



Justification for inclusion of a substance in the Rolling Action Plan (RAP) for UK REACH

Substance Name: Paraffin waxes and Hydrocarbon waxes, chloro (Long-chain chlorinated paraffins, LCCP)

EC: 264-150-0, CAS: 63449-39-8

■ March 2022 (Version 1.1)

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1. Purpose/Aim

This document provides justification for including a substance in the rolling action plan (RAP) under Article 44 of UK REACH.

2. Identity of the substance

2.1 Identifiers of the substance

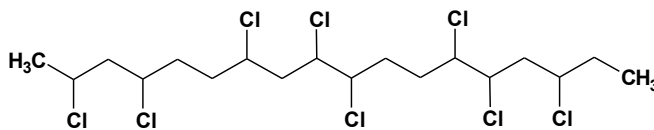
EC name:	Paraffin waxes and Hydrocarbon waxes, chloro
IUPAC name:	Paraffin waxes and Hydrocarbon waxes (C18 and longer), chloro [Chlorinated alkanes (paraffins) predominantly in the carbon number range of C18-C36 and with approximately 20 to 75% chlorine by weight]
CAS no.:	63449-39-8 ¹
EC no.:	264-150-0
Index number in GB Mandatory Classification and Labelling (MCL) list:	Not listed
Molecular formula:	$C_xH_{2x+2-y}Cl_y$, where x = 18 to 36 and y = 1 to 36
Molecular weight or molecular weight range:	420 to 1355 g/mole (approximately)
Synonyms/Trade names:	Long-chain chlorinated paraffins (LCCPs); alkanes, C18-36, chloro; chlorinated paraffins, C18-36; chlorinated paraffin wax; chloroparaffin; chlorinated paraffin waxes and hydrocarbon waxes; hydrocarbon waxes, chlorinated; chlorparaffin; paraffin oils and hydrocarbon oils, chloro
Type of substance:	UVCB

¹ A further Long-chain chlorinated paraffins (LCCPs) substance is Paraffin oils, chloro, CAS: 85422-92-0, and EC: 287-196-3. At the time of publication, this is not currently registered under REACH.

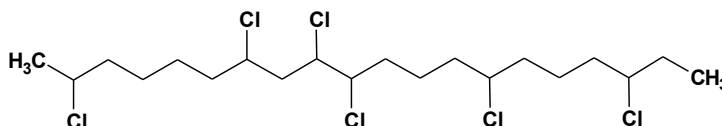
Structural formula:

Example structures

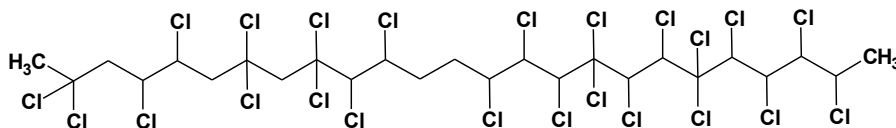
A.



B.



C.



A. $C_{18}H_{30}Cl_8$ LCCP 54% chlorine content by weight (Cl wt.)

B. $C_{20}H_{36}Cl_6$ LCCP 44% Cl wt.

C. $C_{25}H_{29}Cl_{23}$ LCCP 71% Cl wt.

The description of the reference substance in the UK registration is “*chlorinated alkanes (paraffins) predominantly in the carbon number range of C18-36 and with approximately 20 to 75% chlorine by weight.*”

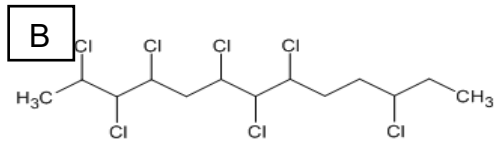
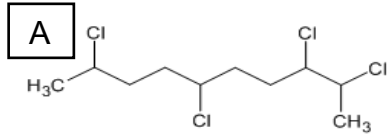
1.2 Similar substances/grouping possibilities

LCCPs are part of the chlorinated paraffins group. Short-chain chlorinated paraffins (SCCPs, CAS no. 85535-84-8) are listed as a Persistent Organic Pollutant (POP) under the United Nations’ Stockholm Convention². The UK performed a Substance Evaluation of medium-chain chlorinated paraffins (MCCPs, CAS no. 85535-85-9) under EU REACH and concluded that it was PBT/vPvB. Subsequently the UK has proposed “*chlorinated paraffins with carbon chain lengths in the range C14–17 and chlorination levels at or exceeding 45 per cent chlorine by weight*” (which includes MCCPs) for identification as a POP.

