~~Confidential~~

Helsinki, 20 June 2023

Addressees
Registrant(s) of Long Chain Chlor Paraffin as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
06 August 2019

Registered substance subject to this decision ("the Substance")
Substance name: Paraffin waxes and Hydrocarbon waxes, chloro
also referred to as Long Chain Chlorinated Paraffins (LCCP)
EC number: 264-150-0
In the context of this decision the Substance is also referred to as Long Chain Chlorinated Paraffins (LCCP)

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***25 September 2026***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VII of REACH

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

3. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

Information required from all the Registrants subject to Annex VIII of REACH

4. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

5. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: EU C.47./OECD TG 210)

6. Bioaccumulation in aquatic species, also requested below (triggered by Annex VIII, Section 9.3., Column 2.).)

Information required from all the Registrants subject to Annex IX of REACH

7. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

8. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

9. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided

10. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided

11. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.23./OECD TG 307 or EU C.24./OECD TG 308))

12. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: EU C.13./OECD TG 305, dietary exposure)

Information required from all the Registrants subject to Annex X of REACH

13. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) by oral route, in rats, specified as follows:
    - Ten weeks premating exposure duration for the parental (P0) generation;
    - The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals as specified further in Appendix 1, or follow the limit dose concept. The reporting of the study must provide the justification for the setting of the dose levels;
    - Cohort 1A (Reproductive toxicity); and
    - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.
    - Lactational transfer evaluation must be investigated at least on lactation day 10 (mid-lactation) by quantification of the substance in the pup blood and/or milk as recommended in the OECD Guidance 151 (paragraphs 22-26). If no exposure to the offspring is confirmed via the mothers milk, direct dosing of the offspring must be conducted to ensure that there is no gap in the exposure before weaning.

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

Appendix 1: Reasons for the decision

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Contents

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

1 An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

1.1. Information provided

2 While you have not provided a specific legal reference for your adaptation of this information requirement, ECHA understands that you have adapted this information requirement by using a weight of evidence approach based on the following experimental data:

(i) *in vitro* gene mutation study in bacteria (1981), with the Substance;

(ii) *in vitro* gene mutation study in bacteria (1986), with the Substance;

(iii) *in vitro* gene mutation study in bacteria (1987), with the Substance;

(iv) *in vitro* gene mutation study in bacteria (1980), with the Substance;

(v) *in vitro* gene mutation study in bacteria (1989), with the Substance;

(vi) *in vitro* gene mutation study in bacteria (1989), with the Substance.

3 To support your adaptation, you have also provided the following statements:

4 "*Taking all of the data on LCCPs into account and considering what is known about shorter chain CPs, it is concluded that LCCPs, as a group, are without significant genotoxic potential*."

5 You conclude from these studies that "*LCCPs, like the SCCPs and the MCCPs, do not induce mutations in bacteria*".

1.2. Assessment of the information provided

6 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

7 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

8 According to Guidance on IRs and CSA R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

9 We have assessed this information and identified the following issue:

10 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Section 8.4.1 at Annex VII includes similar information that is produced by the OECD TG 471. The following aspects of genotoxicity are covered: Detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria including data on the number of revertant colonies using 5 bacterial strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either S. *typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

11 The sources of information (i) to (vi) provide relevant information on detection and quantification of gene mutations (base pairs, substitution or frame shift) in bacteria for some of the following recommended *S. typhimurium strains*: TA98; TA100; TA1535; TA1537 or TA97a or TA97. However, none of the source of information (i) to (vi) provide relevant information on gene mutation in one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

12 Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 471 study.

13 In your comments on the draft decision, you reiterate the existing bacterial data on the Substance, as already assessed above, and cite the LCCP OECD SIDS conclusion on genotoxicity: "*There is adequate data to assess the mutagenic potential of LCCPs. LCCPs, like the SCCPs and the MCCPs, do not induce mutations in bacteria. There is some evidence of weak clastogenic potential in vitro in mammalian cells, with chromosomal aberrations observed in CHO cells (with metabolic activation) and also sister chromatid exchanges (at 5-5000 µg/mL with and without activation); however, no evidence of chromosomal aberrations was seen in a well-conducted in vivo study in rat bone marrow cells, in which the rats received doses of up to 5000 mg/kg bw/day for 5 days by gavage. There was also a negative mouse lymphoma assay conducted by the NTP on C23 (average) liquid LCCP. Taking all of the data on LCCPs into account and considering what is known about shorter chain CPs, it is concluded that LCCPs, as a group, are without significant genotoxic potential*."

14 Your comments on the draft decision are based on the same information which was assessed prior to issuing the draft decision. You do not provide new information regarding the genetic toxicity potential of the Substance in the strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

15 Therefore, the information provided in your comments does not change the outcome of the assessment.

16 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

1.3. Specification of the study design

17 To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

2. Growth inhibition study aquatic plants

18 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

19 You have provided:

(i) a study on toxicity to aquatic algae (1997) with the source substance MCCP;

(ii) a study on toxicity to aquatic algae (1975) with the Substance

20 ECHA understands that you intend to adapt this information requirement by using a Grouping of substances and read-across approach based on experimental data from the source substance.

2.2. Assessment of the information provided

21 We have assessed this information and identified the following issues:

22 You have assigned a reliability score of 3 (not reliable) to the study (ii). ECHA agrees with your assessment of the reliability of this information and the study has not been assessed further.

2.2.1. Read-across adaptation rejected

23 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

24 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

25 We have identified the following issue(s) with the prediction of ecotoxicological properties:

2.2.1.1. Absence of read-across documentation

26 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance(s).

27 You have provided a robust study summary for a study conducted with another substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substance(s).

28 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substances.

2.2.1.2. Adequacy and reliability of the study on the source substance

29 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 201. Therefore, the following specifications must be met:

30 Characterisation of exposure

a) for some substances (*e.g.* adsorbing substances), the results may only be

expressed based on nominal concentrations if the decrease in measured concentrations of the test substance during the test is not accompanied by a decrease in growth inhibition. If a reduction in growth inhibition is observed, a suitable model describing the decline of the concentration of the test material must be used;

b) for volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required;

c) if the concentration of the test material has not been maintained within ±20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations during exposure or on a model describing the decline of the concentration of the test material over the exposure period.

31 Your registration dossier provides an OECD TG 201 study (i) showing the following:

32 Characterisation of exposure

a) you have expressed the effect values based on nominal concentrations. The reduction in measured exposure concentrations was accompanied by a reduction in growth inhibition: measured concentration were: at T0h: 0.12, 0.17, 0.29, 0.56, 0.90, 1.5, 2.4 mg/l, at T96h: <0.025, <0.025, <0.025, <0.025, 0.082, 0.031, 0.056 mg/l, mean growth rate reduction as percent from solvent control at T96h: 95, 92, 84, 89, 82, 85, 84, 86%, all values being statistically significantly different to control;

b) the Substance is strongly adsorbing (log Koc of 6.5-10), and no additional sampling for analysis at 24 h interval was conducted;

c) the concentrations of the test material were <0.025-0.056 mg/L and thus not within ± 20 % of nominal or measured initial concentration throughout the test. You have expressed the effect values based on nominal concentration only. Therefore, it does not correspond to either the geometric mean of measured concentrations during exposure or a model describing the decline of the concentration of the test material over the exposure period.

33 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the effect values are expressed based on nominal test concentrations, however, the test material concentration declined by more than 20% of nominal in the course of the study and the decline was also accompanied by a growth inhibition. Moreover, the sampling frequency was not appropriate to account for the decline of test material in the test solution. Therefore, the reported effect values are unreliable.

34 Therefore, the source study does not adequately and reliably cover the key parameters of the OECD TG 201.

35 Consequently, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Therefore, your read-across approach under Annex XI, Section 1.5. is rejected.

36 In your comments to the draft decision you have not addressed the deficiencies noted above, but you have indicated that the Substance is highly insoluble in water which you consider a justification to omit the study.

