

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 acrylate
Chemical Group:	
EC Number:	241-527-8
CAS Number:	17527-29-6
Submitted by:	Germany
Date:	17/03/2015 Update 22/03/2016

Note

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

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1 IDENTITY OF THE SUBSTANCE

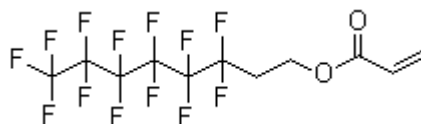
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate
IUPAC name:	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C ₁₁ H ₇ F ₁₃ O ₂
Molecular weight or molecular weight range:	418.1513 g·mol ⁻¹
Synonyms/Trade names:	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester 6:2 FTA

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None.

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			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
The substance is used in industrial settings in the manufacture of polymers.			

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

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> 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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input checked="" type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (6:2 FtA) is an alternative for perfluorooctanoic acid (PFOA, C8-perfluorocarboxylic acid (C8-PFCA)) related substances, which have been proposed for restriction (Oct 2014), therefore increasing use and production of alternatives is expected. Thus, environmental exposure might increase in the future.</p> <p>The intrinsic properties of 6:2 FtA may be of concern. 6:2 FtA is stated to be not readily biodegradable. Nevertheless, it is expected that perfluorohexanoic acid (PFHxA) will be the final degradation product. $\log P(OW) > 4.5$ indicates a potential for bioaccumulation. Bioconcentration factors (BCFs) ≤ 34 are reported for 6:2 FtA, indicating no bioaccumulation. 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. No information on chronic toxicity are available.</p> <p>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.</p>		

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

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

Uses, exposure, toxicological properties and ED potential were not targeted in the manual screening but might be part of the substance evaluation.

Based on a preliminary examination of the available data, information to assess the bioaccumulation potential and the ecotoxicity are required.

In detail, a test on long-term ecotoxicity of 6:2 FtA might be requested because of so far missing chronic data.

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

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Depending on the outcome of the substance evaluation, an analysis of Risk Management Options shall be carried out to identify appropriate risk management measures.