AGREEMENT OF THE MEMBER STATE COMMITTEE

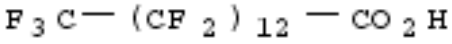
ON THE IDENTIFICATION OF HEPTACOSAFLUOROTETRADECANOIC ACID

AS A SUBSTANCE OF VERY HIGH CONCERN

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

Adopted on 13 December 2012

This agreement concerns

Substance name:	**Heptacosafluorotetradecanoic acid**
EC number:	**206-803-4**
CAS number:	**376-06-7**
Molecular formula:	**$C_{14}HF_{27}O_2$**
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

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (28 August 2012, submission number CW012885-16) on identification of *Heptacosafluorotetradecanoic acid* as a substance of very high concern due to its vPvB properties.

The Annex XV dossier was circulated to Member States on 3 September 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 19 November 2012 and was discussed in the meeting on 10-13 December 2012 of the Member State Committee.

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

Heptacosafluorotetradecanoic acid **is identified as a substance meeting the criteria of Article Article 57 (e) as a substance which is very persistent and very bioaccumulative, 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

A weight of evidence determination according to the provisions of Annex XIII of REACH is used to identify Heptacosafluorotetradecanoic acid (C_{14}-PFCA) as vPvB. All available information (such as 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. The individual results have been considered in the assessment with differing weights depending on their nature, adequacy and relevance. The available results are assembled together in a single weight of evidence determination.

Persistence:
Heptacosafluorotetradecanoic acid (C_{14}-PFCA) has no abiotic degradation studies available. Only one standard screening study is available.

Read across approach within C_8-C_{14}-PFCAs can be applied for the persistence assessment of these substances. $C_{8\text{-}14}$-PFCAs contain a highly similar chemical structure, a perfluorinated carbon chain and a carboxylic acid group. The compounds differ only in the number of CF_2-groups. As a result of comparing the experimental and estimated physico-chemical data of C_8–PFCA (the analogue substance) with experimental and estimated data on $C_{11\text{-}14}$-PFCAs it can be assumed that with increasing chain length water solubility decreases and the sorption potential increases (See Table 12 of the support document). It can be with a sufficient reliability stated that the behaviour of these chemicals follow a regular pattern.

Due to both structural similarity and a regular pattern of physico-chemical properties, $C_{8\text{-}14}$-PFCAs may be considered as a group or a category of substances for the purpose of the PBT/vPvB assessment and the read-across approach can be applied within this group.

In general, the persistence of l C_{11}-C_{14}-PFCAs 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 to the most stable organic compounds. It is not expected that the carboxylic group in PFCAs alters this persistence of these chemicals. This fact is confirmed by a hydrolysis study which obtained a DT_{50} of >92 years for C_8-PFCA in water. Screening studies of $C_{8,9,12,14}$-PFCAs showed no biodegradation

within 28 days. Non-standard abiotic degradation tests with C_8-PFCA could not detect any degradation products under environmentally relevant conditions. Furthermore, screening biodegradation studies on $C_{8,9,12,14}$-PFCAs and one non-standard anaerobic biodegradation simulation test with C_8-PFCA provide evidence of high persistence. Additionally, elements of non-standard higher tier aerobic biodegradation studies on C_8-PFCA provide further support that no biodegradation in water, soil and sediment occurs.

Therefore, based on the information summarized above it is concluded that C_{14}-PFCA 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:

Regarding the bioaccumulation potential for C_{14}-PFCA the available experimental BCF-values of C_{14}-PFCA are above 5000. Furthermore, Table 13 of the support document provides information on BCF, BMF and TMF of $C_{9\text{-}14}$ PFCAs relevant to justify read across in the B assessment. Thus, the B as well as the vB-criteria -are met in accordance with the criteria and provisions set out in Annex XIII of REACH.

Conclusion:

In conclusion, C_{14}-PFCA is identified as a vPvB-substance according to Art. 57e) of REACH and by applying a weight of evidence determination using expert judgement by comparing all relevant and available information listed in Section 3 of Annex XIII of REACH with the criteria set out in Section 1 of the same Annex.

Reference:

1. Support Document *Heptacosafluorotetradecanoic acid* (Member State Committee, 13 December 2012)