# Justification for the selection of a substance for CoRAP inclusion
# – Update –

| | |
|---|---|
| **Substance Name (Public Name):** | 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate |
| **Chemical Group:** | |
| **EC Number:** | 218-407-9 |
| **CAS Number:** | 2144-53-8 |
| **Submitted by:** | Germany |
| **Date:** | 17/03/2015<br>Update 22/03/2016 |

**Note**

This document has been prepared by the evaluating Member State given in the CoRAP update.

## Contents

# 1 IDENTITY OF THE SUBSTANCE

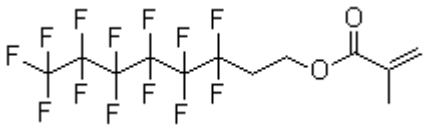
## 1.1 Other identifiers of the substance

**Table 1: Substance identity**

| | |
|---|---|
| **EC name:** | 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate |
| **IUPAC name:** | 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate |
| **Index number in Annex VI of the CLP Regulation** | - |
| **Molecular formula:** | $C_{12}H_9F_{13}O_2$ |
| **Molecular weight or molecular weight range:** | 432.1779 g/mol |
| **Synonyms/Trade names:** | *6:2 FTMA* |

**Type of substance** ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

**Structural formula:**



## 1.2 Similar substances/grouping possibilities

# 2 CLASSIFICATION AND LABELLING

## 2.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI of the CLP regulation.

## 2.2 Self classification

- In the registration:
  Not classified

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  STOT SE 3 H335

  Skin Irrit. 2 H315

  Eye Irrit. 2 H319

## 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal for harmonised classification is publically available.

# 3 INFORMATION ON AGGREGATED TONNAGE AND USES

| From ECHA dissemination site | | |
|---|---|---|
| ☐ 1 – 10 tpa | ☐ 10 – 100 tpa | ☒ 100 – 1000 tpa |
| ☐ 1000 – 10,000 tpa | ☐ 10,000 – 100,000 tpa | ☐ 100,000 – 1,000,000 tpa |
| ☐ 1,000,000 – 10,000,000 tpa | ☐ 10,000,000 – 100,000,000 tpa | ☐ > 100,000,000 tpa |
| ☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa) | | ☐ Confidential |

| ☒ Industrial use | ☐ Professional use | ☐ Consumer use | ☐ Closed System |
|---|---|---|---|

The substance is used in industrial settings in the manufacture of fluorinated polymers. These polymers are used e.g. in paper coatings. 6:2 FTMA is an alternative for perfluorooctanoic acid (PFOA) related substances for which a restriction proposal is currently under consideration. Therefore, increasing use and production of alternatives are expected.

# 4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

| | |
|---|---|
| ☐ Compliance check, Final decision | ☐ Dangerous substances Directive 67/548/EEC |
| ☐ Testing proposal | ☐ Existing Substances Regulation 793/93/EEC |
| ☐ Annex VI (CLP) | ☐ Plant Protection Products Regulation 91/414/EEC |
| ☐ Annex XV (SVHC) | ☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012) |
| ☐ Annex XIV (Authorisation) | ☐ Other (provide further details below) |
| ☐ Annex XVII (Restriction) | |
| | |

# 5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

## 5.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

## 5.2 Selection criteria met (why the substance qualifies for being in CoRAP)

☐ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☒ Fulfils criteria as potential endocrine disrupter

☒ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☐ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

## 5.3 Initial grounds for concern to be clarified under Substance Evaluation

| **Hazard based concerns** | | |
|---|---|---|
| CMR<br>☐C ☐M ☐R | Suspected CMR[1]<br>☐C ☐M ☐R | ☒ Potential endocrine disruptor |
| ☐ Sensitiser | ☐ Suspected Sensitiser[1] | |
| ☐ PBT/vPvB | ☒ Suspected PBT/vPvB[1] | ☒ Other (please specify below) |
| **Exposure/risk based concerns** | | |
| ☒ Wide dispersive use | ☐ Consumer use | ☐ Exposure of sensitive populations |
| ☒ Exposure of environment | ☐ Exposure of workers | ☐ Cumulative exposure |
| ☐ High RCR | ☐ High (aggregated) tonnage | ☐ Other (please specify below) |

3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2 FTMA) is an alternative for perfluorooctanoic acid (PFOA, C8-perfluorocarboxylic acid C8-PFCA) related substancesfor which a restriction proposal is currently under consideration and therefore increasing use and production of alternatives is expected. Thus, environmental exposure might increase in the future.

The intrinsic properties of 6:2 FTMA may be of concern. 6:2 FTMA is stated to be not readily biodegradable. Nevertheless, it is expected that perfluorohexanoic acid (PFHxA) will be the final degradation product. A fish bioconcentration test including PFHxA is available with BCFs ≤ 46 for 6:2FTMA and ≤ 12 for PFHxA. For the assessment of the bioaccumulation potential additional information (e.g. protein binding potential) may be required, since other mechanisms for bioaccumulation than log Kow and BCF are of relevance for these per- and polyfluorinated substances. For 6:2 FTMA a NOEC for algae (72 h) = 0.0078 mg/L and a NOEC for daphnia magna (21d) = 2.16 mg/L are reported.
In addition PFHxA is expected to have a high mobility in the environment, which also needs to be assessed, e.g. in terms of its potential for long-range transport.

