

AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

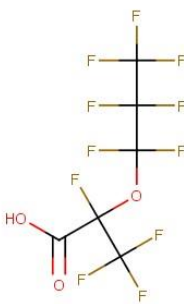
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)

AS SUBSTANCES OF VERY HIGH CONCERN

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹**

Adopted on 26 June 2019

This agreement concerns

Substance names	EC Numbers	CAS numbers	Molecular formulas	Structural formulas
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid (HFPO-DA),	236-236-8	13252-13-6	C ₆ HF ₁₁ O ₃	
and its salts and acyl halides	-	-	-	-

¹Regulation (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

The Netherlands presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (6 March 2019, submission number SPS-014705-19) on identification of *2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)* as substances of very high concern due to their properties for which there is scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH Regulation.

The Annex XV dossier was circulated to Member States on 13 March 2019 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 28 May 2019 and discussed in the meeting on 24-27 June 2019 of the Member State Committee.

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

***2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)* are identified as substances meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances for which there is scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH Regulation.**

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Equivalent level of concern:

2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof), further denoted as HFPO-DA, are identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because in water under environmental conditions these substances exist in the form of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate, for which there is scientific evidence of probable serious effects to the environment and human health which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH Regulation.

Several concerns are caused by the intrinsic properties of HFPO-DA. Elements of concern are triggered by individual intrinsic properties or by different combinations of the properties. Overall, HFPO-DA has a very high potential to cause effects in wildlife and in humans exposed via environment, due to its persistence, mobility, potential for long-range transport, observed adverse effects that may be relevant for human health and the environment (at least the following probable effects for human health: effects on the liver, the kidney, the haematological and immune systems and effects on development, and the following effects for the environment: population relevant effects on birds and mammals) and exposure via plants and fish. The very high persistence together with low adsorption potential and mobility imply a high potential for increasing pollution stock in the environment and for irreversible and increasing exposures of both wildlife and humans exposed via the environment. Furthermore, the low adsorption potential and high water solubility leads to difficulty in removing HFPO-DA using end-of-pipe treatment and means that HFPO-DA is fully bioavailable for uptake via water. Together, these elements of concern lead to a very high potential for irreversible effects once effect levels have been reached, as well as an increasing seriousness of effects while exposures keep increasing.

Due to its intrinsic properties the substance also has a very high potential to cause widespread exposures. It is difficult to decontaminate drinking water resources and there is a large variety of exposure routes for intake via food. Therefore, continuous and increasing exposure in human populations cannot be avoided. Similarly, wildlife populations cannot be protected from the total quantity of the substance released. It follows that both environment and humans are susceptible to adverse effects on a global scale. In summary, the elements above provide scientific evidence of serious effects that are probable for human health and the environment.

The level of concern is considered very high due to the combination of:

- the high potential for irreversible exposure due to very high persistence and in the case of human exposures via environment - difficulty to decontaminate drinking water,
- the high potential for increasing contamination and increasing, fully bioavailable exposures as the intrinsic properties cause a difficulty to remove the substance after release,
- the high potential for rapid and wide geographic scale contamination,
- the high potential for causing serious effects even though those would not be observed in standard tests,
- the observed effects in experimental toxicity studies are of such nature that in combination with the above aspects, they lead to a high potential for serious effects on humans and the environment on a global scale,
- the potential for inter-generational effects,
- high societal concerns.

The main target organs identified in rodent studies include the liver, the kidney, the haematologic system, and the immune system. The substance is furthermore observed to cross the placenta and to distribute into the foetus, to cause early deliveries, decreased gravid uterine weight, and to result in decreased birth weight in pups. The carcinogenic effects observed in rats are included as supportive information, although the carcinogenic potential of the substance is under investigation. In addition, secondary poisoning is of concern for wildlife. The irreversibility of adverse effects that are normally considered as reversible as a consequence of continuous exposure adds to the concern. Furthermore, it may be difficult in practice to manage exposures due to the high mobility of HFPO-DA and the fact that exposures may take place at a different location than where releases occurred and at a different moment in time. The high persistence and high mobility of HFPO-DA together furthermore lead to a concern for co-exposure with other contaminants with similar health effects. Co-exposure may eventually occur and may last for a very long time, because natural degradation processes for these substances are slow or negligible. This is brought into the weight-of-evidence as supportive information.

Monitoring data show HFPO-DA in surface water, sea water, ground water and drinking water at locations with and without apparent emission sources in the vicinity. HFPO-DA is also found in fish, plants and humans close to known emission sites. This indicates that HFPO-DA can be bioavailable that it is probable that exposure may occur through the food chain and via drinking water and that this is already taking place at specific locations.

Limitations of the available remediation techniques raise a concern that the removal of HFPO-DA from drinking water may only be possible with high societal costs. Remediation of environmental pollution may be practically impossible due to HFPO-DAs' high solubility in water, its low adsorption potential and its high mobility. Remediation is also difficult because HFPO-DA will quickly diffuse from contaminated sites.

None of these observations may be of equivalent level of concern in isolation, but in a weight-of-evidence consideration, the above arguments demonstrate that there is scientific evidence of probable serious adverse effects of these substances to the environment and humans, which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH Regulation.

In conclusion, the substances *2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)*, meet the criteria as a substance of very high concern in accordance with Article 57(f) of REACH Regulation because they are substances for which there is scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document (Member State Committee, 26 June 2019)