AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF HENICOSAFLUOROUNDECANOIC 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: **Henicosafluoroundecanoic acid**

EC number: **218-165-4**

CAS number: **2058-94-8**

Molecular formula: **$C_{11}HF_{21}O_2$**

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 CW013799-08) on identification of *Henicosafluoroundecanoic 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):

Henicosafluoroundecanoic 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 Henicosafluoroundecanoic acid as vPvB. All available information (such as results of standard tests, monitoring and modelling, information from the application of the category and analog 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:

Henicosafluoroundecanoic acid (C_{11}-PFCA) has no degradation studies 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 15 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 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 summarised above, it is concluded that C_{11}-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

Results from bioconcentration and bioaccumulation studies in aquatic species:

The whole body BCF for C_{11}-PFCA from the MITI flow-through study conducted with carp is in the range of 2300 – 3700 (National Institute of Technology and Evaluation, 2007). The study of Martin et al. considers that carcass BCFs closely approximate the whole-body BCF. This means the whole-body BCF would be approximately 2700 (mean value). C_{11}-PFCA would therefore be bioaccumulative but not very bioaccumulative if referred to whole body according to Annex XIII of REACH.

However, if taking into account that PFCAs show hepatotoxic effects, focus should rather be given to the higher accumulation potential in liver as bioaccumulation may be used as indicators for toxicity to organisms. Based on the findings there is a potential to reach critical levels that may elicit toxic effects over long-term exposures due to the high bioaccumulation potential to the liver.

BCF values of 5848-6326 (carcass) and 5246-5675 (liver) derived with two calculation methods from an experimental fish feeding study suggest that C_{11}-PFCA is very bioaccumulative.

Other information on the bioaccumulation potential and ability of the substance to biomagnify in the food chain:

Available field based bioaccumulation data show BAF values for C_{11}-PFCA well above the trigger-value of 5000 for various species from different studies.

Various available field-BMFs and even TMFs for C_{11}-PFCA provide evidence on that biomagnification of the substance takes place in nature between different trophic levels of food chains and from the bottom to the top of food chains.

Comparing the different field-BMF and TMF values for $C_{9\text{-}14}$-PFCAs within single studies revealed a trend between chain length and BMF and TMF values, showing that C_{11}-PFCA has a higher biomagnification potential than the longer chained homologues (see Data Matrix in Table 16 of the support document and Figures 1-4). The potential to magnify in the food web declined from C_{11}-PFCA to C_{14}-PFCA indicating that trophic magnification is more pronounced for C_{11}-PFCA than for the longer chained PFCAs. Hence, although C_{11}-PFCA seems to have in laboratory studies a lower bioaccumulation potential than its longer chained homologues, based on field data it has a higher potential to transfer through the food web as demonstrated by high BMF, TMF and BAF values. This observation especially

points to the need of expert judgement based on weight-of-evidence.

A human biomonitoring study indicates that C_{11}-PFCA is eliminated from human serum at a slower rate compared to its longer chained homologues C_{12-14}-PFCAs. These results further support that C_{11}-PFCA shows a higher bioaccumulation potential compared to C_{12-14}-PFCAs in certain studies.

Conclusion on the bioaccumulation potential:

Based on only the BCFs derived from flow-through tests, C_{11}-PFCA clearly fulfils the B criterion but some uncertainty remains whether it fulfils the vB criterion. BCFs derived from BMFs of a fish feeding study are above 5000. Although these laboratory data indicate that the vB criterion may be fulfilled, further confirmation is sought from field data.

Bioaccumulation factors derived in field studies are clearly above the trigger of 5000 which can be considered analogous to a BCF > 5000. Furthermore, the various available field-BMFs and TMFs for this substance provide evidence that biomagnification at high level takes place in nature.. It is important to note that among C_{11-14}-PFCAs, C_{11}-PFCA based on field-BMFs and TMFs has the highest bioaccumulation potential indicating that trophic magnification is more pronounced for C_{11}-PFCA than for the longer chained PFCAs. C_{12-14}-PFCAs fulfill the vB criterion. Although for a large part of available information direct comparison with the vB criterion cannot be made, this information and especially the field data provide clear evidence on that the substance behaves in a way corresponding to bioaccumulation behaviour of substances which by direct comparison of the data to the vB criterion meet the criterion. Consequently, it is concluded that C_{11}-PFCA fulfils both the B and the vB-criteria of REACH.

Conclusion:

In conclusion, C_{11}-PFCA is identified as a vPvB-substance according to Art. 57 (e) of REACH following the application of 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 *Henicosafluoroundecanoic acid* (Member State Committee, 13 December 2012)