene, polypropylene, fluoroplastics, others | Requires addition of other additives (e.g. heat/UV stabilisers, flame retardants), some with unknown risk profiles.  Flame retardancy requirements can be achieved  Production costs 50-200% higher (additional costs for overall electrical installation 10-20% higher). |
| PVC – others (e.g. extruded products) | Wide range of products – not practicable to identify alternatives. | |
| Metalworking fluids | Improved precision casting techniques | May negate the need for MCCPs in some applications.  Not suitable for all applications where MCCPs used. |
| Rubber / plastics other than PVC | Non-substance alternatives not identified for main uses (conveyor belts in mining, bellows for buses/trains, fireproof doors). | |
| Adhesives/sealants | None identified |  |
| Textile treatments | None identified |  |
| Paints/coatings | None identified |  |
| Paper | None identified |  |

### Uncertainties

The following sources of uncertainty could influence decisions on the most appropriate regulatory actions to minimize MCCPs releases as far as technically and practically achievable:

**Identity, composition and analysis of MCCPs**

* The PBT/vPvB properties of MCCPs may not be associated with all constituents (specifically, chain lengths with a chlorine content ≤ 45% w/w) In appraising the type and scope of regulatory risk management options, and alternatives, consideration should therefore be given to uses that could switch to MCCPs with lower chlorine content.
* The variable composition of MCCPs poses a challenge for analysis, and the accuracy of historic environmental exposure data may reflect this. However, there are existing analytical approaches – particularly High Resolution Mass Spectrometry – that may provide the means to ensure the monitorability of any regulatory measures.

**Emissions and environmental risk**

* Based on the data presented in the CSR, the formulation and use of sealants, adhesives and metalworking fluids are responsible for **75%** of all MCCPs released to the environment from REACH registered uses. There must, however, be significant (unquantified) uncertainty around this estimate because uses (tonnages) and emission factors have been represented by single point estimates rather than probability distributions. The uncertainty around emission estimates is highlighted by the apparent ten-fold difference in estimated releases to the environment when comparing calculations from the latest CSR (ca. 300 tonnes/year) with the previous assessment (ca. 3 000 tonnes/year).
* There is also significant uncertainty around the fate of MCCPs in **sludges** from wastewater treatment plants, and in industrial or consumer waste streams. The CSR claims that contaminated sludges from wastewater treatment are not recycled to agriculture, but this claim has not been substantiated and does not seem very plausible. The fate of MCCPs in solid waste streams has not been evaluated in terms of recycling or disposal to landfill or incineration. For example, MCCPs have been detected in landfill leachates (Pilke et al., 2012). Does conventional incineration of refuse destroy MCCPs? Does recycling of PVC release MCCPs?
* The level of disaggregation of sector/use information may not be optimal for the effective targeting of regulatory actions. For example, should PVC formulation, conversion and service life emissions be disaggregated from those for rubber (and other polymers)? Should sealant emissions be similarly disaggregated from those for adhesives?
* The total quantity of MCCPs introduced to the EU in imported articles is unknown, though the KEMI Annex II dossier for RoHS indicates substantial importation in electrical cables (KEMI, 2018). The current level of uncertainty around MCCPs imports would need to be reduced as part of developing a proportionate restriction proposal, but does not undermine the case for restriction as opposed to authorisation.

**Use and availability of alternatives**

* It is not clear to what extent the use of MCCPs with a chlorine content ≤45% by weight is technically feasible in all applications. Similarly, the ability of industry to modify the feedstock to change the chain length distribution, the costs involved, and technical performance of such a product are all unknown.
* The extent to which MCCPs could be substituted with less hazardous chemicals or end uses could be served by other techniques/products is not clear. This is a need for more comprehensive information on which substances may be suitable, the hazardous properties of the alternatives, and on alternative techniques/products.

### Risk management work by other states

**Australia**

The Australian Department of Health published a hazard assessment of MCCPs on their website[[6]](#footnote-6) in June 2019. The review concluded that MCCPs meets the domestic PBT criteria, and that some congener groups may meet the Annex D screening criteria for Persistent Organic Pollutants under the Stockholm Convention. The assessment recommended further work to assess environmental exposure and the case for POPs nomination, including adding MCCPs to environmental monitoring programmes.

**Canada**

Environment and Climate Change Canada reviewed the chlorinated paraffins group in 2008[[7]](#footnote-7). The review concluded that MCCPs is "toxic" as defined in paragraphs 64 (a) and (c) of the Canadian Environmental Protection Act, 1999, on the basis that MCCPs 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 report on a socio-economic study on the manufacture, import and use of both medium and long chain chlorinated alkanes in Canada was completed in March 2019. The report will inform decision making in relation to the risk management of MCCPs.