² Short-chain chlorinated paraffins (Alkanes, C10-13, chloro): straight-chain chlorinated hydrocarbons with chain lengths ranging from C10 to C13 and a content of chlorine greater than 48 per cent by weight

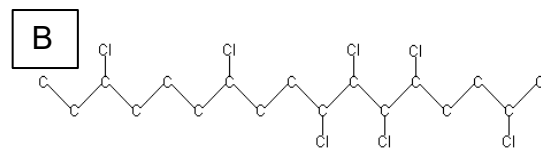
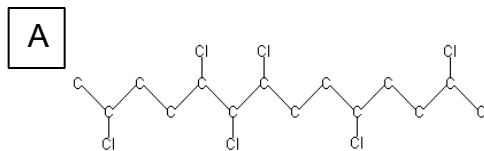
Structural formula:

SCCPs:



- A. $C_{10}H_{18}Cl_4$ SCCP 51% Cl wt.
- B. $C_{13}H_{21}Cl_7$ SCCP 58% Cl wt.

MCCPs



- A. $C_{14}H_{25}Cl_5$ MCCP 48% Cl wt.
- B. $C_{17}H_{29}Cl_7$ MCCP 52% Cl wt.

2. Hazard information (including classification)

2.1 Classification in the GB Mandatory Classification and Labelling List

The substance is not currently listed in the GB Mandatory Classification and Labelling (MCL) list and no proposals to add the substance are planned.

2.2 Harmonised classification in Annex VI of EU CLP

The substance is not listed in Annex VI of EU CLP and no proposals to add the substance are planned.

2.3 Self-classification

- Self-classification in the registration dossier:
 - Not classified
- Self-classification in the ECHA Classification and Labelling (C&L) Inventory³
 - The following hazard classes have been included in notifications submitted to ECHA's C&L Inventory:

Not classified.	
Aquatic Acute 1	H400
Aquatic Chronic 1	H410
Carc. 2	H351
STOT SE 1	H372 (central nervous) (dermal, oral)
STOT RE 2	H373 (liver) (oral)
STOT SE 3	H335
Lact.	H362
Acute Tox. 4	H332
Skin Irrit. 2	H315

³ European Chemicals Agency (ECHA) Classification and Labelling (C&L) Inventory, which includes information submitted by GB-based manufacturers and importers prior to 31st December 2021; <https://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>.

Eye Irrit. 2	H319
Flam. Liq. 2	H225

3. Information on (aggregated) tonnage and uses

3.1 Aggregated tonnages

According to the ECHA dissemination site⁴, the amount manufactured and/or imported into the European Union (EU) is in the range of 10 000 to < 100,000 tonnes per year

There is one UK registration of the substance, stated to be \geq 1000 tonnes per year.

3.2 Uses

The following uses are identified in the registration dossier:

Use Type	Use Identified
Industrial	<ol style="list-style-type: none">1. LCCP Manufacture2. Formulation or re-packing:<ul style="list-style-type: none">• Building and Construction Chemicals• Metalworking Fluids• Lubricants• Polymer/Rubber Compounding• Paper Products3. Uses at industrial sites:<ul style="list-style-type: none">• Production of Cables• PVC• Building and Construction Chemicals• Furniture• Polymer/Rubber Compounding• Painting• Use of Metalworking Fluids• Textile Binders

⁴ Information on substances registered under EU REACH: <https://echa.europa.eu/information-on-chemicals/registered-substances>

	4. Service life <ul style="list-style-type: none">• Flame Retardant (including mining belts)• Production of Cables• Paper Products• Textile Binders• Polymer/Rubber Compounding
Professional	No
Consumer	No
Closed System	No

4. Justification for the selection of the candidate substance

4.1 Legal basis for the proposal

In accordance with Article 44(1) of UK REACH, the substance meets the following criteria for inclusion on the RAP:

Selection Criteria	
CMR ⁵	No
Sensitiser ⁶	No
Endocrine disrupter ⁷	No
PBT/vPvB ⁸	Yes Suspected PBT/vPvB
Substances that are suspected to be persistent, and for which environmental monitoring data or screening laboratory data (such as organic-water partitioning coefficient) indicate the likelihood of widespread distribution in the environment	No
High (aggregated) tonnage (> 1000 tonnes per year)	Yes
Exposure information	Yes

⁵ CMR: known or suspected (e.g., based on structural similarities) carcinogenic and/or mutagenic and/or reprotoxic properties.

