Regulatory Management Option Analysis Conclusion Document

Substance Name: Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salts (HGC-TLF)

EC Number: 700-161-3

CAS Number: not available

Authority: The Netherlands

Date: August 2022

History:

HGC-TLF was subject of substance evaluation by the NL-CA in 2013. A concern with respect to PBT was raised regarding HGC-TLF, more specifically, to one of its degradation products (i.e. PFHpA). The concerned degradation product of HGC-TLF is the same as for the substance evaluated by the BE-CA the same year. The NL-CA and BE-CA drafted in close cooperation the SEv-documents and aligned their additional information requests and conclusions. The BE-CA drafted a CLH proposal for the degradation product PFHpA, resulting in the inclusion of the degradation product in the 18th ATP to the CLP-regulation. The NL-CA has submitted an SVHC-proposal for PFHpA (August 2022).

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Substance composition

Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt (HGC-TLF - "the registered substance (EC 700-161-3)") is a multi-constituent substance. The registered substance (EC 700-161-3) is initially selected and evaluated for its PBT-concern.

Primary biodegradation, atmospheric degradation and/ or metabolism of the constituents yields a number of terminal degradation products, including perfluoroheptanoic acid (PFHpA; EC 206-798-9). PFHpA belongs to the group of perfluorocarboxylic acid (PFCAs).

REACH: CoRAP and Substance Evaluation

The substance (EC 700-161-3) has been selected for the CoRAP by Netherlands in 2013. Though initial grounds for concern related to PBT properties of the registered substance (EC 700-161-3), it was considered more appropriate to focus the Substance Evaluation on its degradation product perfluoroheptanoic acid (PFHpA; EC 206-798-9)*. PFHpA (EC 206-798-9) is a chemical with six perfluorinated carbons. PFHpA (EC 206-798-9) is not registered under REACH.

The reasons for focussing on the degradation product PFHpA (EC 206-798-9) instead of the registered substance (EC 700-161-3) and requesting information as described in the SEv Draft Decision (March 2014) have been summarized below:

- Degradation of the registered substance (EC 700-161-3) will result in the formation of PFHpA at levels higher than 0.1%. PFHpA is already detected in the environment. Due to the voluntary phase-out of PFOA and its precursors (e.g. 8:2 diPAP), it is expected that the amount of PFHpA and its precursor 6:2 diPAP will probably increase over time. Therefore, it was considered justified to conduct the PBT assessment for the registered substance (EC 700-161-3) with the degradation product PFHpA.

- PFHpA is not degraded in the environment and thus fulfils the P- and vP-criteria in accordance with the criteria and provisions set out in Annex XIII of REACH.

- Standardized bioconcentration studies with fish are not suitable to assess the bioaccumulation potential of PFHpA, and presently available monitoring data were insufficient to conclude that PFHpA would meet the B-criterion. Consequently, to demonstrate bioaccumulation of the degradation product PFHpA additional monitoring studies, preferably in humans, were needed. Such complex and time-consuming studies were not considered proportional at the first phase of the substance evaluation process. It was considered that these may be requested if the degradation product PFHpA would meet the T criterion in addition to the P/vP-criteria.[#]

- The limitedly available environmental toxicity data on PFHpA suggest low acute toxicity to algae and daphnids. For the structurally similar compound PFOA, acute and chronic toxicity data for environmental species are available. In the Annex XV dossier of PFOA, it was stated that these studies show low toxicity of PFOA to environmental species, and the $T_{environment}$-criterion was not further investigated. Since PFOA is one fluorinated carbon longer, and thus expected to be more toxic than PFHpA, it was decided not to proceed with elucidating long-term toxicity of PFHpA to aquatic organisms at this stage.

- There are limited human toxicity data available on the degradation product PFHpA. There are no studies available on the reproductive toxicity or repeated dose toxicity of PFHpA. Thus, it could not be determined if PFHpA fulfils the criteria for classification as Repr. (1A, 1B or 2) and/or STOT RE (1 or 2), which are part of the $T_{mammalian}$-assessment under PBT-evaluation.

- There are, however, data available on the chronic toxicity of PFHxA and PFOA, PFCAs that are one fluorinated carbon shorter, respectively, longer. PFHxA was shown to be not very toxic to rats in a 90-day repeated dose toxicity study. PFOA on the other hand, has been classified based on its reproductive toxicity and repeated dose toxicity as Repr. 1B and STOT RE 1 (liver). In addition, for PFNA, which is two fluorinated carbons longer, only recently such a proposal for Harmonized Classification and Labelling has been submitted by the Swedish Competent Authority[$]. Considering that the toxicity of PFCAs increases with the length of their fluorinated carbon chain (Kudo et al., 2006, Mulkiewicz et al., 2007, Latała et al., 2009, Hoke et al., 2012) it was considered not unlikely that PFHpA might also fulfil the criteria for classification as Repr. 1B and/or STOT RE 1.