**Switzerland**

Swiss researchers are working on the environmental distribution of MCCPs (see Glüge *et al*., 2018), and are interested in collaborating in studies that could inform a POPs nomination.

# Justification for the risk management option

## Need for (further) risk management

Substance evaluation of MCCPs has identified it as a PBT/vPvB substance. It is considered to be of relevance under the SVHC Roadmap to 2020 (Table 12).

The use profile of MCCPs suggests a potential for widespread dispersive release to the environment, including during the service life of articles and their subsequent disposal.

Table 12**: SVHC Roadmap 2020 criteria**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| a) Art 57 criteria fulfilled? | ✓ |  |
| b) Registrations in accordance with Article 10? | ✓ |  |
| c) Registrations include uses within scope of authorisation? | ✓ |  |
| d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution? | ✓ |  |

The actual level of risk from different parts of the life cycle is unclear because of uncertainties in the emission estimates, but the substance has been detected widely in the European environment at relatively low concentrations (see Section 4.3.2).

The UK CA considers that the risk management measures currently applied by the lead Registrant are sensible and demonstrate that they have taken some responsibility for safe use. However, they may still not be sufficient to minimise releases to the greatest extent technically and practically feasible. In particular, the lead Registrant has not concluded that MCCPs meets the Annex XIII criteria. The occupational controls and risk management measures identified in the lead Registrant’s CSR are summarised in **Table 13**.

**Table 13: Environmental risk management measures for MCCPs**

| **Use/category** | **Exposure scenario** | **Operational conditions and risk management measures** |
| --- | --- | --- |
| MCCPs manufacture | ES1 | Manufacture of MCCPs within closed or contained systems consisting of a stirred reactor with the addition of chlorine gas at a temperature of 80 to 100 °C.  Closed system; no direct releases to air or water.  Manufacture in accordance with Best Available Techniques for organic fine chemicals manufacture.  Wastewater treatment with 97.1% removal from aqueous stream.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Sewage sludge from Sewage Treatment Plants receiving waste from MCCPs production sites shall not be applied to soil. |
| PVC/rubber formulation | ES2 | Compounding of MCCPs by Banbury or dry blending at 100 to 140 °C or plastisol blending at ambient temperature.  Exhaust recovery and treatment by thermal or catalytic oxidation.  Wastewater treatment with 97.1% removal from aqueous stream.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| PVC/rubber processing | ES3 | Conversion of PVC in open, partially open, or closed systems at elevated temperature.  RMM as for ES2. |
| PVC/rubber service life | ES4 | Wastewater treatment with 97.1% removal from aqueous stream.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Adhesives/sealants formulation and use | ES5 | Sealants and adhesives are formulated by mixing additives with a liquid viscous polymer. The process is conducted at approximately 40 °C and typically under vacuum. Solid waste is generated during cleaning between batches. Sealants and adhesives are applied at ambient temperature.  Collection of disposal of solid waste generated during cleaning in a permitted landfill.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Adhesives/sealants outdoor service life | ES6 | As for ES4. |
| Adhesives/sealants indoor service life | ES7 | As for ES4. |
| Metalworking fluids (MWF) formulation | ES8 | MWF formulation is completed as a batch process typically at ambient temperatures with a maximum of 60C.  Oil capture and recovery systems with effluent concentration of 5 mg/L or less dissolved oil.  Wastewater treatment with 97.1% removal from aqueous stream.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Recovery and treatment of waste oils in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Metalworking fluids professional use - emulsions | ES9 | Mist and evaporated vapors are enriched in water relative to the bulk solution as result of lower vapor pressure of MCCPs and releases to air are considered negligible (EU, 2005). The primary worst case sources of MCCPs to water are overalls (2%), leaks (3%) work-piece dragout (1%).  No direct release of spent MWF or residual oils to sewer.  Disposal of spent MWF in accordance with the Waste Oils Directive, 75/439/EEC.  Recycling/recovery and treatment of oils recovered from swarf.  Wastewater treatment with 97.1% removal from aqueous stream.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Metalworking fluids professional use – neat oils | ES10 | The primary worst case sources of MCCPs to water are overalls (1 to 2%), leaks (1 to 3%) work-piece dragout (1%) and mist (2%). Leaks, mist and dragout losses are assumed controlled by risk management measure as described below.  No direct release of spent MWF or residual oils to sewer.  Disposal of spent MWF in accordance with the Waste Oils Directive, 75/439/EEC.  Recycling/recovery and treatment of oils recovered from swarf.  In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.  In absence of control or losses from dragout, mist generation or residual oil discharge to sewer, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 50 kg/year or effluent oil concentration of 5 mg/L or less dissolved oil.  Potential MCCPs wastewater emissions at well controlled facilities may be confirmed by measurement of adsorbable organic halide (AOX) as a surrogate for MCCPs when there are no other appreciable sources of chlorinated substances in the effluent (EU, 2008).  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Textiles treatment: formulation & use | ES11 | Fixation of 100% of the coating to the textile is assumed.  Process conducted in accordance with the OECD ESD (2004c) and Reference Document on Best Available Techniques for the Textile Industry (July, 2003).  Wastewater treatment with 97.1% removal from aqueous stream.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Textiles – outdoor service life | ES12 | As for ES4. |
| Textiles – indoor service life | ES13 | As for ES4. |
| Paints & coatings formulation and use | ES14 | MCCPs is used in solvent based paints, primarily in industrial applications. Releases to water and air from formulation and industrial use are negligible because the chlorinated paraffin is associated with the solid phase.  Collection of disposal of solid waste generated during cleaning in a permitted landfill.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |
| Paints & coatings – outdoor service life | ES15 | As for ES4. |
| Paints & coatings – indoor service life | ES16 | As for ES4. |
| Paper manufacturing and recycling | ES17 | MCCPs is processed in closed systems in carbon copy manufacture with neglible release.  MCCPs is a carrier solvent for color formers, which are hydrolyzed and released during recycled papermaking pulping.  Collection of disposal of solid waste generated during cleaning in a permitted landfill.  Closed sinks/basins to prevent discharge to waste- and/or surface water  General good hygiene and housekeeping.  Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006). |

