AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

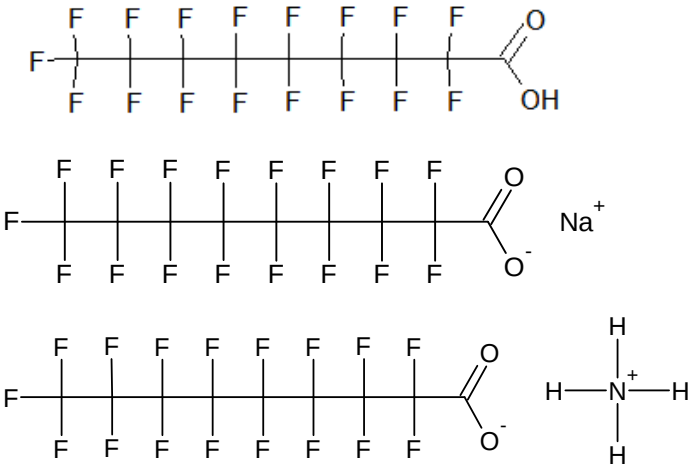
PERFLUORONONAN-1-OIC-ACID AND ITS SODIUM AND AMMONIUM SALTS

AS A SUBSTANCE OF VERY HIGH CONCERN

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

Adopted on 30 November 2015

This agreement concerns

Substance name:	**Perfluorononan-1-oic-acid (PFNA) [1] and its sodium [2] and ammonium salts [3]**
EC number:	**206-801-3 [1], Not applicable [2], Not applicable [3]**
CAS number:	**375-95-1 [1], 21049-39-8 [2], 4149-60-4 [3]**
Molecular formula:	**$C_9HF_{17}O$ [1]**
Structural formula:	

[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 (20 August 2015, submission number EC018886-46) on identification of *perfluorononan-1-oic-acid and its sodium and ammonium salts (PFNA)* as substances of very high concern due to their toxic for reproduction and PBT properties.

The Annex XV dossier was circulated to Member States on 31 August 2015 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 17 November 2015 and agreed in the written procedure of the Member State Committee with closing date of 30 November 2015.

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

Perfluorononan-1-oic-acid and its sodium and ammonium salts **are identified as substances of very high concern because:**

a) they meet the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) as toxic for reproduction 1B, and

b) they meet the criteria of Article 57 (d) of REACH as substances which are persistent, bioaccumulative and toxic (PBT), in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction:

In its opinion of September 2014 on the proposal for harmonised classification and labelling at EU level of *Perfluorononan-1-oic acid (2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluorononanoic acid) (PFNA) and its sodium and ammonium salts*[2], ECHA's Committee for Risk Assessment (RAC) concluded that the evidence is sufficiently convincing to classify PFNA for developmental effects as Repr. 1B, H360Df ("May damage the unborn child. Suspected of damaging fertility") in accordance with the CLP criteria (Regulation (EC) 1272/2008).

Therefore, even though PFNA is not yet listed in Annex VI of CLP (Regulation (EC) 1272/2008) there is evidence based on the RAC opinion on PFNA that *PFNA and its sodium and ammonium salts* meet the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

PBT

A weight of evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance as P and B. The available relevant information has been considered in a weight-of-evidence approach.

Persistency:

PFNA is, based on its stabile structure, not expected to undergo abiotic degradation under relevant environmental conditions. A standard screening study on PFNA supporting this understanding is available.

In general, the persistence of Perfluorinated carboxylic acids (PFCAs), to which PFNA belongs, 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 the persistence (P and vP) of these chemicals. The persistence of five PFCAs (PFOA and C11-C14-PFCAs) (P and vP) was already confirmed by the MSC.

[2] Committee for Risk Assessment. RAC Opinion proposing harmonised classification and labelling at EU level of Perfluorononan-1-oic acid [1]; (2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9 heptadecafluorononanoic acid (PFNA) and its sodium (PFN-S) [2] and ammonium (PFN-A) [3] salts, EC number: 206-801-3 CAS number: 375-95-1. CLH-O-0000004708-66-03/F. Adopted 12 September 2014. Available at: http://echa.europa.eu/documents/10162/0b290fee-19b7-4d7e-8365-312df5d1ae37

Therefore, based on the read-across approach with PFOA, it is concluded that PFNA 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.