Additionally, while it is noted that the registered substance (EC 700-161-3) also has other degradation product such as PFHxA (C6-PFCA), PFPeA(C5-PFCA), etc, and PFHxA is considered the most abundant degradation product, it was considered more appropriate focusing on PFHpA (EC 206-798-9). PFHpA (EC 206-798-9) is one fluorinated carbon longer than PFHxA and thus in regard to PBT properties more relevant. Therefore, the focus of the substance evaluation was the degradation product PFHpA (EC 206-798-9).

In order to clarify the T-criterion for PBT-concern of the registered substance (EC 700-161-3) and taking the above considerations into account, the following information was required for the sodium or potassium salt of PFHpA in the SEv Draft Decision of the registered substance (EC 700-161-3) (March 2014)[&]:

> *Reproduction/Developmental Toxicity screening test in mice, oral route (OECD 422) extended to 90 days for the premating and mating period and extended to 21 days post weaning.*

Based on the results of this OECD 422 study, also a concern for thyroid hormones disruption has been identified. A literature search provided additional information on a thyroid mode of action for PFHpA. *In vivo* neurodevelopmental data are not available for PFHpA. Therefore, it was considered that a concern for endocrine disrupting properties of the registered substance (EC 700-161-3) needed to be further clarified. As an outcome of the SEv follow-up process, a second SEv Draft Decision requesting further information has been sent to the Registrant(s) (December 2018) in which the following information was required[@]:

> *Developmental Neurotoxicity Study in rodents (rats), oral route; OECD TG 426; with the transformation product/metabolite, Sodium perfluorheptanoate*

** It is noted that PFHpA (EC 206-798-9) is also a degradation product of a second perfluor chemical, i.e. ammonium salts of mono- and bis [3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly(substituted alkene)]phosphate (EC 700-403-8), which has been selected by Member State Belgium for the CoRAP in 2013. The substance evaluation of this chemical focused primarily on its degradation product PFHpA and included a request for an OECD 422 study and an OECD 426 study as well. Substance evaluations of both perfluor chemicals (EC 700-161-3 and EC 700-403-8) were performed as cooperation of BE and NL.*

[#] Update November 2020: based on results of Numata et al. (2014), published after the first SEv Draft decision, and taking into account Zhang et al. (2013), PFHpA can be considered bioaccumulative. In the study of Numata et al. (2014), the transfer of series of perfluoralkyl acids (PFAAs) from feed to tissue was studied in fattened pigs. A toxicokinetic model was developed to quantify the absorption, distribution, and excretion of the various PFAAs and to calculate elimination half-life. PFHpA was shown to have an elimination half-life of 74 days. Elimination half-life increased with increasing number of C- and F-atoms. Zhang et al. (2013) investigated the elimination rates of linear $C_{7\text{-}11}$-PFCAs, PFHxS and PFOS, as well as branched PFOA and PFOS, in humans by analyzing paired blood and urine samples. The estimated geometric mean elimination half-lives are 1.0 years in young females and 0.82 years in males and older females for PFHpA, 1.7 and 1.2 years for PFOA, 1.7 and 3.2 years for PFNA, 4.0 and 7.1 years for PFDA, and 4.0 and 7.4 for PFUnDA. This study

shows that while PFHpA elimination is faster than that of PFOA and PFNA, it still takes substantial time, indicating bioaccumulation potential of PFHpA in humans.

As there are no cut-off criteria for half-life values in blood, this has been discussed in the PBT expert group (September 25-26, 2018). None of the members disagreed with considering PFHpA as bioaccumulative.

[$] Update November 2020: PFNA (EC 206-801-3) has currently a harmonised classification as Car. 2 (H351), Repr. 1B (H360Df), Lact. (H362), Acute Tox. 4 (H332), Acute Tox. 4 (H302), STOT RE 1 (H372; liver, thymus, spleen), Eye Dam. 1 (H318) in Annex VI of the CLP-Regulation (EC) 1272/2008.