Articles manufactured with MCCPs in one Member State may be transported to and used in another Member State. Articles may also be imported into Europe. With measured levels in environmental media and biota showing widespread environmental contamination, it is appropriate to consider Europe-wide measures for risk reduction.

## Identification and assessment of risk management options

The following legislative instruments and other initiatives have been assessed for their potential to influence MCCPs releases to the environment.

* REACH: The following elements of REACH have the potential to control emissions to the environment
  + Registration
  + Authorisation
  + Restriction
* The RoHS Directive (2011/65/EU)
* The Persistent Organic Pollutants Regulation ((EU) 2019/1021)
* The Water Framework Directive (2000/60/EC)
* The Industrial Emissions Directive (2010/75/EU)
* The Waste Framework Directive (2008/98/EC)
* Voluntary actions

The baseline against which additional risk management options have been assessed is the registration of MCCPs under REACH. This represents the situation if Member States take no additional regulatory action.

**REACH Registration**

The ECHA website confirms 10 active MCCPs registrations as of 15 August 2019, with 1 joint registration dossier. The Registrants do not currently identify MCCPs as a PBT substance.

Regardless of the current registration status, it is not possible to manage releases from imported articles through the registration process, due to the lack of information on amounts and product types, and unknown identity of all relevant actors in the supply chain.

**REACH Authorisation (including candidate listing)**

MCCPs meets the relevancy criteria in the Roadmap (Table 12). Candidate listing would compel the Registrants (and any future Registrant) to identify MCCPs as a PBT/vPvB substance and review their risk management measures to minimise emissions. It would also provide a flag to users about its undesirable properties, and might be a useful way of confirming the properties of the substance prior to a restriction. Candidate listing would, however, fail to distinguish between the PBT and any non-PBT constituents of MCCPs. Consequently, authorisation would include uses that employ MCCPs with low levels of chlorination (≤45% w/w) that may not be persistent.

Authorisation would be a suitable option if no particular unacceptable risks can be identified for restriction, if imported articles were not a significant source of MCCPs, if service life losses were minor, and if the number of potential applicants were manageable. The authorisation of MCCPs would encourage substitution, but where industry considers this cannot currently be achieved, it allows companies to apply for continued use in specific applications. Authorisation has the potential to remove all non-essential uses while allowing essential uses to continue and creating pressure to move to alternatives in the longer term. Authorisation would require companies to consider the comparative hazards and risks of alternatives, which may include (but is not limited to) the alternatives described in Section 4.3.3. It is not yet known if the use of MCCPs is essential in any applications or products.