37 ECHA understands that you intend to adapt this information requirement under Annex VII Section 9.1.2., Column 2.

38 Under Annex VII, Section 9.1.2., Column 2, first indent, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water. Guidance on IRs and CSA, Section R.7.8.5 explains that there is no scientific basis to define a cut off limit for solubility below which toxicity is unlikely. Therefore, the justification must

demonstrate very low water solubility and low likelihood to cross biological membranes. For the latter, the indicators used for likelihood of a high bioaccumulation potential (Guidance on IRs and CSA, Figure R.11-4) must be considered, including (among others) supporting experimental evidence of hindered uptake (e.g. no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

39 Unless it can reliably be demonstrated that aquatic toxicity is unlikely to occur, the Substance must be considered as poorly water soluble.

40 In your dossier, you provide that the saturation concentration of the Substance in water is <5 µg/L.

41 In your comments to the draft decision you provide in addition:

- information on the solubility of a structural analogue substance, EC 287-477-0, MCCP, in water (0.006 mg/L based on OECD TG 105, full study report provided);
- information on the solubility of the Substance in water based on QSAR Toolbox (v4.5) (e.g. C20-C30, 40-50 % Cl wt = 10^{-6} to 10^{-14} mg/L, plot and result table provided)

42 You have not provided a justification on why and how any information on the analogue substance would be relevant for your Substance and the intended adaptation, as already explained above. Nevertheless, the exact water solubility value is not the decisive element to demonstrate that aquatic toxicity is unlikely to occur, under Annex VII Section 9.1.2., Column 2 adaptation.

43 Even though the water solubility of the Substance is low, the following is lacking, or even contradicting from your claim:

- you have not provided any information to justify the low likelihood of the Substance to cross biological membranes;
- more particularly, you have not provided experimental evidence of hindered uptake and none of the ecotoxicological studies in the dossier can support your claim (see also request 6, 7 and 8).

44 As explained in section 6.1 of this decision, literature data indicates that the Substance, or specific congener groups being part of its composition, is taken up by different organisms of the food chain, implying that it is capable of crossing biological membranes. Based on the information provided, you have not demonstrated that aquatic toxicity is unlikely to occur. The Substance must be considered as poorly water soluble and not highly insoluble. Therefore, your adaptation is rejected.

45 On this basis, the information requirement is not fulfilled.

2.3. Study design and test specifications

46 The Substance is difficult to test due to the low water solubility (< 5 µg/L). OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no

observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

47 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

48 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

3. Long-term toxicity testing on aquatic invertebrates

49 Short-term toxicity testing on aquatic invertebrates is an information requirement under Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

3.1. Triggering of the information requirement

50 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

51 In your dossier, you provide that the saturation concentration of the Substance in water is <5 µg/L.

52 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

53 The information provided and the examination of the information provided, the selection of the requested test and the test design as well as your comments to the draft decision in this regards are addressed under request 7.

Reasons related to the information under Annex VIII of REACH

4. In vitro gene mutation study in mammalian cells

54 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

55 Your dossier contains (I) a negative result for *in vivo* Mammalian Bone Marrow Chromosome Aberration Test, and (II) inadequate data for *in vitro* gene mutation study in bacteria.

56 The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in section 1.

57 The result of the request for information in section 1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

58 Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria provides a negative result.

4.1. Information provided

59 You have provided only studies which are assigned a reliability score of 3 (not reliable).

60 Therefore, it is considered that there is no information provided to fulfil this information requirement.

61 In your comments on the draft decision, you do not agree with the request and provide same comment as for request 1.

62 Your comments on the draft decision are based on the same information which was assessed prior to issuing the draft decision. You have not provided any new information regarding genetic toxicity potential in mammalian cells for the Substance.

63 Therefore, the information provided in your comments does not change the outcome of the assessment.

64 On this basis, the information requirement is not fulfilled.

4.2. Specification of the study design

65 To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

5. Long-term toxicity testing on fish

66 Short-term toxicity testing on fish is an information requirement under Column 1 of Annex VIII to REACH (Section 9.1.3.). However, long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

5.1. Triggering of the information requirement

67 In your dossier you provide that the saturation concentration of the Substance in water is <5µg/L.

68 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

69 The information provided and the examination of the information provided, the selection of the requested test and the test design as well as your comments to the draft decision in this regard are addressed under request 8.

6. Bioaccumulation in aquatic species

70 Under Annex VIII, Section 9.3., Column 2, further information on bioaccumulation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the bioaccumulation properties of the substance.

6.1. Triggering of the information requirement

71 This information requirement is triggered if for example additional information on bioaccumulation as set out in Annex XIII, point 3.2.2, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is (potentially) persistent or very persistent (P/vP); and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (log K_{ow} > 4.5).

72 Your registration dossier provides the following on the Substance:

- the Substance (its constituents) has a high potential to partition to lipid storage (Log K_{ow} of 7.5 - >12);
- it is not possible to conclude on the toxicity of the Substance (see Request 7, 8 and 13 of this decision).

73 Regarding persistence, in the CSA you state that "*half-live estimates are difficult to determine accurately based on the biodegradation data set. Based on the relatively slow degradation rates in studies both the ECB TC NEC PBT Working Group (ECB 2007) and the Environment Agency (UK EA 2009) concluded that LCCPs may meet the criteria for P or vP.*" However, you have not provided a definitive conclusion on persistence in your dossier.

74 As pointed out in a proposal for amendment by a member state authority, there is more recent published information relevant for the persistence assessment of the Substance. In the SVHC dossier of MCCP[2] it is concluded based on the predicted and observed trends in physico-chemical properties that the C15Cl3-15, C16Cl3-16 and C17Cl3-17 congener groups of MCCP meet the 'persistence' (P) and 'very persistent' (vP) criteria of REACH Annex XIII (degradation half-life in sediment > 180 days). As structurally similar LCCPs (with longer carbon chain length and comparable chlorination degree, i.e. Cl% in wt. by wt., if compared to MCCP) are expected to be even less water soluble and more adsorptive than C≤17 CP substances, the same conclusion could also be drawn for LCCPs. For the same reason, the UK Environment Agency concluded, in the absence of reliable measured data to the contrary, that LCCPs meet the persistent (P) and very persistent (vP) criteria in

[2] https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e185f78852

REACH Annex XIII based on likely sediment half-life[3]. In the assessment performed under the Canadian Environmental Protection Act (1999, including Follow-up Report from 2008) it was also concluded that based on their physical/chemical properties, which are similar to those of MCCPs, and increasing carbon-chain length LCCPs are expected to be persistent as defined in the Persistence and Bioaccumulation Regulations of CEPA 1999[4]. In this act a substance is persistent in water, when its half-life is equal ≥ 182 days; in sediments, when its half-life is ≥365 days; or in soil, when its half-life is ≥ 182 days.

75 Based on the available information, not yet included in your dossier, the Substance can be considered to meet the P/vP criteria.

76 Regarding bioaccumulation, the Substance fulfils the screening criteria for being potentially B or vB based on logKow >4.5.

77 In your comments to the draft decision you seem to disagree with the use of this value (i.e. logKow) to trigger the need for bioaccumulation testing. However, you do not provide any further information to substantiate your claim. As explained above, a log Kow range of 7.5 - >12 was reported in your registration for the Substance indicating that the screening criteria for the Substance, or its constituents/congeners thereof, to be B/vB are met (Guidance on IRs and CSA R. 11.4.1.2.1).

78 As explained in Request 12, you used (Q)SAR prediction to conclude on bioaccumulation properties of the Substance. Non-testing data, such as calculations and/or (Q)SAR predictions, can be used in a weight of evidence approach for B and vB assessment (Guidance on IRs and CSA R.11). This implies that a single source of information on such non-testing data cannot be used alone to conclude on bioaccumulation potential.

79 In addition to the above, and as explained in request 12, we also identified issues with the reliability of the prediction.

80 ECHA notes that literature data indicate that the Substance, and in particular specific congener groups being part of the Substance composition, are taken up by organisms and also found in biota of different levels in the food chain as well as in different habitats (e.g. Castro et al., 2019; Castro et al., 2020; de Wit et al. 2020; Yuan et al., 2019; Yuan et al., 2021). Therefore, there are clear indications that the Substance, and in particular specific congener groups show concern of accumulation/biomagnification in the food chain.