*[@]Update November 2020: The SEv process for the registered substance (EC 700-161-3) is currently on hold (this applies to the BE-CA SEv substance (see * above) as well. DE-CA drafted a restriction dossier on 'undecafluorohexanoic acid (PFHxA), its salts and related substances', which is submitted to ECHA. Given that PFHxA is also a degradation product of the registered substance (EC 700-161-3), the restriction proposal on 'undecafluorohexanoic acid (PFHxA), its salts and related substances' thus covers the registred substance (EC 700-161-3) as well (see further section 5.2.5 Restriction).*

[&]Update August 2022 regarding the T-criterion: Based on the results of the OCED 422 study, the BE-CA drafted a CLH proposal for the degradation product PFHpA. This resulted in the the inclusion of the degradation product in the 18th ATP to the CLP-regulation with a harmonized classification of Repr. 1B (H360D) and STOT RE 1 (H372; liver).

REACH process: identification as SVHC

Taking into account that PFHpA is not only considered (very) persistent and bioaccumulative but also toxic, the NL-CA has drafted an SVHC-proposal for PFHpA and submitted this proposal recently (August 2022) to ECHA (https://echa.europa.eu/nl/registry-of-svhc-intentions/-/dislist/details/0b0236e187714636).

Harmonised C&L: Annex VI CLP

A CLH-proposal has been drafted for PFHpA (EC 206-798-9) by Member State Belgium. After discussion in Committee for Risk Assessment, i.e. RAC (ECHA 2020), PFHpA has now been included in Regulation (EU) 2022/692, being the 18th ATP to the CLP-regulation, with a harmonized classification of Repr. 1B (H360D) and STOT RE 1 (H372; liver).

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate. Additional regulatory management options are needed.

In conclusion, the preferred steps would be:

1. Harmonized classification and labelling (CLH)

PFHpA has recently been included in Regulation (EU) 2022/692, being the 18th ATP to the CLP-regulation, with a harmonized classification of Repr. 1B (H360D) and STOT RE 1 (H372; liver).

2. SVHC-identification:

Article 57c and d SVHC identification for the registered substance HGC-TLF (EC 700-161-3) based on the Repr. 1B and PBT-properties of PFHpA.

For the degradation product PFHpA a harmonized classification (Repr. 1B and STOT RE

1) is established (see Step 1). Therefore the $T_{mammalian}$-criterion under PBT-evaluation is met. The degradation product PFHpA and subsequently the registered substance (EC 700-161-3) can considered to be a PBT substance. The registered substance (EC 700-161-3) subsequently meets the criteria for SVHC via article 57d of the REACH Regulation and the registered substance (EC 700-161-3) may be included in the Candidate List.

The NL-CA has drafted an SVHC-proposal for PFHpA and submitted this proposal recently (August 2022) to ECHA (https://echa.europa.eu/nl/registry-of-svhc-intentions/-/dislist/details/0b0236e187714636).

3. Restriction:
An overarching restriction of all PFASs.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	X
Restriction under REACH	X
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

The registered substance (EC 700-161-3) meets the criteria set by article 57c and d for SVHC (see also the table below), given the harmonized classification for Repr. 1B and/or STOT RE 1 for its degradation product PFHpA (EC 206-798-9).

The registered substance (EC 700-161-3) is registered with a full registration in the tonnage band 1-10 tpa with one Dutch registrant. The registered substance (EC 700-161-3) is not yet on the Candidate List, nor is it on Annex XIV.

The degradation product PFHpA (EC 206-798-9) is not registered under REACH. PFHpA is not yet on the Candidate List, nor is it on Annex XIV.

Table: SVHC Roadmap 2020 criteria

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

3.1 Harmonised classification and labelling

Based on the results of the OECD 422 study with the degradation product PFHpA (as requested in March 2014 in the first SEv Draft Decision), PFHpA fulfils the criteria for

Repr. 1B and STOT RE 1. Additionally, it should be explored whether the data would be sufficient for fulfilling the criteria for adverse effects on or via lactation. The process of harmonized classification as initiated by the BE-CA for the degradation product PFHpA has aready been finalised.*

** a CLH-proposal has been drafted for PFHpA (EC 206-798-9) by Member State Belgium with a proposed harmonized classification for Repr. 1B (H360D) and STOT RE 1 (H372; liver). This CLH-process is finalised (https://echa.europa.eu/nl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18333861c) https://www.sgs.com/en/news/2022/05/safeguards-05922-eu-publishes-atp-18-to-the-clp-regulation-on-substances-and-mixtures.*

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

- Option 1: Article 57c and d.

Since the degradation product PFHpA has a harmonized classification Repr. 1B (Article 57c) and/or STOT RE 1 (see RMOA-option "Harmonized classification and labelling (CLH) and/or self-classification"), the $T_{mammalian}$-criterion under PBT-evaluation is met. The degradation product PFHpA can considered to be a PBT substance.