If authorisations were to be granted, in the short-/medium-term it is likely that there would be continued release of MCCPs into the environment, including from imported articles. Some reductions might be achieved depending on the conditions that are included in the authorisation. In addition, if MCCPs is not added to Annex XIV due to other priorities, authorisation might not come into effect for a long time. It could, therefore, be argued that restriction would have a more immediate impact on emissions. However, in granting authorisations, the costs (both economic costs to applicants and environmental costs of continued release) and benefits for each use would be assessed on a case-by-case basis. This would be particularly helpful for sectors where alternatives need to undergo safety testing before they could be introduced or where new substances are being developed and information on hazards and efficacy for these new substances is still being generated. Given the cost of applying for an authorisation, it is expected that where substitutes are readily available companies may prefer substitution.

Authorisation would not apply to imported articles containing MCCPs, such as textiles and electrical equipment. Instead, imported articles would need to be monitored to determine if they are a significant source of MCCPs in the environment. If they are, it might be necessary to develop targeted restrictions according to Article 69(2).

A further complication is the presence of MCCPs in recycled PVC. Directives such as those for Waste Electrical and Electronic Equipment (WEEE) and End-of-Life Vehicles (ELV) set targets for recycling of materials used in Electrical and Electronic Equipment (EEE) and motor vehicles. This includes articles that are made with PVC, some of which will contain MCCPs. As for restrictions, it would be necessary to make provisions to allow the use of recycled polymers containing MCCPs. The authorisation regime might simplify this assessment because it allows provisions to be tailored to specific supply chains whereas a restriction would need to apply equally to all recycled PVC products (unless any are derogated). Potential emissions from recycled articles might need to be considered, along with emissions at/from recycling sites.

The UK CA considers that Authorisation might be an effective regulatory tool to minimise MCCPs releases from the manufacture of MCCPs and the formulation and processing of PVC, rubber, sealants, adhesives, paints, coatings, and metalworking fluids, and the production/recycling of paper. However, Authorisation would be ineffective in minimising releases associated with imported articles, could not be targeted on the identified PBT/vPvB MCCPs constituents, would not be applicable to article service life losses, and would generate a very substantial regulatory workload from the numerous use sectors.

**REACH Restriction**

Restrictions can be introduced when there is an unacceptable risk to human health or the environment arising from the manufacture, placing on the market and use of a substance, and the risk needs to be addressed on a Community-wide basis. When considering a restriction on a substance, the scope is assessed in terms of effectiveness, practicality, monitorability, alternative substances and techniques, and socio-economic impacts.

The lead Registrant’s CSR identifies that the risk characterisation ratios for all registered uses and exposure scenarios are below 1, indicating a low deterministic environmental risk. Nevertheless, since MCCPs has PBT properties and emissions are known to occur in the European environment, it is assumed that an unacceptable risk exists. That risk could be managed using a restriction to eliminate or reduce emissions.

In contrast to authorisation, restriction offers the important advantage of selective targeting of particular compositions of MCCPs, i.e. exempting any chain length and chlorination levels shown not to be associated with PBT/vPvB properties. This could encourage industry to alter MCCPs (and LCCP) manufacturing processes to avoid generating the constituents of concern in the first place. Such an approach would require an analytical method that can reliably distinguish the PBT/vPvB MCCP constituents from the rest. Fortunately, techniques such as High Resolution Mass Spectrometry offer a solution.

Restricting the marketing of MCCPs would address emissions arising from imports of both the substance and articles supplied to the EU. Restriction would apply equally to both imported articles and those manufactured within the EU. However, the lack of information on the actual types and quantities of imported articles and costs/feasibility of using other substances or technologies would need to be addressed in order to enable cost-benefit assessment. So as part of considering a wide ranging restriction the UK CA would want to seek more reliable use and release information, together with socio-economic data.

A wide ranging restriction proposal would be likely to trigger a number of requests for derogation during public consultation; further information on end uses, emissions and exposure would enable more effective and proportionate targeting of a restriction. Nevertheless, a decision to implement an initially narrow restriction scope would not preclude widening the scope later in response to more information.

The introduction of restrictions on MCCPs would require the identification of suitable alternatives for all uses that fall within the scope of the restriction. Consideration would need to be given to the substitutes available (or not), their cost and effectiveness compared to MCCPs, their hazard properties, and timescales for product safety testing and re-certification. Companies would be expected to consider comparative hazards and risks of any substitutes before switching.

Restrictions that place limitations on the supply and use of MCCPs would need to take into account the difficulties of separating materials that may contain MCCPs at the waste sorting stage and the economic benefits of recycling materials which may contain greater concentrations of MCCPs than is desirable in new materials. Although specific derogations for recycled material may be a possible solution, there could be difficulties in enforcement if there are different requirements for recycled and new materials. This is an issue that has also been encountered for other restricted substances used in plastics, such as bis(2-ethylhexyl) phthalate (DEHP), lead in PVC and decaBDE. When a solution for this is found it could also be adopted for MCCPs.

