**AGREEMENT OF THE MEMBER STATE COMMITTEE**

**ON THE IDENTIFICATION OF PENTACOSAFLUOROTRIDECANOIC 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**

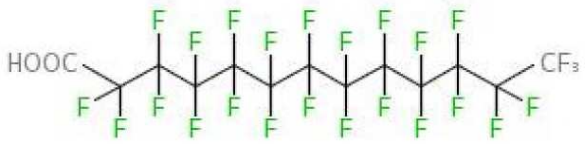
**Substance name:** **Pentacosafluorotridecanoic acid**

**EC number:** **276-745-2**

**CAS number:** **72629-94-8**

**Molecular formula:** **$C_{13}HF_{25}O_2$**

**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 CW012582-28) on identification of *Pentacosafluorotridecanoic 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):

***Pentacosafluorotridecanoic 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 Pentacosafluorotridecanoic acid ($C_{13}$-PFCA) 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:**
Pentacosafluorotridecanoic acid ($C_{13}$-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 13 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 physic-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 summarized above, it is concluded that $C_{13}$-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 $C_{13}$-PFCA there are no available experimental BCF-values. The BCFs of $C_{12}$-PFCA and $C_{14}$-PFCA from fish flow-through bioaccumulation tests are well above 5000 (see Table 14 of the support document). Due to the structural similarity and the regular pattern of physic-chemical properties within this group it can be with a high reliability assumed that also $C_{13}$-PFCA has a BCF larger than 5000, too. A number of field-BMFs and TMFs are available for $C_{13}$-PFCA and they provide evidence that biomagnification of this substance takes place in nature between different trophic levels of food chains and from the bottom to the top of food chains (See Table 14 of the support document). Therefore, based on the information summarized above, it is concluded that $C_{13}$-PFCA fulfils the B and the vB-criteria in Annex XIII of REACH.

**Conclusion:**

In conclusion, $C_{13}$-PFCA is identified as a vPvB-substance according to Art. 57 (e) 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 *Pentacosafluorotridecanoic acid* (Member State Committee, 13 December 2012).