HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

Perfluorohexane-1-sulphonic acid and its salts

EC No 206-587-1

CAS No 355-46-4

Member State(s): Sweden

Dated: 02 December 2016

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Version 1.3

1. HAZARD SUBJECT TO ASSESSMENT

Perfluorohexane-1-sulphonic acid was originally selected for hazard assessment in order to clarify suspected hazard properties: persistence and bioaccumulation.

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Outcome	**Tick box**
According to the authority's assessment the substance does not have PBT/vPvB properties based on the currently available information..	
According to the authority's assessment the substance has PBT/vPvB properties.	√
According to the authority's assessment further information would be needed to confirm the PBT/vPvB properties but follow-up work is not relevant or carried out at present.	

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING[1]

Persistence

PFHxS is, based on its stabile perfluorinated structure, not expected to undergo abiotic degradation under relevant environmental conditions. An available phototransformation study in water, which found neglible degradation via photolysis, support this understanding. There is no study available on biodegradation, why data from structurally similar compounds therefore are considered in an analogue approach using read-across.

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 polarizability and high bond energies make highly fluorinated alkanes the most stable organic compounds. It is not expected that the sulphonic group in PFSAs alters the persistence of these chemicals.

It is, based on known persistence of perfluorinated compounds in general and the close structural similarity between PFHxS and with the very persistent PFOS, which is listed under the Stockholm Convention, but also the similarity with the long-chained PFCAs (C11-C14) which are already included on the Candidate List as vP (ECHA 2012 a-d), concluded that PFHxS meets the criteria for vP as specified in REACH, Annex XIII.

Bioaccumulation

Depending on type of substance, the process driving the bioaccumulation will differ, from hydrophobic partitioning to species and gender specific ADME-properties.

The reported BCF and BAF for PFHxS are below the numeric B-criterion in REACH Annex XIII indicating no high bioaccumulation potential in aquatic organisms. PFHxS is due to its expected

[1] Assessments of PBT properties are based on Annex XIII to the REACH Regulation.

notable water solubility, like the other PFAS expected to quickly be excreted via gill permeation. Furthermore, PFHxS behaves similarly to what previously have been observed for other perfluorinated compounds which preferentially binds to proteins in blood and liver. Ng and Hungerbuhler (2014)[2] concluded that protein interactions are needed to explain some important features of perfluorinated alkyl acids bioaccumulation. According to the same authors (Ng and Hungerbuhler, 2014) the three key features of PFAS bioaccumulation consist of a protein component (especially to describe the accumulation in the blood compartment), elimination and reabsorption as mediated by transporter proteins and a phospholipid component (to describe the distribution into tissues where little or no specific binding occurs). 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 PFHxS and other PFAS compared to water breathing organisms. Therefore, the numerical bioaccumulation (B)/(vB) criteria defined in the REACH regulation Annex XIII (sections 1.1.2 and 3.2.2(a)) are not suitable to assess the bioaccumulation potential of PFHxS.

Annex XIII (section 3.2.2) defines information which shall be taken into account in the assessment and can be used to draw conclusions 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. PFHxS was found in terrestrial species as well as in endangered species. 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 (1790 µg/L in blood serum) show that exposure to PFHxS have the potential to result in high concentrations in biota. 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 assessed into account. The elimination half-lives for PFHxS in non-rodent mammalian species are the longest of all PFSAs and PFCAs for which there are available data. PFHxS is present in human blood of the general population and both gestational and lactational exposure in humans have been shown. Data from human body fluids 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 exceed that of PFOS. The elimination half-life for humans are among the longest of all PBT/vPvB- and POP-substances for which data on human elimination half-lives are available.

Taking all available information together in a weight-of-evidence approach and particularly considering the very long human elimination half-life and the indication of field bioaccumulation which may be even higher than for PFOS, it is concluded that PFHxS fulfils the vB criterion of REACH Annex XIII.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Taking into account the overall data and the input from the PBT expert group, the Swedish Chemicals Agency submitted an intention to put together a dossier for identification of PFHxS as a substance of very high concern according to REACH Article 57 (e). Planned submission date for the SVHC-dossier is February 2, 2017.

[2] Ng, C. A., & Hungerbuhler, K. (2013). Bioconcentration of perfluorinated alkyl acids: how important is specific binding? Environ Sci Technol, 47(13), 7214-7223. doi: 10.1021/es400981a

Follow-up action	**Date for intention**	**Actor**
SVHC	02 / 2017	Swedish Chemicals Agency