The UK CA concludes that Restriction would be a more effective regulatory option than authorisation for minimising releases of MCCPs to the environment, including from imported articles. As a prerequisite, estimates of emissions would need to be refined and a socio-economic analysis conducted, taking into account the availability and technical performance of alternative substances.

**RoHS Directive**

Some uses of MCCPs - for example in the PVC and rubber jackets of electrical cables and wires - fall within scope of the Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment (EEE) Directive (2011/65/EU). This restricts (with some exceptions) the use of listed (Annex II) hazardous substances in the manufacture of various types of electronic and electrical equipment. MCCPs is not currently listed as a restricted substance under RoHS. In June 2018 the Swedish Chemicals Agency (KEMI) submitted a restriction dossier for MCCPs, based on a national prioritisation of chemicals, recommending listing of MCCPs in Annex II of the Directive (KEMI, 2018). The Commission is currently considering the proposal.

The Directive applies to the following types of EEE:

* Large household appliances
* Small household appliances
* IT and telecommunications equipment
* Consumer equipment
* Lighting equipment
* Electrical and electronic tools
* Toys, leisure and sports equipment
* Medical devices
* Monitoring and control instruments including industrial monitoring and control instruments
* Automatic dispensers
* Other EEE not covered by any of the categories above

The Directive does not apply to:

* Equipment which is necessary for the protection of Member States including arms, munitions and war materials intended specifically for military purposes
* Equipment designed to be sent into space
* Equipment which is specifically designed and is to be installed as part of equipment that is excluded or does not fall within the scope of RoHS Directive, which can fulfil its function only if it is part of that equipment, and which can only be replaced by the same specifically designed equipment.
* Large scale stationary industrial tools
* Large scale fixed installations
* Means of transport for persons or goods, excluding electric two wheeled vehicles which are not type approved
* Non-road mobile machinery made available exclusively for professional use
* Active implantable medical devices
* Photovoltaic panels intended to be used in a system that is designed assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial or residential applications.
* Equipment specifically designed solely for the purposes of research and development only made available on a business to business basis.

The KEMI report estimated that approximately 2,100 tonnes of MCCPs were imported by EU states in 2014, in 15,000 tonnes of PVC coated cables.

The UK CA concludes that the RoHS Directive provides a potentially effective regulatory option for a very restricted domain of applicability. This option is already being considered by the Commission. It could be a parallel measure to a REACH restriction, but companies can still request exemptions. The UK CA considers that it may be more efficient to tackle this source as part of a REACH restriction, though the two regulatory instruments are not mutually exclusive.

**The Persistent Organic Pollutants Regulation ((EU) 2019/1021)**

The Persistent Organic Pollutants Regulation restricts the production, placing on the market and use of substances classed as Persistent Organic Pollutants (POPs). It implements the global Stockholm Convention on POPs. Specific time limited use exemptions are permitted.

To be considered for listing as a POP, a substance must be persistent, bioaccumulative, have adverse effects on human health and the environment, and must have the potential for long range transport.

As MCCPs meets the PBT/vPvB criteria in a European context, the UK CA consider that it fulfils the criteria for persistence, bioaccumulation, and adverse effects. Although of low volatility, MCCPs is expected to adsorb strongly to particulates. The atmospheric transport of airborne particulates provides a potential route for long range transport.

The long-range atmospheric transport potential of MCCPs has been considered by Environment Canada (2008). They concluded that the atmospheric half-lives for vapour phase MCCPs ranged from 2.7 to 7.1 days, with the longest half-lives for MCCPs with the highest chlorine contents and also with the shorter chain lengths (for comparison, EU (2005) estimated that the atmospheric half-life was of the order of 1 - 2 days for MCCPs with chlorine contents between 40% and 56% Cl w/w). They concluded that MCCPs have estimated vapour pressures (~4.5×10–8 to 2.27×10–3 Pa at 20 – 25 ºC) and Henry’s law constants (~0.014 to 51.3 Pa.m3/mol) that are in the range of values for some persistent organic pollutants that are known to undergo long-range atmospheric transport, such as lindane, heptachlor and mirex (the corresponding values for these reference substances were not given). This suggests that long-range atmospheric transport could be a possibility for some constituents of MCCPs. It would be important to determine the LRT potential of the specific constituents associated with PBT properties.

MCCPs has been detected in environmental samples from remote regions, such as the Arctic, including in top predators. Only limited information is available on the actual carbon chain length distribution and chlorine contents of the MCCPs detected in environmental samples, although advances in analytical methodologies have meant that this has been possible in some of the more recent studies.