81 In your comments to the draft decision you state that the above mentioned references are "*not on studies of LCCP as registered in the EU*". However, you did not provide any justification on which basis you question the relevance of this data. Therefore, ECHA is not in the position to reply to your comment.

82 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.

83 Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

[3] Environment Agency (2022) Persistent, Bioaccumulative and Toxic (PBT) properties of Long Chain Chlorinated Paraffins LCCPs), Environment Agency, Bristol
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1091341/Persistent_Bioaccumulative_and_Toxic_PBT_properties_of_Long_Chain_Chlorinated_Paraffins_LCCPs_-_report.pdf

[4] Chlorinated paraffins (2008) Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health, Canadian Environmental Protection Act, 1999
https://www.canada.ca/content/dam/eccc/migration/main/lcpe-cepa/documents/substances/pc-cp/cps_followup-eng.pdf

84 The examination of the available information or adaptations, the selection of the requested test, the test design, as well as the additional data you provide in your comments to the draft decision to meet the information requirement are addressed in Request 12.

Reasons related to the information under Annex IX of REACH

7. Long-term toxicity testing on aquatic invertebrates

85 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

7.1. Information provided

86 You have provided:

(i) A study on long-term toxicity on aquatic invertebrates (1983, report number BL/B/2290) with the Substance;

(ii) A study on long-term toxicity on aquatic invertebrates (1994) with the Substance;

(iii) A study on long-term toxicity on aquatic invertebrates (1984) with the Substance;

(iv) A study on long-term toxicity on aquatic invertebrates (1993) with the Substance;

(v) A study on long-term toxicity on aquatic invertebrates (1983, report number BL/B/2288) with the Substance;

(vi) A study on long-term toxicity on aquatic invertebrates (2007) with the Substance.

7.2. Assessment of the information provided

87 We have assessed this information and identified the following issues:

88 You have assigned a reliability score of 4 (not assignable) to the study (iii). ECHA agrees with your assessment of the reliability of this information and the study has not been assessed further.

7.2.1. The provided studies do not meet the information requirement

89 To fulfil the information requirement, a study must comply with the OECD TG 211 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

90 Key parameter to be measured

a) the concentrations of the test material leading to no observed effect (NOECs) on the following parameters are estimated:
   - the reproductive output of *Daphnia* sp. expressed as the total number of living offspring produced at the end of the test, and
   - the survival of the parent animals during the test, and
   - the time to production of the first brood.

91 Technical specifications impacting the sensitivity/reliability of the test

b) the test is conducted on *Daphnia magna* Straus as test species or any other clearly identified daphnids if the selected species meets the validity criteria and appropriate justification is provided;

c) the test concentrations are below the limit of solubility of the test material in the

dilution water;

92 Test solution preparation methods

d) a solvent must not be used for multi-constituent substances and UVCBs;

e) if water-accommodated fractions (WAFs) are used, they must be prepared separately for each dose level;

93 Characterisation of exposure

f) analytical monitoring must be conducted;
g) A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;
h) if the concentration of the test material in semi-static tests:
    i. is expected to remain within ± 20 % of the nominal concentration, then the test material concentration must be determined (in one replicate) in the highest and lowest test concentrations when freshly prepared and at the time of renewal on one occasion during each week of the test,
    ii. is not expected to remain within ± 20 % of the nominal concentration, then all test concentrations must be determined when freshly prepared and at the time of renewal on one occasion during each week of the test.

94 Your registration dossier provides studies, which you describe as long-term toxicity to aquatic invertebrates studies, showing the following:

95 Key parameter measured

a) In studies (i), (ii), (iv), (v) and (vi) the concentrations of the test material leading to no observed effect NOECs) were not estimated on the following parameter(s):
    - the time to production of the first brood;

    In studies (i) and (v), in addition, the following key parameter was not determined:
    - the reproductive output of *Daphnia* sp. expressed as the total number of living offspring produced at the end of the test;

96 Technical specifications impacting the sensitivity/reliability of the test

b) in studies (i) and (v) the test was conducted on *Mytilus edulis* which is not a daphnid species without further justification;
c) in study (iv) the test concentrations were 2.0, 4.0, 8.0, 16, 32 and 64 µg/L and your report in your dossier a limit of solubility of the test material in water of < 5 µg/L;

97 Test solution preparation methods

d) in studies (i), (v) and (vi) a solvent (i.e. Acetone, or dimethylformamide) was used even though the Substance is a UVCB;

e) In studies (ii) and (iv) test concentrations were prepared by using dilutions of WAFs;

98 Characterisation of exposure

f) In study (iv) no analytical monitoring of exposure was conducted;
g) In study (ii) the analytical method used to determine test material concentrations was based on organic Cl only but not specific for the Substance.

In study (vi) it was based on measuring radioactivity of labelled C25, 43 %Cl, and you did not provide justification why this particular constituent can be considered key component of the Substance;

h) Study (ii) was a semi-static test and the test material concentration was determined only in the prepared WAF solution before dilution, but not in the actual test solutions and not at the different concentration levels or before the renewal

99 Based on the above,

- The information provided does not cover all the key parameter(s) required by the OECD TG 211 (studies (i), (ii), (iv), (v) and (vi)).
- The Substance is difficult to test based on its low water solubility of < 5 µg/L and there are critical methodological deficiencies resulting in the rejection of the studies (i) to (vi).
- Due to the lack of (study iv) or because of using non-substance specific (study (ii) and (vi)) analytical monitoring methods or inappropriate sampling scheme (study (ii)) to determine test material concentrations, it is not possible to verify if the test organisms were exposed to the Substance. Moreover, in study (vi) you state that the analytical method does not allow to differentiate between truly dissolved and non-dissolved substance. In this study, tested concentrations were above the solubility limit of the Substance. Consequently, you did not prove that the test organisms were actually exposed to the dissolved Substance. Therefore, (no) effect values reported in study (ii), (iv) and (vi) are not reliable.
- Use of a solvent as in study (i), (v) and (vi) or serial dilution of a WAF as done in study (ii) and (iv) to obtain final test solutions are both methodological procedures that are not applicable for UVCBs as they might give preferential dissolution of one or more components and therefore affect toxicity.
- Furthermore, as regards study (i) and (v), in the lack of any justification we cannot verify whether results obtained with other species than *Daphnia magna* were relevant and reliable to conclude on the (absence) of the hazard of the Substance.

100 Therefore, the requirements of OECD TG 211 are not met in any of the provided studies (i) to (vi).

101 In your comments to the draft decision you consider study (vi) as valid based on the fact that it uses C25 radiolabelled compound which you claim to be the average carbon chain length for most LCCP products.

102 You did not explain how tracing the constituents with the average carbon chain length only provides conclusive proof of test material stability in the study and by this proof of appropriate exposure conditions that are representative for the Substance and in accordance with respective test guideline. Therefore, the deficiency as explained under g) remains. Further, you did not address the other deficiencies listed above under (a) and d) for study (vi). Therefore, the requirements of OECD TG 211 are not met for study (vi).

103 In addition, in your comments to the draft decision you also indicate that the Substance is highly insoluble in water without further explaining the relevance of this to the current information requirement.

104 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

105 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

106 Therefore, you have not demonstrated that this information can be omitted.

107 On this basis, the information requirement is not fulfilled.

7.3. Study design and test specifications

108 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 2.

8. Long-term toxicity testing on fish

109 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

8.1. Information provided

110 You have provided:

(i) A study on adult fish: sub(lethal)effects (1983) with the Substance;

(ii) A study on adult fish: sub(lethal)effects (1979) with the Substance;

(iii) A study on fish, juvenile growth test (1974) with the Substance;

(iv) A study on fish, juvenile growth test (1983) with the Substance

8.2. Assessment of the information provided

111 We have assessed this information and identified the following issues:

112 You have assigned a reliability score of 3 (not reliable) to the study (iii). ECHA agrees with your assessment of the reliability of this information and the study has not been assessed further.

