AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

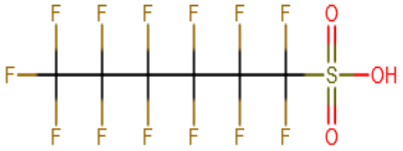
PERFLUOROHEXANE-1-SULPHONIC ACID AND ITS SALTS

AS SUBSTANCES OF VERY HIGH CONCERN

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

Adopted on 15 June 2017

This agreement concerns

Substance name	EC Number	CAS number	Molecular formula	Structural formula
Perfluorohexane-1-sulphonic acid	206-587-1	355-46-4	$C_6HF_{13}O_3S$	
and its salts	-	-	-	-

[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 (3 March 2017, submission number SPS-013184-17) on identification of *Perfluorohexane-1-sulphonic acid and its salts (PFHxS)* as substances of very high concern due to their very persistent and very bioaccumulative (vPvB) properties.

The Annex XV dossier was circulated to Member States on 9 March 2017 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 May 2017 and discussed in the meeting on 12-16 June 2017 of the Member State Committee.

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

Perfluorohexane-1-sulphonic acid and its salts (PFHxS) are identified as substances meeting the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as they are very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII of the REACH Regulation.

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN

Persistency and bioaccumulation (vPvB)

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify PFHxS as vPvB. All available relevant information, such as the results of standard tests, monitoring and modelling, information from the application of read-across and (Q)SAR results, was considered together in a weight-of-evidence approach.

Persistence

PFHxS has a stable perfluorinated structure and is not expected to undergo abiotic degradation under relevant environmental conditions. An available photo-transformation study in water, which found negligible degradation via photolysis, supports this understanding. There is no study available on biodegradation, so data from structurally similar compounds are therefore used in a read-across approach. A read-across with PFOS is applied for biodegradation screening test and a read-across with PFOS and PFOA is applied for the simulation tests (in water, sediment and soil).

The persistence of PFSAs and PFCAs can, in general, be explained by the shielding effect of the fluorine atoms, blocking e.g. nucleophilic attacks on the carbon chain. High electronegativity, low polarisability and high bond energies make highly fluorinated alkanes extremely stable organic compounds. It is not expected that the sulphonic group in PFSAs alters the persistence of these chemicals. The persistence of PFOS and the eight entries of PFCAs included into the Candidate List has already been confirmed.

Therefore, based on the knowledge of the stability of the C-F bond and the read-across approach with PFOS and PFOA, it is concluded that PFHxS is expected to undergo extremely limited degradation in the environment and thus fulfils the persistent (P-) and very persistent (vP) criteria in accordance with the criteria and provisions set out in Annex XIII of REACH.

Bioaccumulation

The reported bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) for PFHxS are below the numerical criteria 2000/5000 in REACH Annex XIII, but it is worth noting that one of the BAF values (European chub, BAF plasma) is close to the threshold of 2000 (log BAF of 3.3 equivalent to a BAF of 1995). The latter value suggests that the substance is a borderline B for some aquatic species. In addition, due to the surface-active properties of the substance the appropriateness of the available BCF test and the usefulness of its result may be questioned. Further, PFHxS is expected to quickly be excreted in fish via gill permeation like the other PFSAs and PFCAs, due to its expected notable water solubility. PFHxS, like other PFSAs and PFCAs, do not follow the behaviour of traditional hydrophobic compounds with partitioning into fatty tissues, but instead bind to proteins in blood and liver. Hence, bioconcentration in gill breathing organisms and the accumulation in lipids is not the most relevant endpoint to consider for these types of substances. Field studies show that air-breathing organisms are more likely to bioaccumulate PFHxS and other PFAS compared to water breathing organisms. Therefore, the numerical bioaccumulation (B)/(vB) criteria defined for aquatic species in the REACH regulation Annex XIII (sections 1.1.2 and 1.2.2) are not suitable to assess the bioaccumulation potential of PFHxS.

REACH Annex XIII (section 3.2.2) defines information which shall be taken into account in the B assessment and can and should be used to draw conclusions in a weight-of-evidence approach. In addition to BCF-data, such data are based on Section 3.2.2(b) of Annex XIII to REACH, for example, data on the bioaccumulation potential in terrestrial species, such as elevated levels in endangered species. PFHxS was found in terrestrial species as well as in endangered species as the polar bear. The highest concentrations of PFHxS detected in wildlife have been observed in the arctic top predator polar bear (>500 µg/kg in polar bear liver). This finding and the high concentrations of PFHxS found in humans exposed to contaminated drinking water (up to 1790 µg/L in blood serum) show that exposure to PFHxS has the potential to result in high concentrations in biota including humans. 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 behaviour of the substance into account. Both gestational and lactational exposure in humans have been shown for PFHxS, 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 PFHxS: Elimination half-lives in humans range from 7-8 years and above. Data from time trend studies on human samples indicate that the bioaccumulation of PFHxS even exceeds that of PFOS.