⁶ Known or suspected (e.g., based on structural similarities) skin and/or respiratory sensitisers.

⁷ Known or suspected (e.g., based on reproductive effects and/or structural similarities) endocrine disruptors.

⁸ PBT: Known or suspected Persistent, Bioaccumulative and Toxic. vPvB: known or suspected very Persistent and very Bioaccumulative.

4.2 Initial grounds for concern to be clarified under substance evaluation

Hazard based concern:

- **Suspected PBT/vPvB**

The substance has previously been reviewed in a number of national and international assessment programmes^{9,10,11}, which were a result of identified or suspected concerns for SCCPs and MCCPs.

In their UK registration dossier of LCCPs, the registrant concludes the substance is not PBT/vPvB with the following reasoning: *“While it is uncertain if LCCPs meet the P or vP [criteria], they clearly do not meet the criteria for B, vB, or T. As such, LCCPs are not considered PBT or vPvB ... This conclusion is supported by reviews conducted by the European Chemical Bureau (ECB) TC NES PBT Working Group, the OECD High Production Volume Programme, and the UK Environment Agency [same references as above]”.*

The 2019 conclusion that MCCPs meet the REACH PBT/vPvB criteria was based on new data which were not available at the time of the previous LCCPs assessments. As a result, in 2021 the Environment Agency updated the PBT evaluation presented in the assessment¹⁰ above¹⁰ performed under the UK Co-ordinated Chemicals Risk Management Programme (UKCCRMP). The draft conclusions of this update are that LCCPs are highly likely to be persistent (P) and very persistent (vP) according to REACH Annex XIII, the potential for significant bioaccumulation cannot be excluded, and the available aquatic toxicity information does not fully cover all product types. The main arguments are:

- No degradation studies are available for LCCPs that meet current regulatory standards and the key studies cited in the EU REACH registrations cannot be considered reliable. Based on analogy with available data for SCCPs and MCCPs, the potential for biodegradation is dependent on chain length and degree of chlorination. In the absence of reliable measured data, LCCPs meet the P/vP criteria in sediment based on read-across from MCCPs.

⁹ Environment Agency (2009). Environmental Risk Assessment: Long-Chain Chlorinated Paraffins. Science Report. SCHO0109BPGR-E-E.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/290855/scho0109bpgr-e-e.pdf

¹⁰ https://hvpchemicals.oecd.org/ui/SIDS_Details.aspx?id=fe49a841-7d94-4cb0-9b2c-421c1a63e669

¹¹ <https://echa.europa.eu/documents/10162/53d22bf8-517b-41fb-9808-84a9535b4574>

- Shorter chain length LCCP congeners meet the very bioaccumulative (vB) screening criterion based on log K_{ow} values exceeding 5. Experimental data using *Daphnia* suggest that a high level of bioaccumulation for some constituents of LCCPs cannot be ruled out, although a definitive conclusion cannot be drawn due to limitations in the published information. Bioaccumulation in air-breathing organisms becomes more important as chain length and chlorination level increase, and LCCPs have been detected in a wide range of aquatic and terrestrial wildlife, including top predators. Trophic magnification has been claimed in some academic papers, but this is based on analysis of single tissues and small sample numbers, so is not reliable.
- Invertebrates appear to be the most sensitive trophic group in the available aquatic ecotoxicity tests, but the data do not cover all degrees of chlorination of the LCCP products. This means that the toxicity of some of the potentially more bioavailable congeners is not known.
- There are no environmental hazard data in the UK REACH registration dossier as these are not currently required until October 2023 for grandfathered registrations at ≥1000 tpa. The starting point for UK REACH Substance Evaluation will be the Environment Agency's 2021 assessment, which is based on data from the academic literature and ECHA public dissemination site.

