

## COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

ECHA accepts no responsibility or liability for the content of this table.

**Last data extracted on 04.07.2023**

**Substance name: undecafluorohexanoic acid; [PFHxA] [1] sodium undecafluorohexanoate; [NaPFHx] [2] ammonium undecafluorohexanoate; [APFHx] [3] other inorganic salts of undecafluorohexanoic acid [4]**  
**CAS number: 307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4]**  
**EC number: 206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4]**  
**Dossier submitter: Germany**

### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
30.06.2023	Germany	Gesamtverband Textil und Mode e.V.	Industry or trade association	1
Comment received				
On the basis of the attached „Statement concerning the proposed classification and labeling of PFHxA and its inorganic salts“ the German Textile and Fashion Association rejects the proposed classification as reproductive toxic category 1B. We fully support the content and conclusion of the EuDICO report (attached).				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Stellungnahme PFHxA t+m TEGEWA.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
29.06.2023	Sweden		MemberState	2
Comment received				
We thank the German CA for the evaluation of reproductive toxicity and specific target organ toxicity – repeated exposure of PFHxA; NaPFHx; APFHx and other inorganic salts of undecafluorohexanoic acid. The read-across approach from the sodium/ammonium salts to PFHxA and its anion, in line with previous CLH-proposals for the perfluorinated carboxylic acids (PFCAs) perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluoroheptanoic acid (PFHpA), is supported.				

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany	Verband TEGEWA e.V.	Industry or trade association	3
Comment received				
Verband TEGEWA e. V. is an association representing chemical companies based in Germany, Switzerland and Netherlands manufacturing and marketing inter alia chemicals for leather and textile production and treatment.				

Our focus in this contribution is the use of modified polymers with C6 fluorine compounds for water, oil and stain repellency for a limited number of textile and leather applications when safety and personal protection aspects are involved or for high technology applications, especially when future technologies are involved.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Stellungnahme PFHxA t+m TEGEWA.pdf

## TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
30.06.2023	United Kingdom	Health and Safety Executive	National Authority	4
Comment received				
<p>Reproductive Toxicity</p> <p>On page 23 of the CLH report, an increase in the number of dams with complete litter loss is reported in phase I of the Charles River 2011 reproductive and developmental toxicity study, and on page 24, a significant drop in the viability index is also reported, at the same doses. The toxicokinetics data indicate that PFHxA is detected in breast milk in humans. We would welcome a discussion of the perinatal pup mortality reported between PND 0-4 and whether they may be linked to effects on or via lactation.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
30.06.2023	Germany	Gesamtverband Textil und Mode e.V.	Industry or trade association	5
Comment received				
<p>see attachment „Statement concerning the proposed classification and labeling of PFHxA and its inorganic salts“</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Stellungnahme PFHxA t+m TEGEWA.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
29.06.2023	Sweden		MemberState	6
Comment received				
<p>Fertility</p> <p>The Swedish CA supports the proposal of no classification for adverse effects on fertility based on the weight of evidence evaluation and lack of data to support a classification. However, we also note that all studies were performed using the rat as model species, and as for the developmental toxicity of PFHxA (as well as for PFOA and PFNA), the mouse has been shown to be a more sensitive species. It cannot be ruled out that adverse effects on fertility could have been observed if similar studies had been performed using the mouse.</p> <p>Developmental toxicity</p> <p>The Swedish CA supports the proposal of classification for adverse effects on development, Repr. 1B, H360D.</p> <p>Clear adverse effect on development, in the absence of relevant maternal toxicity, were observed in the key developmental and perinatal/postnatal reproductive toxicity study in mice (Charles River Laboratories, 2011a; 2011b), in particular:</p>				

- Significantly increased number of stillborn pups at 500 mg/kg bw/day and increased number of stillborn pups at 350 mg/kg bw/day (phase I) as well as significantly increased number of stillborn pups at 175 mg/kg bw/day (phase II) as compared to the respective controls,
- Decreased postnatal viability at PND4: 72.7% and 87.9% vs. 99.1% at 500, 350 and 0 mg/kg bw/day, respectively, as well as at PND20: 61.6% and 80.8% vs. 96.8 at 500, 350 and 0 mg/kg bw/day.

These effects follow the same pattern of increased perinatal mortality and decreased postnatal viability as was observed in studies in mice for the PFCA structural homologues PFHpA, PFOA and PFNA, all leading to Repr. 1B classifications for adverse effects on development for these substances. Similarly, the rat was for these PFCAs shown to be less sensitive than the mouse, likely at least in part due to the more rapid excretion in rats (in particular female rats) as opposed to in mice (Borg and Håkansson, 2012). Thus, the mouse is a more suitable model species than the rat.

#### Adverse effects on or via lactation

The Swedish CA agrees with the Dossier Submitter that the information available does not support classification under this category.

#### Other comments:

The references to the Charles River Laboratories (2011a; 2011b) study reports are sometimes in the text (e.g. page 37) intermixed and not correct.

#### References:

Borg and Håkansson, 2012. Environmental and Health Risk Assessment of Perfluoroalkylated and Polyfluoroalkylated Substances (PFASs) in Sweden. Table 29: Serum half-lives of PFASs congeners in different species. ISBN 978-91-620-6513-3. Available at: <https://www.diva-portal.org/smash/get/diva2:770762/FULLTEXT01.pdf>

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2023	Germany	Verband TEGEWA e.V.	Industry or trade association	7
Comment received				
Verband TEGEWA e.V. does not agree with the proposed classification of the three substances as Repr. 1B, H360D. The reason for our objection can be found in the attached "Statement concerning the proposed classification and labelling of PFHxA and its inorganic salts" by [REDACTED], EuDiCo GmbH, Leverkusen. TEGEWA fully supports the content and the conclusion of this statement and therefore questions the CLH proposal.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Stellungnahme_PFHxA_t+m_TEGEWA.pdf				

### OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
30.06.2023	Germany	Gesamtverband Textil und Mode e.V.	Industry or trade association	8
Comment received				
see attachment „Statement concerning the proposed classification and labeling of PFHxA and its inorganic salts“				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment [Stellungnahme\\_PFHxA\\_t+m\\_TEGEWA.pdf](#)

Date	Country	Organisation	Type of Organisation	Comment number
29.06.2023	Sweden		MemberState	9
Comment received				
<p>The Swedish CA supports the Dossier Submitter's conclusion that the effects by PFHxA observed within the dose-ranges for STOT RE-classification does not show sufficient adversity to warrant classification. However, it is also noted that all studies were performed using the rat, which is less sensitive than the mouse, and it cannot be ruled out that adverse effects could have been observed within the dose-ranges for STOT RE-classification if similar studies had been performed in the mouse, as was the case for the closest PFCA homologue PFHpA (STOT RE-1 (liver)). Therefore, in absence of a relevant study on PFHxA the Dossier Submitter could consider to read-across data from PFHpA for classification in STOT RE 1 or 2 for liver effects.</p>				

#### PUBLIC ATTACHMENTS

1. [Stellungnahme\\_PFHxA\\_t+m\\_TEGEWA.pdf](#) [Please refer to comment No. 3, 7]
2. [Stellungnahme\\_PFHxA\\_t+m\\_TEGEWA.pdf](#) [Please refer to comment No. 1, 5, 8]