Also the registered substance (EC 700-161-3) can be identified as a PBT substance in line with REACH Annex XIII. Subsequently, the registered substance (EC 700-161-3) meets the criteria for SVHC via article 57d of the REACH Regulation and the registered substance (EC 700-161-3) may be included in the Candidate List and eventually in Annex XIV, the Authorisation List of REACH.

The NL-CA has drafted an SVHC-proposal for PFHpA and submitted this proposal recently (August 2022) to ECHA (https://echa.europa.eu/nl/registry-of-svhc-intentions/-/dislist/details/0b0236e187714636).

- Option 2: Article 57f for ED.

In a second SEv Draft Decision (December 2018), an OECD 426 is required based on a concern for thyroid hormone disruption. It is noted that the SEv process on the registered substance (EC 700-161-3) is still ongoing and currently it is not clear when the requested data will be presented.

If the degradation product PFHpA would fulfil the ED-criteria and thus be identified as an endocrine disruptor (human), its precursor will be identified as an endocrine disruptor as well. Subsequently, the registered substance (EC 700-161-3) would meet the criteria for SVHC via article 57f of the REACH Regulation and the registered substance (EC 700-161-3) may be included in the Candidate List and eventually in Annex XIV, the Authorisation List of REACH.

Though it is noted that the available data on PBT properties and reproduction toxicity are considered to be sufficient to identify the substance as SVHC, additional identification as endocrine disruptor will contribute to the authorization process. All environmental and human health impacts for which the substance is identified as an SVHC needs to be taken into account when considering an authorization. Neurotoxic effects will contribute to the health impact, in addition to the impact attributed to reproduction toxicity. Furthermore, endocrine disruption effects on human health can be considered non-threshold effects, which will affect the impact assessment. This identification could also benefit other legislations (food contact materials, drinking water, …). Indeed, it cannot be excluded that the substance is used in food contact materials. Moreover, the substance can enter the environmental compartment. Pollution of water streams cannot be excluded. If the substance is identified as an ED, measures should be taken to protect consumers.

Overall, the NL-CA questions the feasibility of option 2 (article 57f) and considers not awaiting the results of the OECD 426 (requested in a second Draft Decision during the SEv-process) before proceeding with the SVHC-identification. Moreover, it is noted that the SEv-process of the registered substance (EC 700-161-3) is currently put on hold. Overall, option 1 (SVHC-identification via article 57d, in addition to article 57c) is considered more appropriate and the NL-CA has recently submitted an SVHC-dossier for the degradation product PFHpA.

Though not required according to the formal criteria as laid down in the REACH-Regulation, Member States are in general recommended setting a harmonised CLH via the Committee for Risk Assessment (RAC) (in this case: Repr. 1B and STOT RE 1 for PFHpA, see section 5.2.1) preceding the SVHC-process (in this case: in order to establish the PBT-status of PFHpA and subsequently that of the registered substance (EC 700-161-3)). This will increase the burden of proof with respect to hazard of the chemical under evaluation. Moreover, this will speed up the SVHC-process. Therefore, the NL-CA recommends combining the RMOA-option SVHC-identification (via article 57d, in addition to article 57c) with the RMOA-option Harmonized classification and labelling (which has recently been finalised).

3.3 Restriction under REACH

The registered substance (EC 700-161-3) and its degradation product PFHpA (EC 206-798-9) belong to the group of PFAS (per- and polyfluoroalkyl substances). PFAS constitute a group of thousands man-made chemicals that are widely used in various technical applications in society due to their unique physical and chemical properties. The extreme persistence of PFAS leading to irreversible human and environmental exposure is a reason for major concern. Some PFAS, such as the well-known PFOA and PFOS, have been extensively investigated and regulated, while for many other PFAS there is still very limited or completely missing knowledge about their current uses and hazards. In December 2019, a proposal for an EU-strategy for PFASs was presented to the European Commission by Environmental officials from Sweden, the Netherlands, Germany, and Denmark. The process of an overarching restriction of all PFASs (initiated by various Member States, including the Netherlands and Germany) is currently ongoing now. The submission of the Annex XV restriction dossier is expected in January 2023.

3.4 Other Union-wide regulatory measures

There is (currently) no need for other Union-wide risk management measures for the substance.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
CLH dossier for PFHpA	2019 – CLH has been recently been adapted in 18th ATP	Belgium
Annex XV SVHC dossier for PFHpA	August 2022	The Netherlands
Annex XV restriction dossier for PFAS (including HGC-TLF)	January 2023	Sweden, the Netherlands, Germany, Denmark and Norway