AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

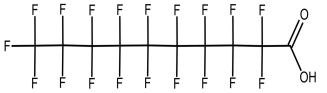
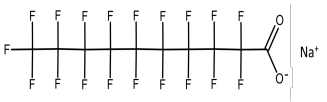
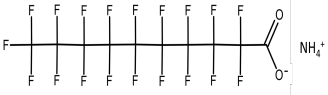
NONADECAFLUORODECANOIC ACID (PFDA) AND ITS SODIUM AND AMMONIUM SALTS

AS SUBSTANCES OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) 1907/2006[1]

Adopted on 2 December 2016

This agreement concerns

Substance names	EC Numbers	CAS numbers	Molecular formulas	Structural formulas
Nonadecafluorode-canoic acid (PFDA)	206-400-3	335-76-2	$C_{10}HF_{19}O_2$	
and its sodium	Not applicable	3830-45-3	$C_{10}F_{19}NaO_2$	
and ammonium salts	221-470-5	3108-42-7	$C_{10}H_4F_{19}NO_2$	

[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (30 August 2016, submission number SPS-012445-16) on identification of *Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts* as substances of very high concern due to their toxic for reproduction (CMR) and persistent, bioaccumulative and toxic (PBT) properties.

The Annex XV dossier was circulated to Member States on 6 September 2016 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 22 November 2016 and agreed in the written procedure of the Member State Committee with closing date of 2 December 2016.

Agreement of the Member State Committee in accordance with Article 59(8):

Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts **are identified as substances meeting the criteria of Article 57 (c) and (d) of Regulation (EC) 1907/2006 (REACH):**

- **as these substances meet the criteria for classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008[2], and**
- **they are persistent, bioaccumulative and toxic (PBT) in accordance with Annex XIII of the REACH Regulation.**

[2] Index number 607 720 00 X of Draft Commission Regulation (EU) amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (10th ATP) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, supporting RAC opinion and favourable opinion of the Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Committee) of 26 October 2016.

UNDERLYING ARGUMENTATION

FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN

Toxicity for reproduction:

Nonadecafluorodecanoic acid (PFDA) and its ammonium (PFD-A) and sodium (PFD-S) salts is covered by index number 607-720-00-X in the draft Commission Regulation (EU) amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (10th ATP) of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and where it is classified for developmental effects as Repr. 1B, H360Df ("May damage the unborn child. Suspected of damaging fertility") in accordance with the CLP criteria (Regulation (EC) No 1272/2008). This draft Commission Regulation follows the opinion of the ECHA Committee for Risk Assessment of 4 December 2015 (https://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling), adopted in accordance with Art 37(4) of the CLP Regulation (Regulation 1272/2008). The REACH Committee gave its favourable opinion on the draft Commission Regulation on 26 October 2016.

Therefore, PFDA and its sodium and ammonium salts meet the criteria of Article 57 (c) of the REACH regulation.

Persistency, bioaccumulation and toxicity (PBT)

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify PFDA and its ammonium and sodium salts as PBT. All available information (such as the results of standard tests, monitoring and modelling, information from the application of the category approach (grouping, read-across) and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence

PFDA is, based on its stable structure, not expected to undergo abiotic degradation under relevant environmental conditions.

In general, the persistence of PFDA can be explained by the shielding effect of the fluorine atoms, blocking e.g. nucleophilic attacks to the carbon chain. High electronegativity, low polarizability and high bond energies make highly fluorinated alkanes the most stable organic compounds. It is not expected that the carboxylic group in PFCAs alters this persistence of these chemicals. The persistence of six PFCAs (PFOA/APFO, PFNA and C11-C14 PFCAs) (P and vP) was already confirmed by MSC prior to their inclusion into the Candidate list.

Therefore, based on the knowledge of the stability of the C-F bond and the read-across approach with PFOA, PFNA and C11-C14 PFCAs it is concluded that PFDA is expected to undergo extremely limited degradation 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.

Bioaccumulation

Due to its expected notable water solubility, PFDA is, like the other PFCAs, expected to be quickly excreted in fish via gill permeation. Hence, bioconcentration in gill-breathing organisms is not the most relevant endpoint to consider, as reflected by the differences between bioaccumulation data for gill-

and air-breathing organisms. Field studies show that air-breathing organisms are more likely to bioaccumulate PFDA and other PFCAs compared to gill-breathing organisms. Based on the BCF values for PFDA it cannot be excluded that PFDA is bioaccumulative in fish: BCF values range from 450 to 2700 for carcass, liver and blood. Conclusions on bioaccumulation should be based on whole body values and carcass is seen as a good approximation for whole body. Based on the BCF of carcass PFDA does not bioaccumulate in fish. However, PFDA does not accumulate in lipid but rather binds to protein and membrane phospholipids, therefore the carcass or whole-body BCF values are less relevant. Based on the BCF value in the blood of rainbow trout (2700±350), PFDA can be considered bioaccumulative.