Bioaccumulation:

There are no experimental BCF values available for PFNA. The numeric criterion as suggested in REACH Annex XIII (sections 1.1.2 and 3.2.2(a)) for a bioaccumulative substance in aquatic species is not expected to be fulfilled for PFNA based on read across. Due to its expected notable water solubility, PFNA is, like the other PFCAs, expected to quickly be excreted via gill permeation. Furthermore, PFNA is present mainly in protein rich tissues like blood and liver (OECD, 2006; Kelly et al. 2009). Hence, bioconcentration in gill breathing organisms and the accumulation in lipids is not the most relevant endpoint to consider. Field studies show that air-breathing organisms are more likely to bioaccumulate PFNA and other PFCAs compared to water breathing organisms. Therefore, the numerical bioaccumulation (B) criterion defined in the REACH Regulation Annex XIII (sections 1.1.2 and 3.2.2(a)) is not suitable to assess the bioaccumulation potential of PFNA.

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. PFNA has been found in terrestrial species as well as in endangered species as shown for the polar bear and in beluga whale. These findings indicate a bioaccumulation potential and are of high concern.

Furthermore, Annex XIII (section 3.2.2 (b)) requires to consider data from human body fluids or tissues and to take the toxicokinetic behavior of the substance assessed into account. For PFNA, 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 toxic substances. On top of that, data from human body fluids clearly provide quantitative proof of the bioaccumulation of PFNA: Elimination half-lives in humans are more than 1 year. In addition, recent studies, taking into account relevant confounding factors, show that PFNA blood concentrations in humans increase with increasing age.

Finally, 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 PFNA, field studies provide trophic magnification factors (TMFs) or biomagnification factors (BMFs) for 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 > 1 in several food chains, for example for wolves and beluga whales.

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

Conclusion on bioaccumulation:

1. PFNA accumulates in humans
    a. PFNA is present in human blood of the general population,
    b. Elimination half-lives are > 1.7 years,
    c. Human elimination half-lives seem to be the longest amongst the available mammalian data, whereas the elimination half-lives in laboratory mammals vary highly depending on the study conditions,
    d. PFNA levels increase with age after adjusting for relevant confounding factors.
2. There is evidence that PFNA preferentially bioaccumulates in air-breathing mammals, including endangered species and humans
    a. BMFs range from 1.4 – 24 based on estimated whole body values,
    b. TMFs range from 2.9 to 9.88 referring to either whole body measurements or estimated whole body values.
3. PFNA does not seem to consistently accumulate in water breathing animals
    a. No experimental BCFs are available for PFNA. For the closest structural analogues BCFs range from 4.0 to 27 (PFOA) and from 450 to 2700 (PFDA),
    b. Whole body BAFs range from 0 to 3981,
    c. Whole body BMFs range from 0.13 to 5.3 whereas most of the data are below 1,
    d. Whole body TMFs range from 0.33 to 1.22 in aquatic piscivorous food webs.
4. The bioaccumulation data on PFNA in environmental species, in laboratory mammals and in humans is consistent with the data on other long-chain perfluorinated carboxylic acids, such as PFOA.
    a. Recent models to explain the substantial bioaccumulation of PFCAs take 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.

Overall, taken all available information together in a weight-of-evidence approach, the elimination half-lives from humans and other mammals show that PFNA bioaccumulates. The available field data also indicate that bioaccumulation and trophic magnification occur in certain food webs in the environment. The data on PFNA are in line with the

expected regular pattern of fate properties of the already assessed PFOA and C_{11}-C_{14}-PFCAs. 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 RAC opinion on PFNA and its sodium and ammonium salts that indicates that these substances meet the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of the REACH Regulation. As a consequence the toxicity criterion of REACH Annex XIII is fulfilled.

In conclusion, PFNA and its sodium and ammonium salts meet the criteria for PBT substances according to Article 57 (d) of the REACH Regulation.

Reference:

Support Document *PFNA and its sodium and ammonium salts* (Member State Committee, 30 November 2015)