Listing of MCCPs in Annex A (elimination) or Annex B (restriction) of the Stockholm Convention could be implemented with a threshold concentration level to allow recycling of contaminated materials where this represents the best environmental option.

In conclusion, POPs listing is a potentially applicable and effective risk management option, provided that recognises the complexity of the substance – including the finding that only some constituents have PBT properties – and can be implemented in such a way as to allow continued recycling of contaminated materials. POPs listing could be initiated in parallel or subsequent to an EU restriction, and could involve other non-EU countries that are currently contemplating action.

**Water Framework Directive (2000/60/EC)**

The WFD provides a framework for the status assessment and protection of inland surface waters, transitional waters, coastal waters and groundwater. It does not directly address emissions to air or land, although river basin management plans can seek to influence such activities. It places duties on Member States to regulate the release of discharges into the aquatic environment. The Directive itself does not provide any mechanisms to control emissions directly; local emissions to the environment would be controlled by national measures such as environmental permits.

Annex X of the Directive established a list of Priority Substances and Priority Hazardous Substances for control. Annex X and the associated Environmental Quality Standards have been amended in a daughter directive, 2008/105/EC, the EQS Directive.

Identification of MCCPs as a Priority Substance or (more likely) Priority Hazardous Substance (PHS) would require the Commission to establish Environmental Quality Standards (EQS), at the European level, for receiving waters or biota. Member States would then be obliged to plan and deliver programmes of measures to achieve the EQS, where it is technically feasible and not disproportionately costly to do so. If MCCPs were to be designated as a PHS, then Member States would also have to carry out measures for the cessation or phasing out of discharges, emissions and losses to the aquatic environment.

MCCPs is not currently specified as either a Priority Substance or a PHS. The UK, supported by industry, prepared a dossier in relation to including MCCPs in Annex X, but an Expert Group review meeting in May 2010 decided that MCCPs should not go forward to the next step in the process (draft EQS derivation). It may now be appropriate to review that decision. Several substances with related structures or functions, and associated with similar concerns (in particular C10-13 chloroalkanes (SCCPs)), have been designated as PHS, so there may be a consistency case for designating MCCPs as a PHS.

Experience in the UK suggests river basin plans have been of limited effectiveness in reducing releases of PS/PHS to the environment. However, PS/PHS designation has driven extensive monitoring investigations by the sewerage utilities that is generating enhanced understanding of indirect releases via the sewerage network. This, and the potential cost to the sewerage utilities of enhanced sewage treatment to meet prospective permit limits, has increased the sector’s interest in emission sources and is expected to lead to more effective trade effluent control. The UK CA notes, however, that while PS/PHS permit limits for UK sewerage utilities are risk based, they are determined by consideration of EQS and “no deterioration” in water quality, and do not necessarily seek to minimise releases to the environment. Furthermore, there are significant technical challenges to reliably measuring MCCPs concentrations in environmental media, arising from the UVCB nature of the substance.

PS/PHS permit limits would also potentially apply to direct discharges to water from industrial sites. However, many larger sites are regulated under the Industrial Emissions Directive (see below), in which case Best Available Technology considerations would apply to releases. The Directive could, however, provide some impetus for emission reductions with respect to smaller industrial sites that are out of scope for the Industrial Emissions Directive.

The UK CA concludes that whilst providing a potential monitoring tool and indirect emission reduction mechanism (with associated costs for EU Member State regulatory authorities and potentially sewage treatment utilities), the WFD seems unlikely to be able to deliver a consistent and harmonised level of emission reduction across Europe within a reasonable time frame.

**Industrial Emissions Directive (2010/75/EU)**

The Industrial Emissions Directive (IED) requires operators of industrial installations to obtain a permit from the national authorities to continue operating. Permits place a requirement for the use of Best Available Techniques (BAT) to reduce emissions and the impact on the environment as a whole.

The Directive will apply to some sites that use MCCPs, because of the nature and size of the installations. Parts of the life cycle affected include:

* MCCPs production;
* Metalworking (only large companies in the ferrous and non-ferrous metals sectors);
* PVC and rubber/polymers production (mainly larger installations; does not apply to processing alone);
* Paint application (only the largest companies).

All installations covered by Annex I of the Directive must obtain a permit from the national authorities to continue operating. Permits place a requirement for the use of Best Available Techniques (BAT) to reduce emissions and the impact on the environment as a whole, and must include emission limit values for pollutants, in particular those listed in Annex III to the Directive, likely to be emitted from the installation concerned in significant quantities. In addition, the Directive provides for emission limit values to be established at the Community level. Such emission limits would apply to the categories of installations listed in Annex I to the Directive.

