Kemikalieinspektionen
Swedish Chemicals Agency

RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Substance name: Perfluorohexane-1-sulphonic acid [1] and its salts, e.g. ammonium perfluorohexane-1-sulphonate [2], potassium perfluorohexane-1-sulphonate [3]

EC No: 206-587-1 [1], 269-511-6 [2], 223-393-2 [3]

CAS No: 355-46-4 [1], 68259-08-5 [2], 3871-99-6 [3]

Member State(s): Sweden

Dated: 02 December 2016

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude other Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The vPvB properties of PFHxS were first discussed at the 9th PBT EG meeting in May 2015. The assessment has after that been through two written procedures and continuously been refined based on the comments received The PBT EG provides informal scientific advice on questions related to the identification of PBT and vPvB properties of chemicals. This advice is non-binding and does not anticipate or interfere with decision-making under the REACH Regulation, which exclusively remains the responsibility of the competent bodies designated in the REACH Regulation.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	✓
Harmonised classification and labelling	
Identification as SVHC (authorisation)	✓
Restrictions *(might be possible at a later stage)*	✓
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

Whether PFHxS would be classified has not been assessed.

3.1.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

It is based on known persistence of perfluorinated compounds and the close structural similarity with the very persistent PFOS proposed that PFHxS meet the criteria for vP as specified in REACH, Annex XIII.

A more pragmatic approach is required when deciding on the bioaccumulation of substances for which the traditional numerical criterion on bioaccumulation are not appropriate. This as these substances do not follow the behaviour of traditional hydrophobic compounds with partitioning into fatty tissues. Factors that have been brought forward to explain important features of perfluorinated alkyl acid bioaccumulation are binding to proteins (especially to describe the accumulation in 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). It is from monitoring data clear that PFHxS preferentially bioaccumulates in air-breathing mammals, including endangered species and humans..

The available studies on temporal trends in humans indicate increasing levels of PFHxS. The elimination half-life of PFHxS is the longest measured of all PFASs in humans, monkeys and pigs. The elimination half-life for humans are even among the longest of all PBT/vPvB- and POP-substances for which data on human elimination half-lives are available. From the outcome of the PBT fact sheet it is clear that PFHxS poses properties that indicate a very high bioaccumulation potential in humans with high binding to blood proteins, low clearance and high elimination half-life. Furthermore, PFHxS should be considered as a substance fulfilling the vB criterion.

Hence, PFHxS fulfils the criteria for article 57e in the REACH regulation.

PFHxS-related substances (which are based on the chemical structure $C_6F_{13}SO_2X$, where X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers) can be degraded to PFHxS in the environmental. According to REACH, if a substance transforms and/or degrades to a substance with vPvB-properties, the substance itself must be regarded as a vPvB-substance and treated as such with regard to emission estimation and exposure control. Therefore PFHxS-related substances need to be covered by risk management measures as well in order to limit PFHxS in the environment successfully. Hence, PFHxS-related substances also fulfil the criteria for article 57e.

Although PFHxS or its related substances does not fulfil the relevancy criteria according to the SVHC Roadmap 2020 (no full registration yet), the identification of PFHxS and its related substances as vPvB and also as a possible replacement for PFOS are reasons for inclusion in the Candidate List. Furthermore, an inclusion of PFHxS and its related substances in the Candidate List would clearly establish that the substance has vPvB properties and should therefore be substituted wherever possible.

A PBT-fact sheet for PFHxS was first discussed at the 9th PBT EG meeting in May 2015. The assessment has after that also been through two written procedures and continuously been refined based on the comments received. The comments received from the group supported the vPvB-proposal.

PFHxS would have a low priority for inclusion in Annex XIV and inclusion in Annex XIV would not cover PFHxS in imported articles.

After the inclusion of PFHxS and its related substances in the Candidate List, a restriction might be considered as a next step, provided that sufficient information on e.g. occurrence in articles and exposure of humans and the environment is available. Experience and the outcome of the ongoing restriction proposal on PFOA will be important to take into account before deciding that a restriction on PFHxS and its potential precursors is appropriate.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor

Annex XV dossier for SVHC	02-2017	Sweden (Swedish Chemicals Agency)