Other concerns

Chlorinated fatty acid methyl esters (CFAMES) have been reported as possible impurities or components of commercial chlorinated paraffin mixtures, and they have a high affinity for transthyretin and thyroid receptor proteins *in vitro*¹². The relevance of the data to the LCCP products supplied in the UK is not currently clear and requires further consideration.

Some recent evidence has been published¹³ which suggests that some LCCP congeners may undergo biotransformation to SCCP and MCCPs, both of which have PBT/vPvB properties. This needs further investigation.

Based on information supplied to the Environment Agency, some LCCP products may contain a significant amount of chain lengths that fall into the range of MCCPs. As MCCPs

¹² Sun Y, Cui H, Li T, Tao S, Hu J, Wan Y. Protein-affinity guided identification of chlorinated paraffin components as ubiquitous chemicals. *Environ Int.* 2020 Dec;145:106165. doi: 10.1016/j.envint.2020.106165. Epub 2020 Oct 11. PMID: 33053452.

¹³ He C, van Mourik L, Tang S, Thai P, Wang X, Brandsma SH, Leonards PEG, Thomas KV, Mueller JF. *In vitro* biotransformation and evaluation of potential transformation products of chlorinated paraffins by high resolution accurate mass spectrometry. *J Hazard Mater.* 2020 Oct 10:124245. doi: 10.1016/j.jhazmat.2020.124245. Epub ahead of print. PMID: 33082018.

have been concluded to be PBT/vPvB, the concentration of these in any LCCP products on the UK market needs to be clarified.

More representative physico-chemical property information is needed for the congener groups that are present in LCCPs at different chlorination levels. In particular, new measured water solubility and octanol-water partition coefficient (log Kow) values would aid the interpretation of the environmental fate and behaviour, and ecotoxicity data, and refine exposure modelling.

Exposure/risk based concerns

- **Wide dispersive use**
- **Exposure of environment**
- **High (aggregated) tonnage**

LCCPs are manufactured at high tonnage in the UK and has wide dispersive uses. There is a possibility that the use pattern could change (and level of supply increase) in future in response to international risk management activity on MCCPs. As the substance is not self-classified as hazardous by the registrant, and they do not consider it has PBT/vPvB properties, a Chemical Safety Assessment is unlikely to have been performed, and a current environmental exposure assessment is likely not available. Environment Agency (2009) did identify possible environmental risks from several lifecycle stages, but it was noted that the conclusions were uncertain because of limitations in the available information. An up-to-date exposure assessment would help to clarify whether there are any conventional PEC/PNEC risks, and would provide context for future risk management if any of the hazard concerns are confirmed.

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

Regulatory Process	Action
Dossier Evaluation	No action
Annex 15 – SVHC identification	No action
Annex 14 - Authorisation	No action
Annex 17 - Restriction	No action
Plant Protection Products Regulation	No action
Biocidal Products Regulation	No action
Other	No action

4.5 Preliminary indication of information that may need to be requested to clarify the concern

Determination of water solubility and log K_{OW} of individual or groups of LCCP congeners using OECD Test Guideline (TG) 105 (column elution method) and OECD TG 123 Slow Stirring Method respectively.

Testing to assess the bioaccumulation potential of the C_{18-25} chain lengths, for example OECD TG305 *Bioaccumulation in Fish: Aqueous and Dietary Exposure*.

Testing to assess the aquatic toxicity of different congener groups to invertebrates, for example OECD TG 211 *Daphnia magna Reproduction Test*.

Further information on CFAMES, for example experimental determination of their likelihood to be formed from LCCPs or be present at impurities within LCCPs, and if required *in vitro* or *in vivo* environmental endocrine disruption testing.

Further *in vitro* investigation of the potential of LCCP congeners to undergo biotransformation to SCCP and MCCPs.

Further details of current uses and information on releases to the environment from the life cycle (which may include a request for monitoring data).

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Further information regarding the composition of LCCP products, in particular information regarding carbon chain lengths and chlorination levels.



Further information

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