IED has the potential to limit emissions from permitted sites. However, many downstream users, such as professional users of paints, sealants and adhesives, and smaller metalworking sites, are unlikely to fall under the control of the Directive. IED only controls part of the lifecycle, and will have no effect on the service life emissions or release from the disposal of articles containing MCCPs.

On the basis that the provisions of the IED will not apply to all the sites where MCCPs may be used, and that the provisions do not apply to key life cycle stages that may create emissions, the UK CA have concluded that the Directive does not provide sufficient means for minimising all environmental emissions of MCCPs.

**Waste Framework Directive (2008/98/EC)**

This directive sets out basic requirements for the management of defined wastes using a hierarchy approach to ensure recovery or disposal without risk to water, air, soil, plants or animals. Costs are borne by the waste producer or waste holder.

Since MCCPs is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H401), any waste mixture containing it at a concentration above 0.25% w/w would be considered to be hazardous waste. Waste oils (such as some types of metal working fluid) must be collected separately (where technically feasible) and Member States may, according to national conditions, apply additional measures such as technical requirements, producer responsibility, economic instruments or voluntary agreements. Waste treatment facilities must obtain permits from the relevant competent authority, which specify technical and other requirements for each type of operation permitted, as well as the safety and precautionary measures to be taken (with monitoring conditions where necessary). Waste management plans must be produced by Member States, which may include economic and other instruments in tackling various waste problems, and awareness campaigns directed at specific sets of consumers. There are no provisions within this directive for information gathering.

The UK CA has concluded that this Directive would not be effective in minimising MCCPs emissions and environmental exposure, although it could reduce exposure from certain waste streams – particularly from metal working plants.

**Voluntary actions**

Voluntary initiatives could be introduced by Industry to raise awareness of MCCPs and its hazardous properties, encourage migration to alternative products and practices, and increase collection, reuse and recycling of materials where this represents the best practicable environmental option. Companies could:

* Communicate measures to reduce emissions to the environment throughout the whole supply chain without regulatory controls.
* Participate in, and facilitate, engagement with interested parties, including stakeholders and regulators.

A programme similar to the Voluntary Emissions Control Action Programme (VECAP) (<http://www.vecap.info/>) could be adopted. The VECAP was developed and implemented by manufacturers and users of several brominated flame retardants. The VECAP demonstrates that industry is willing to take responsibility for the management of flame retardants at the production and product manufacturing stage in an auditable way. It provides support and guidelines to participating companies on how to control and reduce potential emissions of flame retardants to the environment. VECAP is committed to continuous improvement, reviewing what happens in practice each year through a survey, and encouraging users to adopt the industry’s Code of Good Practice and the Best Available Techniques (BAT).

If a similar voluntary initiative were put in place for MCCPs, some reduction in point source emissions from industrial facilities would be expected. Baseline and post-implementation monitoring would be required to quantify emissions and any reductions achieved. The take-up of such a scheme by downstream users would also affect the overall level of emission reduction achievable.

It is important to note that VECAP will have no impact on articles (including those that are imported) as it is not designed to address service life emissions.

The PVC industry has developed a voluntary commitment, VinylPlus, that aims to increase the sustainability of the PVC industry. The programme, which runs to 2020, has set and monitors performance against targets under five themes:

Controlled-loop management (recycling)

Reducing organo-chlorine emissions

Sustainable use of additives

Sustainable use of energy and raw materials

Sustainability awareness

The UK CA concludes that voluntary initiatives could play an important role in reducing MCCPs emissions and environmental exposure. However, it is difficult to see how this approach could be as effective or consistent as a REACH restriction.

## Conclusions on the most appropriate (combination of) risk management options

**Table 14** summarises the expected performance of the five options that the UK CA considers most relevant for further consideration. They represent regulatory alternatives, although they are not strictly mutually exclusive.

