



Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): **Amphoteric Fluorinated Surfactant**

EC Number: Confidential

CAS Number: Confidential

Authority: Belgian CA

Date: 20/03/2018

Cover Note

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

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	3
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	4
3.1	Classification	4
3.1.1	Harmonised Classification in Annex VI of the CLP	4
3.1.2	Self classification	5
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	5
4.1	Tonnage and registration status	5
4.2	Overview of uses	6
5.	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	7
5.1.	Legal basis for the proposal	7
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	7
5.3.	Initial grounds for concern to be clarified under Substance Evaluation	7
5.4.	Preliminary indication of information that may need to be requested to clarify the concern	8
5.5.	Potential follow-up and link to risk management	8

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Amphoteric Fluorinated surfactant
IUPAC name (public):	Confidential
Index number in Annex VI of the CLP Regulation:	NA
Molecular formula:	Confidential
Molecular weight or molecular weight range:	Confidential
Synonyms:	NA

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

Confidential

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
	REACH Processes	Evaluation
<input type="checkbox"/> Compliance check, Final decision		
<input type="checkbox"/> Testing proposal		
REACH Processes	Authorisation	<input type="checkbox"/> CoRAP and Substance Evaluation
		<input type="checkbox"/> Candidate List
	<input type="checkbox"/> Annex XIV	

	Restriction	<input type="checkbox"/> Annex XVII ¹
Harmonised C&L		<input type="checkbox"/> Annex VI (CLP) (see section 3.1)
Processes under other EU legislation		<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009
		<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation		<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)
		<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)		<input type="checkbox"/> Assessment
		<input type="checkbox"/> In relevant Annex
Other processes / EU legislation		<input type="checkbox"/> Other (provide further details below)
Further details	/	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

NA

¹ Please specify the relevant entry.

3.1.2 Self classification

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

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site *		
<input type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input checked="" type="checkbox"/> 10 – 100 tpa	<input 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

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):

² Dissemination website consulted on 25-09-2017

https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

Confidential

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 type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ³	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input 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)

³ 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

<p>Partly confidential</p> <p>The test substance (constituent) was not 'readily biodegradable' in an OECD 301B (CO₂ Evolution) test.</p> <p>The breakdown products of the substance are potential PBT/vPvB, this needs to be further clarified.</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 checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Information on degradation products and clarification of the PBT/vPvB concern of the degradation products is needed.</p> <p>Information on uses and exposure will allow to assess the risk for the environment.</p>	

5.5. Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Potential identification as SVHC (PBT/vPvB).</p>			