Finally, Annex XIII (section 3.2.2 (c)) foresees that the potential for biomagnification in food chains of a substance is assessed, as part of a weight-of-evidence approach. It is not possible to draw a conclusion on trophic magnification for PFHxS due to limited reliability of the available data. However, the available field data provide biomagnification factors (BMFs) for several predator/prey relationships for PFHxS. In air-breathing predators the resulting BMFs are larger than 1, especially for polar bears suggesting a potential of biomagnification that is supported by monitoring data.

The elimination half-life of PFHxS in mammalian species are similar to that of PFOS in mice, male rats, pigs, monkeys and humans. The elimination half-lives observed for PFHxS in pigs, monkeys and humans are the longest observed for any PFAS, followed by those for PFOS. The main reason why e.g. PFOA was considered to meet the B-criterion of REACH was that it was concluded to bioaccumulate in humans based e.g. on its presence in human blood of the general population, the long elimination half-life in human blood of 2-4 years and that the levels increase with age. This holds true also for PFHxS but it has an elimination half-life in human blood of ca 7-8 years (or longer), which is at least 2-4 times longer than the elimination half-life of PFOA.

Depending on the type of substance, the process driving the bioaccumulation will differ, from hydrophobic partitioning to species and gender specific ADME-properties. Elimination half-lives are recognised as relevant bioaccumulation metrics and PFHxS has in comparison with PBT/vPvB[2] and POP[3]-substances among the longest human elimination half-lives reported.

The information summarised above is in high accordance with the bioaccumulation data on PFOS, the bioaccumulation potential of which corresponds to “vB” as it is included under the Stockholm Convention on POPs. A read-across to PFOS is performed as part of the weight-of-evidence.

Conclusion:

1. PFHxS accumulates in humans:

    a. PFHxS are present in human blood of the general population

[2] PBT/vPvB = persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
[3] POP = persistent organic pollutants

b. Time trend studies indicate that the human bioaccumulation potential of PFHxS may even be larger than that of PFOS.

c. The human elimination half-life for PFHxS is > 7 years which is the longest of all perfluoroalkyl and polyfluoroalkyl substances (PFAS) for which data are available. It is also comparable to the longest human elimination half-lives recorded for known PBT/vPvB- and POP-substances such as some PCBs.

2. There is evidence that PFHxS preferentially bioaccumulates in air-breathing mammals, including endangered species and humans

a. The elimination half-lives observed for PFHxS in pigs (713 d in males & females) and monkeys (141 d in males) are the longest observed for any PFAS.

b. BMFs (polar bear liver/seal liver) range from 20 to 373. There are uncertainties associated with these calculated numbers that may have resulted in under- or overestimations of the BMFs.

c. It accumulates in the air-breathing food chains at least as much as PFOS, and more than the long-chained PFCAs which have already been identified as vB on the Candidate List.

d. It is not possible to conclude on trophic magnification factor (TMF) on aquatic foodweb containing air-breathing mammals due to the limited reliability of the available data

e. Elevated levels of PFHxS have been measured in both humans (up to 1790 µg/L in blood serum) and wildlife (>500 µg/kg in polar bear liver) showing that exposure to PFHxS has the potential to result in high levels in biota.

3. Even if PFHxS appear to be a borderline “B” in some water-breathing animals, bioaccumulation potential of PFHxS in water-breathing animals is not expected to be very high since PFHxS can be quickly excreted in fish via gill permeation like the other PFSAs and PFCAs, due to its notable water solubility (2.3 g/L).

a. BCF range from 9.6 (whole body) to 100 (liver)

b. Whole body BAFs range from 380 (fish, crab) to 1995 (fish)

c. Whole body BMFs range from 0.14 (fish, lab data) to 10 (fish, field data). There are uncertainties associated with these calculated numbers that may have resulted in under- or overestimations of the field BMFs.

d. It is not possible to conclude on TMF on water breathing aquatic foodwebs due to the limited reliability of the available data

Thus, taking all available information together in a weight-of-evidence approach, and particularly considering the very long human and non-rodent mammalian elimination half-lives, supported by the indication of field bioaccumulation (which may be even higher than for PFOS and the long-chained PFCAs already identified as vB), PFHxS fulfil the vB criterion of REACH Annex XIII.

Therefore, it is concluded that the substances *Perfluorohexane-1-sulphonic acid and its salts (PFHxS)* meet the criteria for vPvB substances according to Article 57(e) of REACH.

Reference:

Support Document (Member State Committee, 15 June 2017)