**Table 14: Performance of the most relevant RMOs compared to REACH registration**

| **Factors** | **Restriction** | **Authorisation** | **RoHS** | **POPs** | **Voluntary measures** |
| --- | --- | --- | --- | --- | --- |
| Effectiveness for minimising emissions and exposure | **High** – can be targeted at the uses of highest concern, including imports | **Medium –**would not cover imported articles | **Low –**  only covers electrical items, but includes imports | **High** – similar to restriction | **Medium** – measures could encourage substitu-tion |
| Time to outcome (years) | **≥ 3.5 years** in terms of preparing and processing a proposal and entry into force | **≥ 5 years** in terms of SVHC identification, Annex XIV prioritization and processing of applications | **Not known** | **Equal to or longer than restriction** | **Not known** |
| Practicality | **High** – provided that a suitable analytical method is developed | **Low** – a large number of uses could potentially require authorisation | **Not known** | **As restriction** | **Not known** |
| Proportionality (cost effectiveness) | **High** –targeting possible if suitable exposure and socio-economic information is provided | **Medium** – only companies that cannot substitute will need to apply, but if there are many applicants, the combined release could still be relatively high | **Not known –** all relevant uses are within scope, including those with low emission (low risk) | **As restriction** | **Not known** |
| Regulatory consistency | **High** – level playing field for domestic and imported articles | **Medium –** applicants will be treated equally but imported articles are outside scope | **High** – level playing field for domestic and imported articles | **As restriction** | **Medium -** Depends on the level of take-up and awareness within supply chains |
| Robustness to uncertainty in sources and emissions | **Medium –** level of risk is based on available data on emissionsand assumptions | **High** – applicants should be able to provide a good degree of detail about uses (losses during service life may be more difficult to assess) | **Medium –** uses can be exempted on request if suitable argument is provided | **As restriction** | **Not known** – depends how it would be applied (e.g. all users or based on a threshold) |

In conclusion, the UK CA recommends that **MCCPs should be included on the Candidate List and that subsequently a REACH restriction should be initiated.** The restriction would require the collection of additional relevant socio-economic data and better information on releases, if possible. This could then form the basis of **a subsequent POP nomination**. It may be possible to co-operate with non-EU countries such as Switzerland, Canada and Australia in this regard.

## References

EA (2010). Analysis of the most appropriate risk management options for Alkanes, C14-17, Chloro (Medium Chain Chlorinated Paraffins).

EC (2005). European Union Risk Assessment Report: Alkanes, C14-17, chloro- . 3rd Priority List, Volume 58. European Commission Joint Research Centre, EUR 21640 EN.

<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/european-union-risk-assessment-report-alkanes-c14-17-chloro-addendum-final-report-2007-risk>

EC (2007). European Union Risk Assessment Report: Alkanes, C10-13, chloro-. Final Combined Draft updated risk assessment, August 2007. Accessed (2 May 2012) at <http://esis.jrc.ec.europa.eu/doc/risk_assessment/ADDENDUM/sccp_add_010.pdf>.

Glüge J, Schinkel L, Hungerbühler K, Cariou R and Bogdal C (2018). Environmental Risks of Medium-Chain Chlorinated Paraffins (MCCPs): A Review. Environ. Sci. Technol., 52, 6743−6760.

<https://www.ncbi.nlm.nih.gov/pubmed/29791144>

HSE (2008) Conclusion of substance evaluation for transitional dossiers for Medium-chain chlorinated paraffins

<https://echa.europa.eu/documents/10162/13630/trd_uk_mccp_en.pdf/99f3adcd-6481-46f7-a3de-3961158fcf94>

KEMI (2018). RoHS Annex II Dossier MCCPs. Proposal for a restriction of a substance in electrical and electronic equipment under RoHS.

<https://ec.europa.eu/environment/waste/rohs_eee/pdf/SE%20ROHS%20Annex%20II%20Dossier%20MCCP.pdf>

Pilke et al. (2012).How to control and manage hazardous substances in the Baltic Sea region? Final summary report of the COHIBA project. COHIBA Project Consortium.

<https://www.lung.mv-regierung.de/dateien/a3_cohiba_final_summary_report_2012.pdf>

1. Involving at least two substances: Paraffin oils, chloro (CAS no. 85422-92-0, EC no. 287-196-3; and Paraffin waxes and hydrocarbon waxes, chloro (CAS no. 63449-39-8, EC no. 264-150-0). [↑](#footnote-ref-1)
2. Production and all uses are scheduled for elimination, with the exception of use as a fire retardant in dam sealants and rubber used in conveyor belts in the mining industry. Parties should take action to eliminate these uses once suitable alternatives are available. [↑](#footnote-ref-2)
3. C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed August 2019) [↑](#footnote-ref-3)
4. *ECHA dissemination site accessed on 14 August 2019.* [↑](#footnote-ref-4)
5. This assessment of potential alternatives for MCCPs has not considered the quantities of specific alternatives that may have to be used to achieve the same effect as that provided by MCCPs. Where a substantially greater percentage loading is required for an alternative substance, this can affect the technical properties of a material. It will be necessary to take this into consideration in any decisions about the suitability of alternatives for MCCPs. [↑](#footnote-ref-5)
6. https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/MCCPs#RiskCharacterisation [↑](#footnote-ref-6)
7. https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/chlorinated-paraffins.html [↑](#footnote-ref-7)