8.2.1. The provided studies (i) and (iv) do not meet the information requirement

113 To fulfil the information requirement, a study must comply with the OECD TG 210 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

114 Key parameters to be measured

a) parameters related to the survival and development of fish in early life stages from the stage of fertilized egg until the juvenile life-stage following exposure to the test substance are measured, including:
   i. the stage of embryonic development at the start of the test, and
   ii. hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
   iii. the appearance and behaviour of larvae and juvenile fish, and
   iv. the weight and length of fish at the end of the test.

115 Validity criteria

b) the analytical measure of the test concentrations is conducted.

116 You have provided studies (i) and (iv), which you describe as long-term toxicity to fish studies, showing the following:

117 Key parameters to be measured

a) study (iv) was conducted on animals of 1.4 – 3.2 g weight and study (i) does not provide information on the lifestage of the tested animals. Both do not correspond to an early-life stage for rainbow trout, from the stage of fertilized egg to juvenile. The following parameters were not covered in both studies (i) and (iv):
   i. the stage of embryonic development at the start of the test, and
   ii. hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
   iii. the appearance and behaviour of larvae and juvenile fish, and
   iv. the weight and length of fish at the end of the test.

118 Validity criteria

b) in study (i) no analytical monitoring of exposure was conducted.

119 Based on the above:

- studies (i) and (iv) do not cover the key parameter(s) required by the OECD TG 210;
- study (i) does not meet the validity criteria of OECD TG 210 since analytical monitoring was not conducted.

120 Therefore, the requirements of OECD TG 210 are not met for study (i) and study (iv).

8.2.2. The OECD TG 204 used for study (ii) is not a valid test guideline to meet this information requirement

121 To fulfil the information requirement, a study must be a long-term fish test. Guidance on IRs and CSA, Section R.7.8.4.1. specifies that only studies in which sensitive life-stages (juveniles, eggs and larvae) are exposed can be regarded as long-term fish tests.

122 In study (ii) described as being equivalent or similar to an OECD TG 204 study only adults/juveniles were exposed to the test material.

123 This study does not provide information on the toxicity of the test material to all relevant sensitive life-stages (i.e. juveniles, eggs and larvae). OECD TG 204 only provides information on prolonged acute toxicity and, based on the above, it does not qualify as a long-term fish test. Therefore, this information is rejected.

124 In your comments to the draft decision you also indicate that the Substance is highly insoluble in water without further explaining the relevance of this to the current information requirement.

125 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

126 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

127 Therefore, you have not demonstrated that this information can be omitted.

128 Taken together, the information requirement is not fulfilled.

8.3. Study design and test specifications

129 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

130 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 2.

9. Soil simulation testing

131 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

132 The Substance has low water solubility (<0.5 µg/L), high partition coefficient (log Kow 7.5 - >12) and high adsorption coefficient (log $K_{oc,soil}$ of 6.5-10) and therefore has high potential for adsorption to soil.

9.1. Information provided

133 You have provided:

(i) A biodegradation in soil study (1987) with the Substance.

9.2. Assessment of information provided

134 We have assessed this information and identified the following issue:

9.2.1. The provided study does not meet the information requirement

135 To fulfil the information requirement, a study must comply with the OECD TG 307 (Article 13(3) of REACH). Therefore, the following specifications must be met:

136 Key parameters to be measured

a) the study covers the following:
- the rate of aerobic and anaerobic transformation of the test material in four soil types, and
- the identity and rates of formation and decline of transformation products in at least one soil type.

137 In study (i) which you describe as biodegradation in soil study:

138 Key parameters

a) the parameter monitored was formation of chloride ion using a mixed bacterial inoculum isolated from soil:
- no transformation rate was determined for the test material and the study was not conducted in soil,
- no formation rate of chloride ion was determined and no other transformation products were identified.

139 Based on the above, the information provided does not cover the key parameter(s) required by the OECD TG 307.

140 Therefore, the requirements of OECD TG 307 are not met.

141 On this basis, and in absence of an adaption in the dossier, the information requirement is not fulfilled.

142 In your comments to the proposal for amendment you have indicated your agreement with the reasoning provided in the proposal for amendment from a member state authority with regards to the conclusion on P/vP properties of the Substance and lack of need to perform further testing. On this basis, you agree that the Substance can be concluded as P/vP based on an adaptation according to Annex XI section 1.5 of REACH, using biotransformation data on sediment on the analogue substance EC 287-477-0 (MCCP). You also acknowledge that this conclusion is in line with the SEv process conducted by UK.

143 ECHA agrees that the adaptation according to Annex XI section 1.5 of REACH, using biotransformation data on sediment on the analogue substance EC 287-477-0 (MCCP) may address the information requirement if provided in the dossier. However, as the relevant information is currently not provided in your dossier, you remain responsible for complying with this decision by the set deadline.

9.3. Study design and test specifications

144 In case no adaptation is submitted, the following must be considered for the study design.

145 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

146 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

147 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

148 In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

149 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.). Further considerations with regards to the choice of test material(s) are set out under Section 12.3 of this decision, which applies correspondingly to this request.

10. Sediment simulation testing

150 Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

151 The Substance has low water solubility (<0.5 µg/L), high partition coefficient (log Kow 7.5 - >12) and high adsorption coefficient (log $K_{oc,soil}$ of 6.5-10) and therefore has high potential for adsorption to sediment.

10.1. Information provided

152 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substance:

(i) a biodegradation in sediment study (1998) with the analogue Medium-Chain Chlorinated Paraffin, CAS 85525-85-9;

153 In addition, you have provided the following justification to omit the study:

154 "*the study does not need to be conducted because the substance is highly insoluble in water*"

10.2. Assessment of information provided

155 We have assessed this information and identified the following issues:

10.2.1. Read-across adaptation rejected

156 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

157 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

158 We have identified the following issue(s) with the prediction of environmental fate properties:

10.2.1.1. Absence of read-across documentation

159 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance(s).

160 You have provided a robust study summary for a study conducted with another substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substance(s).

161 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance(s).

10.2.1.2. Adequacy and reliability of the study on the source substance

162 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 308. Therefore, the following specifications must be met:

163 Key parameters

a) the study covers the following key parameters:
   - the rate of aerobic and/or anaerobic transformation of the test material on at least two sediments, and

- the identity and rates of formation and decline of transformation products;

164 Technical specifications impacting the sensitivity/reliability of the test

b) for an aerobic study, two sediments differing with respect to organic carbon content and texture are used, including:
   - a sediment with high organic carbon content (2.5-7.5%) and a fine texture, and
   - a sediment with low organic carbon content (0.5-2.5%) and a coarse texture.

165 In study (i), which you describe as biodegradation in sediment study:

166 Key parameters

a) The following is covered:
   - the rate of transformation of the test material was determined only in one sediment and
   - the identity and rates of formation and decline of transformation products was not determined. Instead you determined degradation by means of "*the difference between toluene-extractable 14C measurements (taken to represent unchanged chlorinated paraffin) and total 14C measurements"* only;

167 Technical specifications impacting the sensitivity/reliability of the test

b) the test was conducted in only one sediment which also contained oligochaetes.

168 Based on the above,

- the information provided does not cover all the key parameter(s) required by the OECD TG 308
- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically the presence of oligochaetes in the test medium might have considerably impacted the biodegradation behaviour of the test material in the study and therefore its results are not reliable. Further, you did not determine identity of the 14C test material, so that it cannot be concluded whether the measured radioactivity represents the parent or potential degradation products. The study results are derived based on the assumption that 14C-labelled test material which is not extractable with toluene can be considered as degraded even though you did not further determine its identity. Guidance on IRs and CSA R.11 states on non-extractable residues that "…*the residues should be regarded, (…), as non-degraded substance, unless, on a case-by-case basis, it can reasonably be justified or analytically demonstrated that a certain part of the residues can be considered to be irreversibly bound*." You did not explain as to why the non-extractable C14 test material can be considered as degraded. Therefore, derived half-lives might overestimate the biodegradation rate and are thus not reliable.

169 Therefore, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG.

10.2.2. Your justification to omit the study has no legal basis

170 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.4., column 2.

