COMMENTS ON THE DRAFT RISK PROFILE PREPARED IN ACCORDANCE TO ANNEX E TO THE STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS

Substance name: Chlorinated paraffins with carbon chain lengths in the range C14-17 and chlorination levels at or exceeding 45 per cent chlorine by weight
EC number: -
CAS number: -

The substance has been proposed for its inclusion in the Stockholm Convention on persistent organic pollutants

Start date of the consultation: 24/05/2022
End date of the consultation: 19/07/2022

Disclaimer: Comments provided during consultation are made available in this document as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The table does not contain any confidential information.

Comment number	Date/type/Org.	Comments
1	**Date:** 2022/07/15 **Type:** On behalf of an organisation **Organisation:** World Chlorine Council	**Comment:** As the World Chlorine Council, we thank the European Chemicals Agency for enabling our comments to this process. Building on our previous notes, we believe that there is a need to have a clear substance identity in this proposal that uses using specific chemical nomenclature when reviewing and regulating complex or Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substances, such as chlorinated paraffins (CP). The following are several general considerations for how this could be applied to the nomination process: • Complex/ UVCB substances should be defined as narrowly and precisely as possible for POPs consideration. In practice this may mean defining substances based on specific CAS numbers and/or other specific definitions that allow for the easy differentiation of the listed UVCB substance from other substances. This would be consistent with existing Convention nominations. • UVCB substances are typically defined based on how they are manufactured. Common

		characteristics used to define UVCBs are starting materials (feedstocks), chemical reactions used in the manufacturing process, conditions of the manufacturing process, etc. • Data (endpoint, exposure, uses, etc.) on the UVCB substance as manufactured and used in commerce should receive greater priority in assessments than data on related substances or constituents (especially if those constituents are UVCBs themselves). Read-across of concerns/ hazards from one UVCB substance to another should be done on a case-by-case basis for each endpoint and must include a clear justification for each endpoint. We encourage the application of these considerations for this and future evaluations of complex substances. We would also encourage consideration of some specific items from the proposal as detailed below: Paragraphs 2 and 3 – This proposal is built upon the assessment of a specific CP substance (CAS 85535-85-9; EC 287-477-0) as registered under the EU REACH regulation and noted in Table 1. The application of this evaluation to other CP substances should be done with great care as the broader the scope of the substances attempted to be covered under this assessment, the less clear it may become to some as to the exact substances covered under the proposed listing. We believe this is a particular concern for broader CP substances that are not typically defined by their carbon-chain length (e.g. those from outside of Europe/ North America). One approach to dealing with this would be to consider separate evaluations, and listings if appropriate, on the various broader CP substances themselves. This would certainly be warranted as these are highest volume CP produced globally. Considering the existing POP listing of C10-13 chloroalkanes ("SCCP") has yet to be globally adopted and applied to all CP substances that contain C10-13 chloroalkane constituents, there is strong possibility that this could also occur with C14-17 chloroalkanes. The term congener is used in Paragraph 2 without any definition and in the specific context appears to equate "CP products" with "these congeners". Given that the term congener is used extensively, it should be clearly defined at the beginning of the report. In addition, the discussion on defining congeners should state that these are groupings of CP isomers based on molecular weight and that they are themselves complex groupings without any identifiable constituents. It should also be noted that the analytical method employed in a CP analysis to determine congener groups will have an impact on the identification/quantification of the specific congeners present as it is known that there can be considerable variability from laboratory to laboratory on the identification/ quantification of congeners (a feature already identified in the published scientific literature on these

		substances). Paragraph 6 – An additional reference to Tomy 1997 regarding the thousands of individual isomers present in CPs is Yuan (2020). This paper also contains a statistical analysis on the chlorination locations on alkane chains. Table 5 – The predicted total releases are not necessarily consistent with those predicted by the ECHA-recognised Chesar tool. Chesar uses calculations based on established phys/ chem properties of MCCP so it remains unclear why such a large proportion released into air is attributed when considering the low vapour pressure of MCCP. In addition, any releases that go through sewage treatment sludge, and subsequently to incineration, should not count as a release into the environment. Paragraph 51 – The summary of the newly completed OECD 314B biodegradation study on C14-17 chloroalkanes at 52% Cl (wt.) is not correct. First, this is a simulation study, as explicitly stated in the guideline, for the biodegradation of a substance in wastewater treatment. It is not a screening assay and thus should be considered under 'environmental simulation data'. Secondly, follow-up studies confirm that the tritiated test material behaves similarly to the non-radiolabelled test material in this bioassay (study available upon request). This hot versus cold comparison study was run at much higher concentrations (~150 times higher) to allow for the use of GC-μECD to measure the disappearance of the cold test material. Even at this much higher concentration, there was relatively rapid and extensive (over 90%) biodegradation in this test system of both the radiolabelled and non-radiolabelled chloroalkanes within 9 days. Furthermore, the pattern of biodegradation was roughly the same for both test materials. Given this follow-up study we believe it is inappropriate to include speculative comments regarding the nature of tritium in "protein related substances" and the reference to Nivesse et al., 2021. Finally, this study was appropriately conducted based on the globally accepted guideline which allows for the accommodation of poorly soluble chemicals using techniques to disperse the test material. Surfactants are commonly present in wastewater in the milligram/L range (Matthijs et al. 1999) and thus would be expected to be present at concentrations higher than those used in this study (443 μg/L final added concentration). It should also be noted that the test concentrations of MCCPs used in this testing were approximately 10 times higher than its water solubility limit in the primary study and over 1000 times higher in the comparison study. As such we question the dismissal of this study, and its results, simply because the results do not

		align with other biodegradation studies. This study simply illustrates that MCCP is biodegradable under some test conditions and not under others. This is likely true for most chemicals, particularly poorly soluble chemicals, which are not readily bioavailable to the inoculum in the test system. Paragraph 78 – We believe that is unreasonable to summarily reject the BAT evaluation (a tool which ECHA have been consulted on). This evaluation does not rely primarily on any single study and, moreover, it considers a range of different metrics as opposed to primarily focusing on BCF. Whilst BCF may be the primary metric for the evaluation bioaccumulation in some regulatory schemes, it is not the only metric and in the global assessment considering a range of metrics (as the BAT tool does) is worthy of consideration. Paragraph 184 – As the EFSA 2020 review of CPs is cited in this paragraph, we believe it would be appropriate to capture the risk conclusions from this assessment (see section 4.4.1 of the 2020 EFSA review). Appendix 3, Table 10 – Slackwax (petroleum), chloro, CAS 2097144-44-8, is not a CP substance that contains C14-17 chloroalkanes. This substance was just recently added to the U.S. chemical (TSCA) inventory in 2017 and is a C18+ chloroalkane substance. U.S. EPA has a full chemical characterisation of this substance.