AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine

AS A SUBSTANCE OF VERY HIGH CONCERN

under Articles 57 and 59 of Regulation (EC) 1907/2006

Adopted on 28 November 2022

This agreement concerns

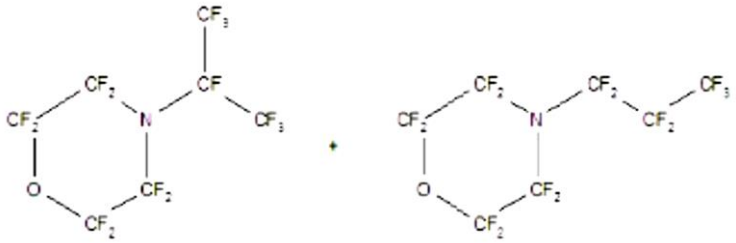
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine

EC number: 473-390-7

CAS number: -

Molecular formula: $C_7F_{15}NO$

Structural formula:



The Member State Committee agreed that:

1. **Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine is a substance under Article 57 (e) of Regulation (EC) 1907/2006 (REACH), which is very persistent and very bioaccumulative (vPvB) in accordance with the criteria and provisions set out in Annex XIII of REACH.**

2. **Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine must be added to the Candidate list of substances of very high concern**.

Annex 1: Scientific evidence for identification of a substance of very high concern

The information below is based on Support Document (Member State Committee, 28 November 2022)

Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (referred to as EC 473-390-7 in this document) is identified as very persistent and very bioaccumulative (vPvB) according to Article 57(e) of Regulation (EC) No 1907/2006 (REACH).

A weight-of-evidence determination according to the provisions of Annex XIII of REACH has been used to identify EC 473-390-7 as vPvB. All available information such as the results of standard tests, information from the application of the analogue approach (read-across) and Quantitative Structure-Activity Relationship ((Q)SAR) results was considered together in a weight-of-evidence approach.

EC 473-390-7 is a substance that consists of two main constituents that are structural isomers. Their chemical structures are very similar. Therefore, the vPvB assessment performed for EC 473-390-7 is also valid for the two individual constituents.

Persistence:

Based on a weight-of-evidence approach and considering assessment information in accordance with REACH Annex XIII Section 3.2.1.(d), it is concluded that EC 473-390-7 is very persistent due to its C-F bonds which cannot be broken under environmental conditions, and the abundant presence of fluorine atoms shields the carbon skeleton from other transformation reactions. This is supported by a ready biodegradation study (OECD TG 310; reliable with restrictions) which showed no degradation of EC 473-390-7 and by QSAR predictions (low reliability). No abiotic degradation is expected for this substance. Based on structural similarity, persistence in the air compartment is expected for EC 473-390-7 as analogous substances like perfluorocyclobutane show half-lives of more than 1000 years.

In summary, EC 473-390-7 is considered to be very persistent in all environmental compartments as no indications are found that it can undergo abiotic or biotic degradation under relevant environmental conditions. Half-lives are expected to largely exceed the triggers for persistence (P) and very persistent (vP) criteria (degradation half-life >60 days in water and degradation half-lives >180 days in sediment or soil) of REACH Annex XIII, exhibiting extreme persistence beyond current regulatory criteria.

Bioaccumulation:

The substance screens as bioaccumulative according to REACH Guidance Chapter R.11 based on its log n-octanol/water partition coefficient (K_{ow})>4.5. Based on the results from an experimental bioconcentration study (reliable with restrictions) with EC 473-390-7, a kinetic bioconcentration factor (BCF_k) and a steady-state bioconcentration factor (BCF_{ss}) were determined. Detailed analysis of the available test data leads to a BCF_k of 9585 with a 95% confidence interval of 5492−16726. Assuming that steady-state was reached in the study and applying the least conservative mathematical approach a BCF_{ss} of 8418 L/kg is calculated. Taking into account the underlying assumption, it is concluded that the real BCF_{ss} can only be greater than 8418 L/kg, and that this value represents a minimal estimation. The very low depuration rate constant (k_2 of 0.0633 d^{-1}) derived from this bioconcentration test further confirms the bioaccumulation potential of EC 473-390-7 for aquatic organisms.

Using a weight-of-evidence approach and considering that the lower limit of the 95% confidence interval for the BCF_k (i.e., 5492) and the estimation of the minimal BCF_{ss} (i.e., 8418 L/kg) are greater than 5000 and the low depuration rate constant (k_2 of 0.0633 d^{-1}) of EC 473-390-7 is indicative of a BCF >5000, it is concluded that EC 473-390-7 meets the 'bioaccumulation' criterion (B) and the 'very bioaccumulative' criterion (vB) for aquatic organisms in accordance with Annex XIII, points 1.2.1. and 1.2.2. of the REACH Regulation.

Regarding the bioaccumulation potential for terrestrial organisms, based on screening data (log octanol-air partition coefficient (K_{oa})) EC 473-390-7 is not expected to be bioaccumulative for air-breathers. However, this screening information cannot be fully confirmed by available information on toxicological and pharmacokinetic studies in mammals as uncertainties remain regarding available toxicokinetic data.

In conclusion:

Based on the information available and using a weight-of-evidence determination, it is concluded that Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (EC 473-390-7) meets the criteria for a very persistent and very bioaccumulative substance in accordance with Annex XIII of the REACH Regulation, and thereby it fulfils the criteria set out in REACH Article 57(e).

Annex 2: Procedure

1. On 26 August 2022, Belgium presented a proposal under Article 59(3) and Annex XV of the REACH Regulation on identification of Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine as a substance which satisfy the criteria of Article 57 (e) of REACH.
2. On 2 September 2022, the Annex XV dossier was circulated to Member States and the Annex XV report was made available to interested parties on the ECHA website as required by Articles 59(3) and 59(4).
3. Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine received comments from both Member States and interested parties on the proposal.
4. On 16 November 2022, the dossier was referred to the Member State Committee (MSC) and agreed in the written procedure of the MSC with closing date of 28 November 2022.