171 Your justification to omit this information due to the substance being highly insoluble is not among any legal grounds for adaptation under Section 9.2.1.4, Column 2 of Annex IX or Annex XI to REACH.

172 Therefore, you have not demonstrated that this information can be omitted on any valid legal basis.

173 On this basis, and in the absence of another adaptation from the dossier, the information requirement is not fulfilled.

174 In your comments to the proposal for amendment you have indicated your agreement with the reasoning provided in the proposal for amendment from a member state authority with regards to the conclusion on P/vP properties of the Substance and lack of need to perform further testing. On this basis, you agree that the Substance can be concluded as P/vP based on an adaptation according to Annex XI section 1.5 of REACH, using biotransformation data on sediment on the analogue substance EC 287-477-0 (MCCP). You also acknowledge that this conclusion is in line with the SEv process conducted by UK.

175 ECHA agrees that the adaptation according to Annex XI section 1.5 of REACH, using biotransformation data on sediment on the analogue substance EC 287-477-0 (MCCP) may address the information requirement if provided in the dossier. However, as the relevant information is currently not provided in your dossier, you remain responsible for complying with this decision by the set deadline.

10.3. Study design and test specifications

176 In case no adaptation is submitted, the following must be considered for the study design.

177 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

178 In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

179 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

180 In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

181 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; Guidance on IRs and CSA, Section R.11.4.1.).

182 In the comments to the draft decision you claim that the Substance is highly insoluble and therefore the requested OECD TG 308 or its technical specifications would not be appropriate for the Substance. You did not provide any substance-related evidence to support your claim on the inappropriateness of the test method or its specifications.

183 The OECD TG 308 provides in particular that this test is applicable to water-soluble and poorly water-soluble compounds. As regards to water solubility, no lower limit is specified under which the study would be not feasible.

184 Further considerations with regards to the choice of test material(s) are set out under Section 12.3 of this decision, which applies correspondingly to this request.

11. Identification of degradation products

185 Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

11.1. Information provided

186 You have provided the following information:

(i) In a biodegradation in soil study (1987) with the Substance chloride was identified as degradation product.

11.2. Assessment of information provided

187 We have assessed this information and identified the following issues:

11.2.1. The provided study is not reliable

188 As explained under Request 9, section 9.2, of this decision the provided study is not reliable.

11.2.2. The information provided does not cover all relevant transformation/degradation products

189 To fulfil the information requirement, information on the identity of relevant transformation/degradation products must be provided (Annex XIII, fifth paragraph; Guidance on IRs and CSA, Section R.11.4.1.). For a study conducted according to OECD TG 307 relevant transformation/degradation products that must be identified include:

- those representing over 10% of the applied dose, and
- those accumulating over time during the test.

190 Study (i), which you describe as biodegradation study in soil, shows degradation of the Substance based on formation of chloride. In this study, no other transformation/degradation products that correspond to over 10% of the applied radioactivity / that accumulate over time during the test were identified and no justification was provided.

191 Therefore, and as also explained under section 9.2, study (i) does not comply with the requirements of OECD TG 307 as it does not provide information on the identity of all relevant transformation/degradation products.

192 Therefore, the information requirement is not fulfilled.

193 Information on identity of relevant transformation/degradation products is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

194 In your comments to the draft decision you provide:

- a claim that identification of degradation products is impossible due to the general fact that individual isomers of the Substance's composition cannot be identified. You did not further substantiate this claim.
- an OECD TG 314B study (2022) with MCCP, 52% Cl wt. in which no degradation products were identified, except for the formation of H_2O

195 Firstly, ECHA notes that the Substance is a UVCB. Guidance on PBT/vPvB assessment R.11 Section 4.1.1. provides how identification of degradation products can be accomplished for UVCB substances taking into account that not every (single) constituent of the parent can be identified individually. In any case, the information on degradation products is needed for PBT/vPvB assessment of the Substance. Therefore, degradation products must be identified to such extend that allows drawing a conclusion on the PBT/vPvB properties of the degradation products.

196 Secondly, ECHA understands that you intend to apply a read-across approach according to Annex XI Section 1.5.

11.2.3. Read-across adaptation rejected

197 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

198 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

199 We have identified the following issue(s) with the prediction of environmental fate properties:

11.2.3.1. Absence of read-across documentation

200 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance(s).

201 You have provided a robust study summary for a study conducted with another substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substance(s).

202 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance(s).

11.2.3.2. Study not adequate for risk assessment / classification and labelling

203 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

204 For that purpose, the identification of the transformation/degradation products should be done according to the OECD TGs 307, 308 and 309 (Guidance on IR and CSA Section R.7.9.4.1).

205 You have provided a study performed according to OECD TG 314 B with the source substance.

206 OECD TG 314 B is not a recognised test method to identify relevant degradation products. This is because it does not reflect environmentally relevant conditions. You have not provided any further justification why this study type is adequate.

207 Identification of degradation products is critical for PBT/vPvB assessment under Annex XIII. Since the study provided follows a design that does not reflect environmentally relevant conditions, the results it suggests, i.e. the lack of degradation products formed in your case, are considered not adequate to conclude on the PBT/vPvB assessment and risk assessment of the Substance. Therefore, the results of this study are not adequate for the purpose of classification and labelling and/or risk assessment.

208 On this basis, and in the absence of another adaptation from the dossier, the information requirement is not fulfilled.

11.3. Study design and test specifications

209 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation need to be investigated. You must obtain this information from the degradation studies requested in Requests 9 or 10.

210 To determine the degradation rate of the Substance, the requested studies according to OECD TG 307 and 308 (Requests 9 and 10) must be conducted at 12°C and at a test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

12. Bioaccumulation in aquatic species

211 Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

12.1. Information provided

212 You have adapted this information requirement by using Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs). To support the adaptation, you have provided:

(i) A calculation of three BCF values based on three logKow values using the equation: $\log BCF = -0.20 \times (\log Kow)^2 + 2.74 \times \log Kow - 4.72$

12.2. Assessment of information provided

213 We have assessed this information and identified the following issue:

12.2.1. Assessment of your (Q)SAR adaptation

214 Under Annex XI, Section 1.3., among others the following conditions must be fulfilled whenever a (Q)SAR approach is used:

(1) the substance must fall within the applicability domain of the model,

(2) results need to be adequate for the purpose of risk assessment or classification and labelling.

215 With regard to these conditions, we have identified the following issue(s):

12.2.1.1. The substance is outside the applicability domain of the model

216 Under Guidance on IRs and CSA Section R.6.1.5.3., a substance must fall within the applicability domain specified by the model developer.

217 The applicability domain of the model you used is defined in EU TGD Part III Section 4.5.3 and the upper limit of the model is defined to be at logKow of 10.

218 The logKow values used as input for the prediction were: 9.7, 10.3, and 17.

219 The logKow values used as input for the prediction exceed the threshold up to which the equation can be reliably used.

220 Therefore, you have not demonstrated that the Substance falls within the applicability domain of the model and the reported BCF values are considered not reliable.

12.2.1.2. The prediction does not cover all constituents of the Substance

221 Under Guidance on IRs and CSA SectionR.6.1.7.3. a prediction is adequate for the purpose of classification and labelling and/or risk assessment if the following cumulative conditions are met:

- the composition of the substance is clearly defined, and
- different constituents of the same substance are predicted individually.

222 Your registration dossier provides the following information:

- In Section 1.1 of your technical dossier, you define the Substance as UVCB
- In Section 1.2, you indicate the following constituent in the composition of your Substance: "[redacted]"
- For the assessment, you provided BCF predictions using the following logKow values:
  - logKow = 9.7 to represent C18-C20;
  - logKow = 10.3 to represent C20-C30 (liquid);
  - logKow = 17 to represent C20-C30 (solid)

223 You have used three logKow values for the prediction in order to represent three considerably broad ranges of carbon chain lengths while the Substance is composed of an undefined number of constituents beyond these carbon chain lengths. Further, you did not specify which chlorination degree of the respective constituents the chosen logKow values are sought to represent. Moreover, you have not explained why the chosen logKow values are adequate to represent the respective carbon chain length range. Therefore, you have not covered all constituents of the Substance.