Furthermore, scientific studies report on the endocrine disrupting properties of some degradation products and metabolites of 6:2 FtA. Several in vitro studies report on 6:2 FTOH estrogenic activity (Ishibashi et al., 2007; Ishibashi et al., 2008; Maras et al., 2006; Liu et al., 2007). This is supported by two *in vivo* studies (Ishibashi et al., 2008; Liu et al., 2009). Since no data are available on adverse endocrine effects of 6:2 FTOH but concerns on its estrogen mode of action seems to be well founded but not yet characterised, its potential endocrine disrupting effect should be assessed in the course of the substance evaluation.

The available *in vitro* assays conducted with PFHxA give rise to the concern that PFHxA might interact with the thyroid hormone signaling (Weiss et al. 2009; Ren et al. 2015; Vongphachan et al. 2011; Naile et al. 2012). Given that no *in vitro* or *in vivo* data are available for aquatic species, this concern should be further investigated in the upcoming substance evaluation.

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

## 5.4 Preliminary indication of information that may need to be requested to clarify the concern

| | |
|---|---|
| ☐ Information on toxicological properties | ☐ Information on physico-chemical properties |
| ☒ Information on fate and behaviour | ☒ Information on exposure |
| ☒ Information on ecotoxicological properties | ☐ Information on uses |
| ☒ Information ED potential | ☐ Other (provide further details below) |

Based on a preliminary examination of the available data, information to assess the bioaccumulation potential, endocrine disrupting properties and the ecotoxicity are required.
In detail, a test on long-term ecotoxicity of 6:2 FTMA might be requested because of high toxicity to algae and so far missing chronic data. Furthermore, such as tests might be needed for PFHxA as well. To clarifiy the bioaccumulation potential a testing on whether PFHxA binds to proteins would be needed.
Furthermore, tests to assess the endocrine disrupting potential of the metabolites/degradation products of 6:2 FTMA might also be requested in order to clarify concerns on adverse effects related to the estrogen mode of action of 6:2 FTOH and to assess the potential thyroid disrupting mode of action of PFHxA.

Additionally, a detailed evaluation of the available data may lead to further information requirements.

## 5.5 Potential follow-up and link to risk management

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|---|---|---|---|
| ☒ Harmonised C&L | ☒ Restriction | ☒ Authorisation | ☐ Other (provide further details) |

Depending on the outcome of the substance evaluation, an analysis of Risk Management Options shall be carried out to identify appropriate risk management measures.

References:

Ishibashi, H., Ishida, H., Matsuoka, M., Tominaga, N., and Arizono, K. (2007). Estrogenic effects of fluorotelomer alcohols for human estrogen receptor isoforms alpha and beta *in vitro*. Biol.Pharm.Bull. 30, 1358-1359.

Ishibashi, H., Yamauchi, R., Matsuoka, M., Kim, J.W., Hirano, M., Yamaguchi, A., Tominaga, N., and Arizono, K. (2008). Fluorotelomer alcohols induce hepatic vitellogenin through activation of the estrogen receptor in male medaka (Oryzias latipes). Chemosphere 71, 1853-1859.

Liu, C., Du, Y., and Zhou, B. (2007). Evaluation of estrogenic activities and mechanism of action of perfluorinated chemicals determined by vitellogenin induction in primary cultured tilapia hepatocytes. Aquat.Toxicol. 85, 267-277.

Liu, C., Yu, L., Deng, J., Lam, P.K., Wu, R.S., and Zhou, B. (2009). Waterborne exposure to fluorotelomer alcohol 6:2 FTOH alters plasma sex hormone and gene transcription in the hypothalamic-pituitary-gonadal (HPG) axis of zebrafish. Aquatic toxicology 93, 131-137.

Maras, M., Vanparys, C., Muylle, F., Robbens, J., Berger, U., Barber, J.L., Blust, R., and De, C.W. (2006). Estrogen-like properties of fluorotelomer alcohols as revealed by mcf-7 breast cancer cell proliferation. Environ.Health Perspect. 114, 100-105.

Naile, J.E., Wiseman, S., Bachtold, K., Jones, P.D., and Giesy, J.P. (2012). Transcriptional effects of perfluorinated compounds in rat hepatoma cells. Chemosphere 86, 270-277.

Ren, X.M., Zhang, Y.F., Guo, L.H., Qin, Z.F., Lv, Q.Y., and Zhang, L.Y. (2015). Structure-activity relations in binding of perfluoroalkyl compounds to human thyroid hormone T3 receptor. Archives of toxicology 89, 233-242.

Vongphachan, V., Cassone, C.G., Wu, D., Chiu, S., Crump, D., and Kennedy, S.W. (2011). Effects of perfluoroalkyl compounds on mRNA expression levels of thyroid hormone-responsive genes in primary cultures of avian neuronal cells. Toxicol Sci 120, 392-402.

Weiss, J.M., Andersson, P.L., Lamoree, M.H., Leonards, P.E., van Leeuwen, S.P., and Hamers, T. (2009). Competitive binding of poly- and perfluorinated compounds to the thyroid hormone transport protein transthyretin. Toxicol Sci 109, 206-216.