REACH Annex XIII (section 3.2.2) defines information which shall be taken into account in the assessment and can be used to draw conclusions on the assessment even when the numerical criterion is not applicable. Such data are, for example, data on the bioaccumulation potential in terrestrial species, such as elevated levels in endangered species. PFDA has been found in terrestrial species as well as in endangered species e.g. the polar bear and the beluga whale. These findings indicate a bioaccumulation potential.

Furthermore, REACH Annex XIII (section 3.2.2 (b)) requires to consider data from human body fluids or tissues and to take the toxicokinetic behaviour of the substance assessed into account. For PFDA, gestational and lactational exposure in humans has been shown, which is of special concern as the foetus and newborn babies are highly vulnerable to exposure by xenobiotic substances. On top of that, data from human body fluids clearly provide quantitative proof of the bioaccumulation of PFDA; elimination half-lives in humans are ≥ 4 years. In addition, recent studies, taking into account relevant confounding factors, show that PFDA blood concentrations in humans increase with increasing age.

Finally, REACH Annex XIII (section 3.2.2 (c)) foresees that the potential for biomagnification in food chains of a substance is assessed. The available field data provide evidence that bioaccumulation and trophic magnification do occur in certain food webs in the environment. For PFDA, field studies provide trophic magnification factors (TMFs) or biomagnification factors (BMFs) in aquatic and terrestrial food chains. When air breathing organisms are the top predators in these food chains, biomagnification could be demonstrated by calculation of TMFs and BMFs to be > 1 in several food chains, for example for wolves, dolphins and beluga whales.

The data summarised above is in high accordance with the bioaccumulation data on the other PFCAs. Altogether these show a regular pattern of bioaccumulation which depends on the chain-length of the perfluorinated alkyl.

Conclusion:

1. PFDA accumulates in humans.
    a. PFDA is present in human blood of the general population. PFDA has also been detected in human brain, lungs and kidney.
    b. Elimination half-lives are ≥ 4 years, which is longer than for PFNA and PFOA.
    c. PFDA levels increase with age after adjusting for relevant confounding factors.

2. There is evidence that PFDA preferentially bioaccumulates in air-breathing mammals, including endangered species and humans.
    a. BMFs range from 2.4 to 8.8 based on estimated whole body values in marine food web.
    b. TMFs range from 2.2 to 12.1 referring to either whole body measurements or estimated whole body values in marine wood web.

3. For part of the aquatic food chains investigated, PFDA accumulates in water-breathing animals.
   a. BCFs range from 450 (carcass) to 2700 (in blood).
   b. whole body BAFs range from 714 to 7943.
   c. whole body BMFs range from 0.21 to 4.4.
   d. whole body TMFs range from 0.39 to 3.67 in aquatic piscivorous food webs.

4. The bioaccumulation data on PFDA in environmental species, in laboratory mammals and in humans are consistent with the data on other long-chain perfluorinated carboxylic acids. Recent mechanistic bioconcentration models explain the substantial bioaccumulation of PFCAs by taking into account the observed pattern of animal tissue distribution, the relationship between chain length and bioaccumulation and the species and gender-specific variation in elimination half-life.

To conclude, taken all available information together in a weight-of-evidence approach, the elimination half-lives from humans and other mammals show that PFDA bioaccumulates. The available field data also indicate that bioaccumulation and trophic magnification occur in certain food webs in the environment. The data on PFDA are in line with the expected regular pattern of fate properties of the already assessed PFOA/APFO (B), PFNA (B) and C11-C14 PFCAs (vB). Therefore, it is considered that the B criterion of REACH Annex XIII is fulfilled. Whether the vB criterion is fulfilled has not been assessed.

Toxicity
There is evidence based on the draft Commission Regulation on the harmonised classification and labelling of various substances including PFDA and its sodium and ammonium salts (draft 10th ATP), following the related RAC opinion, and the favourable opinion of the REACH Committee on that draft Commission Regulation, that these substances meet the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of the REACH Regulation. Consequently, the toxicity criterion of REACH Annex XIII is fulfilled.

In conclusion, the substances *PFDA and its sodium and ammonium salts* meets the criteria for a CMR and PBT substance according to Article 57(c) and (d) of REACH.

Reference:

Support Document (Member State Committee, 2 December 2016)