224 Therefore, you have not demonstrated that the prediction is adequate for the purpose of classification and labelling and/or risk assessment.

225 Based on the above, as the conditions of the adaptation under Annex XI, Section 1.3. are not met, your adaptation is rejected.

226 In your comments to the draft decision you do not provide any information to address the deficiencies noted above. However, you provide results of a new QSAR prediction using BCFBAF v3.01 model with $C_{20}Cl_{5,6,8 \text{ and } 18}$, $C_{25}Cl_{7,8,10, \text{ and } 22}$ and $C_{30}Cl_{8,9,12,\text{and } 26}$ constituents respectively, indicating BCF values ranging from 0.89-25.75 L/kg wet-weight.

227 The conditions as explained under section 15.2.1. must be met when a (Q)SAR approach is used under Annex XI, Section 1.3.

228 With regard to these conditions, we have identified the following issue(s) with the information you provided in your comments.

12.2.1.3. Lack of documentation of the model (QMRF) and the prediction (QPRF)

229 Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and Guidance on IRs and CSA R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;
- an unambiguous definition of the algorithm, the descriptor(s) of the model and its applicability domain,
- an estimate of the goodness-of-fit and of the predictivity of the model, including information on training set and validation statistics.

230 Guidance on IRs and CSA R.6.1.6.3. also states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the model prediction(s), including the endpoint,
- a precise identification of the substance modelled,
- the relationship between the modelled substance and the defined applicability domain,
- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

231 You have not provided information about the model or the prediction.

232 In absence of such information, ECHA cannot establish that the model can be used to meet this information requirement.

233 Based on the above, as the conditions of the adaptation under Annex XI, Section 1.3. are not met, your adaptation is rejected.

234 On this basis, the information requirement is not fulfilled.

12.3. Study design and test specifications

235 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted whenever technically feasible. The low water solubility (<0.5 µg/L) and the high adsorption potential (log K_{ow} of 7.5- >12 / log K_{oc} of 6.5-10) of the Substance indicate significant uncertainty on the feasibility of a study using aqueous exposure. Therefore, in this case, the test is requested to be performed using dietary exposure. You must also attempt to estimate the corresponding BCF value from the dietary test (OECD 305-III) data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO (2017)16).

236 As explained under Request 6, section 6.1, there are indications that congener groups[5] being part of the Substance composition are of concern for bioaccumulation. Further, different congener groups may differ in their bioaccumulation behaviour. OECD TG 305 states that "the whole procedure is governed essentially by the accuracy, precision and sensitivity of the analytical method used for the test substance". Therefore, and also in line with specifications in Appendix 4 section 2.1 of this decision, in order to obtain adequate and reliable results to conclude on the B and vB properties of the Substance, the analytical method used to monitor concentrations of the test material in this study, and based on which ultimately BMF values will be derived, must be sufficiently specific, precise and accurate, so that the bioaccumulation behaviour of the different congener groups of the constituents can be determined.

237 The assessment must consider all the compositions reported in the registration dossiers.

238 The reported boundary composition of the Substance covers different compositional profiles and indicates that the Substance consists of [redacted]. The test material or the test materials must be selected so that results represent all relevant congener groups present in the reported compositions of the Substance.

239 For instance, if you choose to use only one test material, it may be prepared as a mixture of different compositions you have described in section 1.2 of your IUCLID dossier, to cover the whole relevant range of carbon-chain lengths and chlorination degrees as defined in the boundary composition (C18-C31 20-75% Cl wt. with an analytical method that enables the simultaneous monitoring of each congener group present in the samples object of the study. Alternatively, the different compositions manufactured could be tested separately.

240 With regard to the required sensitivity of the analytical method, it is important to consider that the minimum level of BMF value that could be derived should be in the range of 0.05 to be able to discriminate between bioaccumulative and non-bioaccumulative substances (based on a BMF of 0.1 corresponding to bioaccumulative substances). This means that for each congener group, the limit of detection in fish should not be higher than 1/20th of the concentration in food. If this sensitivity cannot be achieved by testing the whole substance, testing smaller subfractions should be considered.

241 In any case the test material should be selected in a way that the monitoring enables quantification of at least congener groups having chain lengths between C18 and C25 and chlorination degree of 40 to 50% wt.

[5] The wording 'congener group' refers to a group of constituents sharing the same empirical formula irrespective of the position of the chlorine substituents on the carbon chain (e.g. the $C_{18}Cl_9$ congener group).

242 A justification on the choice of the test material(s) and its preparation must be provided.

243 Suitable analytical methods can be found in scientific literature and in international standards. Typically, the following techniques have shown to fit the purpose of the requested determination:

- GC or GCXGC - APCI-qTOF-HRMS: gas chromatography (GC) coupled to high-resolution mass spectrometry (HRMS) often with hybrid HRMS mass analyzers, such as quadrupole-time of flight (QTOF) with soft ionization promoted by atmospheric pressure chemical ionization (APCI) to preserve the molecular ion information
- Chlorine-enhanced RPLC-ESI-Orbitrap: a liquid chromatography-high resolution mass spectrometry, the ultra HPLC pumping system coupled to a Q-Exactive mass spectrometer fitted with either a Heated Electrospray (HESI) [6] or an Atmospheric Pressure Chemical Ionisation (APCI) source[7].

244 In your comments to the draft decision you claim that this test method according to OECD TG 305 or its technical specifications, in particular the dietary route of exposure, would not be appropriate for the Substance. You refer to information from a structural analogue substance (C14, 50%Cl) but you provide no further documentation how this information is relevant for the Substance. You did not provide any evidence with the Substance to support your claim on the inappropriateness of the test method or its specifications. We note that, as reported in the SVHC supporting document of MCCP, an OECD TG 305 study (dietary exposure) was performed on C14 chlorinated n-alkane, 50% Cl wt. Based on structural similarity between MCCP and the Substance, it can be expected that an OECD TG 305 study on the Substance is feasible.

245 In your comments to the proposal for amendment from a member state authority with regards to the study design of the bioaccumulation request you indicate, a) your intention to assess bioaccumulation based on OECD TG 317 instead of the requested OECD TG 305; and b) your reasoning with regards to the choice of test material and analytical considerations.

a) Test guideline to assess bioaccumulation in aquatic species

246 You agree that, due to low solubility properties, the Substance can only be tested via dietary route of OECD TG 305, as requested above. Nevertheless, you indicate your intention to fulfil this information requirement by performing an OECD TG 317 study, i.e. bioaccumulation study on terrestrial organisms, as you consider sediment and soil the most relevant compartments, based on persistence assessment, and further analytical consideration addressed in point b) below. You consider that OECD TG 317 is preferable to both an OECD TG 315 study and the proposed OECD TG 305 study. You further claim that LCCP will be more poorly absorbed compared to MCCP, therefore this could impact OECD TG 305 feasibility, results validity and relevance.

247 ECHA acknowledge the difficult to test properties of the Substance and considers, as stated above, that OECD TG 305 dietary route is preferred. To ensure study feasibility, we strongly suggest, in line with the OECD TG 305-III paragraph 125, the performance of a preliminary study to optimise test conditions and design including diet spiking, and analytics.

248 With regards to OECD TG 317 and OECD TG 315, and considerations of alternatives to vertebrate animal testing, please note that any of these tests alone cannot fulfil the standard information requirement for bioaccumulation in aquatic species (emphasis added) of Annex IX, Section 9.3.2 of REACH. Furthermore, this information is relevant for PBT assessment of the Substance, as explained in Request 6. Data on terrestrial and sediment

[6] https://www.sciencedirect.com/topics/chemistry/electrosprays
[7] https://www.sciencedirect.com/topics/chemistry/atmospheric-pressure-chemical-ionization

organisms may be used in a Weight of Evidence approach for bioaccumulation assessment. OECD TG 317 and OECD TG 315 measure the biota-soil/sediment accumulation factor (BSAF) for which no thresholds are set so far. Hence, data from OECD TG 317 or OECD TG 315 study (i.e. BSAF) cannot be directly compared to BCF (as obtained in OECD TG 305) and for instance, a case-by-case assessment based on expert judgement of the reliability and relevance of available information would be required in order to be able to give BSAF values an appropriate weight in the B and vB assessment. We also remark that conclusion on B/vB criteria (which refers to BCF in aquatic species) is required and independent of the compartment on which P/vP is concluded. Test material and analytical considerations

b) You indicate your intention to follow a testing strategy where tier 1 would consist of a bioaccumulation test performed with the radiolabelled test material C18 30% Cl wt. (single chain). Additional testing (tier 2) of single chains of higher C-length would be considered in case tier 1 would allow conclusion that the test material is B/vB.

249 In your reasoning you consider C18 30% Cl wt. to be the most bioavailable fraction of the Substance hence, results indicating that B/vB criteria is not met for this test material could be extrapolated to all constituents of the Substance.

250 Furthermore, you claim that cold testing (i.e. performed with non-radiolabelled test material) is likely to produce non-conclusive data due to lower solubility of C18 30% Cl wt., compared to MCCP, C14 50% Cl wt. since LCCP would be less absorptive.

251 ECHA reiterates that to reach a conclusion regarding B/vB of the Substance the test material must be representative of the Substance as registered. Therefore, you must ensure that the carbon-chain length and chlorination levels are properly represented in the test material(s). For instance, as indicated in the results of your market survey, only 1.3% of the LCCP products are below 40% Cl wt. The chlorination degree may impact assimilation and excretion potential, as already indicated above and identified for MCCPs. The bioaccumulation potential is not exclusively driven by the carbon-chain length as your comment seems to suggest.

252 Bearing in mind that it is not yet demonstrated that proposed test material C18 30% Cl wt. (single chain) can be considered to have the highest bioaccumulation potential in comparison to other constituents of the Substance, the proposal to test single chain materials raises the concern of representativeness and conservativeness. We acknowledge your statement that over 100 000 individual isomers compose LCCP hence, when a single isomer or congener group is confirmed not B/vB this would not allow direct conclusion for all the relevant constituents.

253 ECHA considers that there is no conclusive indication that cold method would not be feasible to assess bioaccumulation of at least C18-25 40-50% Cl wt. Namely, you have not demonstrated that assumed low or slow uptake of LCCP would result in concentrations below the detection limit. We note that use of radiolabelled test materials is not mandatory. A radiolabelling strategy by use of an individual (isomer) radiolabelled standard, as internal standard, can be very useful, as a complementary measure for accurate quantification, in correcting extraction losses and analytical efficiency and variability. However, the use of a single (radiolabelled) isomer instead of (selected) representative test material(s) would not provide all required information to conclude on B/vB, in particular would not inform on the present congener groups, as indicated in your comments.

Reasons related to the information under Annex X of REACH

13. Extended one-generation reproductive toxicity study

254 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X to REACH (Section 8.7.3.).

13.1. Information provided

255 You have adapted this information requirement by referring to Column 2 of Annex IX, Section 8.7.3. To support the adaptation, you have provided following information:

(i) You suggested the Substance's lack of genetic toxicity, indicated a low order of systemic toxicity and the lack of evidence of toxicity to the reproductive organs in standard repeated dose studies. You stated that "*no evidence of an adverse effect on fertility (standard reproductive/fertility parameters were unaffected) has been found in a well-conducted fertility study of MCCPs*", a structural analogue of the Substance. You stated that there is "*no evidence that these grades of LCCP cause developmental effects in either rats or rabbits*" and that "*there are no indications that LCCPs have modes of action related to endocrine disruption*". You concluded that "*Based on these Specific Rules for Adaptation and the available data for LCCPs, it is considered that an extended one-generation reproductive toxicity study of LCCP is scientifically unjustified and would not be in the interest of animal welfare.*"

13.2. Assessment of the information provided

256 We have assessed this information and identified the following issue(s):

13.2.1. Your justification to omit the study has no valid legal basis

257 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex X, Section 8.7.3., column 2.

258 Your justification to omit this information does not refer to a legal ground for adaptation under Annex X or XI to REACH. Rather, your justification for adaptation of the information requirement refers to the provisions of Annex IX, 8.7.3, Column 2 which are related to triggering of extensions of the basic test design. Your justification and the legal basis you invoke is firstly not relevant to your tonnage level, and secondly is related to the design of an EOGRTS and not to an adaptation possibility for this information requirement.

259 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X to REACH.

260 Since your justification does neither refer to the general rules set out in Annex XI nor to the relevant and specific rules set out in Annex X, Section 8.7.3., column 2, the adaptation is rejected.

261 In your comments on the draft decision, you reiterate your reasons why you consider that further testing is not necessary, including that the "*LCCP has been evaluated in numerous chronic and developmental toxicity studies and there is no indication of adverse effects on reproductive organs or in utero development*", that no effects on fertility was observed with the analogue substance MCCP and "*overall it is anticipated that the LCCPs are unlikely to pose a hazard to fertility*".

262 These reasons have already been addressed in section 13.2.1. and you do not provide any new information on the Substance nor do you claim a new adaptation.

263 Therefore, the information provided in your comments does not change the above conclusion that your adaptation is rejected.

264 In addition, you state that before conducting the EOGRTS, the potential Vitamin K deficiency should be investigated (to avoid total loss of the F1 generation), as maternal toxicity and neonatal deaths due to Vitamin K deficiency were observed with the analogue substance MCCP.

265 However, there are no Substance-specific information which suggest that the Substance induces Vitamin K deficiency in the available sub-chronic-, and chronic-, and developmental- toxicity studies in rats and mice. These studies do not indicate effects associated with Vitamin K deficiency

266 Also, the mechanistic information is not necessary for conducting an EOGRTS because the study is designed to identify hazards related reproductive toxicity irrespective of cause.

267 Furthermore, the dose-setting in the EOGRTS is based on toxicity observed in the parental (P0) animals (Section 13.3.3.), i.e. the highest dose level may not be set to avoid deaths in the F1 generation.

268 On this basis, the information requirement is not fulfilled and requested study need to be generated

13.3. Specification of the study design

13.3.1. Species and route selection

269 A study according to the test method OECD TG 443 must be performed in rats with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

13.3.2. Pre-mating exposure duration

270 The length of pre-mating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

271 Ten weeks pre-mating exposure duration is required to obtain results adequate for classification and labelling and/or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration (Guidance on IRs and CSA, Section R.7.6.).

272 In this specific case, ten weeks exposure duration is supported by the lipophilicity of the Substance (Log K_{ow} = >4.5) to ensure that the steady state in parental animals has been reached before mating.

273 Therefore, the requested pre-mating exposure duration is ten weeks.

13.3.3. Dose-level setting

274 The aim of the requested test must be to demonstrate whether the classification criteria of the most severe hazard category for sexual function and fertility (Repr. 1B; H360F) and developmental toxicity (Repr. 1B; H360D) under the CLP Regulation apply for the Substance (OECD TG 443, para. 22; OECD GD 151, para. 28; Annex I Section 1.0.1. of REACH and Recital 7, Regulation 2015/282), and whether the Substance meets the criteria for a Substance of very high concern regarding endocrine disruption according to Art.57(f) of REACH as well as supporting the identification of appropriate risk management measures in the chemical safety assessment.

275 To investigate the properties of the Substance for these purposes, the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility, but no deaths (i.e., no more than 10% mortality; Section 3.7.2.4.4 of Annex I to the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, para. 18) in the P0 animals.

276 In case there are no clear evidence of an adverse effect on sexual function and fertility, the limit dose of at least 1000 mg/kg bw/day or the highest possible dose level not causing severe suffering or deaths in P0 must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

277 In summary: Unless limited by the physical/chemical nature of the Substance, the highest dose level in P0 animals must be as follows:

(1) in case of clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, the highest dose level in P0 animals must be determined based on such clear evidence, or
(2) in the absence of such clear evidence, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or
(3) if there is such clear evidence but the highest dose level set on that basis would cause severe suffering or death, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or
(4) the highest dose level in P0 animals must follow the limit dose concept.

278 You have to provide a justification with your study results demonstrating that the dose level selection meets the conditions described above.

279 Numerical results (i.e. incidences and magnitudes) and description of the severity of effects at all dose levels from the dose range-finding study/ies must be reported to facilitate the assessment of the dose level section and interpretation of the results of the main study.

13.3.4. Lactational transfer

280 OECD TG 443, paragraph 17 specifies that toxicokinetic data (TK) data from previously conducted dose range-finding or other studies are extremely useful in the planning of the study design, selection of dose levels and interpretation of results. Of particular utility are data which verify exposure of developing foetuses and pups to the test compound (or relevant metabolites). In the OECD GD 151 (paragraphs 22-26) it is specified that if pups do not receive the substance in milk or by direct dosing, there is a gap in exposure during a potentially critical window of development, from birth until the pup starts to eat for itself (in dietary studies) or when direct dosing commences (gavage studies) typically at weaning. Where there is no clear toxicity to the offspring during the lactation phase, it may be related to the lack of transfer of the test substance to the offspring via the milk.

281 The publicly available information on chlorinated paraffins[8] indicate that the Substance is present in human milk, and was detected in nearly all (86%) of the analysed human milk samples. Furthermore, the structurally similar substance medium chain chlorinated paraffins (MCCPs, EC 287-477-0) has harmonised classification with Lact. H362, "May cause harm to breast-fed children". In a dose-range finding study (similar to OECD 421) maternal exposure leaded to internal haemorrhaging and deaths in the lactating rat pups[9]

[8] Zhou, Y., et al. 2020. Chlorinated Paraffins in Human Milk from Urban Sites in China, Sweden, and Norway. Environmental Science & Technology 2020 54 (7), 4356-4366 DOI: 10.1021/acs.est.9b06089
[9] IRDC (International Research and Development Corporation), 1985. Reproduction Range-Finding Study in Rats. Chlorinated Paraffin: 52% chlorination of intermediate chain length nparaffins. Sponsor: Chlorinated Paraffin Consortium. Report No 438-049.

282 Based on above, there is a concern on the effects of the Substance on the developing offspring during the critical window of development from birth until weaning. Therefore, to ensure that there is no gap in exposure during a potentially critical window of development from birth until weaning, lactational transfer of the substance to the offspring during the lactation must be evaluated as part of a work designed to aid dose selection. Lactational transfer evaluation must be investigated at least on lactation day 10 (mid-lactation) by quantification of the substance in the pup blood and/or milk as recommended in the OECD Guidance 151 (paragraphs 22-26). If no exposure to the offspring is confirmed via the mothers milk, direct dosing of the offspring must be conducted to ensure that there is no gap in the exposure before weaning.

283 Sufficient information on samples preparation and the analytical methodology should be provided.

13.3.5. Further expansion of the study design

284 The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex IX/X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in Guidance on IRs & CSA, Section R.7.6.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

In addition, the following publications have been cited in this decision:

Castro M, Sobek A, Yuan B, Breitholtz M (2019). Bioaccumulation potential of CPs in aquatic organisms: Uptake and depuration in Daphnia magna. Environmental Science and Technology, 53, 9533−9541

Castro M, (2020). Chlorinated Paraffins: improved understanding of their bioaccumulation and toxicity in Daphnia magna. Department of Environmental Science. Stockholm University, Stockholm, ISBN 978-91-7911-072-7, ISBN 978-91-7911-073-4

de Wit C A, Bossi R, Dietz R, Dreyer A, Faxneld S, Garbus S E, Hellström P, Koschorreck J, Lohmann N, Roos A, Sellström U, Sonne C, Treu G, Vorkamp K, Yuan B, Eulaer I, 2020 Organohalogen compounds of emerging concern in Baltic Sea biota: Levels, biomagnification potential and comparisons with legacy contaminants. Environmental International, 144 106037 https://doi.org/10.1016/j.envint.2020.106037

Yuan B, Vorkamp K, Roos AM, Faxneld S, Sonne C, Garbus SE, Lind Y, Eulaers I, Hellström P, Dietz R, Persson S, Bossi R, de Wit CA. Accumulation of Short-, Medium-, and Long-Chain Chlorinated Paraffins in Marine and Terrestrial Animals from Scandinavia. Environ Sci Technol. 2019 Apr 2;53(7):3526-3537. doi: 10.1021/acs.est.8b06518. Epub 2019 Mar 20. PMID: 30848596.

Yuan B, McLachlan M S, Roos A M, Simon M, Strid A, de Wit C A, 2021, Long-chain chlorinated paraffins have reached the artic. Environmental Science and Technology Letters. 8, 753-759. DOI: 10.1021/acs.estlett.1c00470

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 04 June 2021.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee. In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

Deadline to provide the information

The deadline to provide the information requested in this decision is 36 months from the notification of this decision. ECHA considers this deadline sufficient to perform all requested studies in the decision, considering current longer lead times in contract research organisations; technical difficulties to conduct the tests; and the fact that all tests can be performed in parallel.

In the comments on the draft decision, as well as in the comments to the proposal for amendment, you have further raised difficulties that could prevent from meeting the deadline given in the decision:

- Lead times of CROs before starting a study are currently 6-12 months;
- Technical difficulties due to the nature of the Substance requiring more time for test material synthesis (e.g. if radiolabelling is required) as well as development of analytical methods for the test material and/or its degradation products.

In this regard, ECHA points out that the final deadline considers in its practice standard times for carrying out OECD TG tests. Furthermore, the deadline granted by ECHA takes into account currently longer lead times in contract research organisations as well as the expected technical difficulties due to the Substance nature raised in your comments to the draft decision and the proposal for amendments.

ECHA in general considers additional time for possible sequential testing regarding the information requirements relating to biodegradation and bioaccumulation in line with its general recommendations for the PBT/vPvB assessment in Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11. In this case, however, a Member State authority submitted in their proposal for amendment to conduct the requested bioaccumulation and

persistency studies in parallel, as the conclusion from international assessments already indicates that the substance fulfils the criteria to be P and vP, without need for further testing. We note your agreement that available information allows conclusion on P/vP properties of the Substance, and further refer to the reasons for Request 6 on the matter that the available information supports P/vP conclusion. Therefore, the need for sequential persistence and bioaccumulation testing as normally recommended in Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 for the PBT/vPvB assessment, does not apply in this case and the requested simulation, if deemed necessary by you, and bioaccumulation testing shall be conducted in parallel.

In your comments on the proposal for amendment you finally also mentioned the decisions of the Board of Appeal in cases A-005-2011, Honeywell Belgium, and A-009-2014, Albemarle Europe. However, Case A-005-2011 concerned a request for further information under Column 2 of Section 8.6.4. of Annex X where no specific information requirement is set out, and Case A-009-2014 concerned a request for further information under substance evaluation. Neither of these decisions therefore has a bearing on the present evaluation decision.

The Member State Committee unanimously agreed on the draft decision during its MSC-82 meeting. ECHA adopted the decision under Article 51(6) of REACH.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[10].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.
- The reported composition must also include other parameters relevant for the property to be tested, in this case specification on identity and quantity of the different congener groups present in the tested material

[10] https://echa.europa.eu/practical-guides

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[11].

In your comments to the draft decision you asked for further guidance on the choice of the appropriate test material that is to be used to conduct the requested studies.

As explained above, when generating new data, you must ensure that the test material used is representative for all registrants of the Substance and does not underestimate the hazard.
This includes, in particular for substances with more than one constituent, e.g. UVCBs, also considerations on the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity/environmental fate, the selected test material must contain that constituent/impurity.
In any case, you must identify, characterise, and report in sufficient detail the composition of the test material used and/or its transformation products, where relevant, so that hazardous properties can be identified and attributed accordingly, where applicable.

For more information, please consult ECHA Guidance on information requirements and chemical safety assessment, e.g. Chapters R.7 as well as R.11 as well as respective OECD Test Guidelines in case of test specific considerations.

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In general, it is advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. In this specific case, as explained in the Appendix 2, sequential testing is not considered necessary. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

2.2. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA,

[11] https://echa.europa.eu/manuals

Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.