

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): hexafluoropropene

Chemical Group:

EC Number: 204-127-4

CAS Number: 116-15-4

Submitted by: Italy

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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

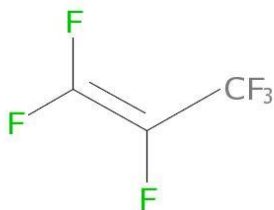
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	hexafluoropropene
IUPAC name:	1,1,2,3,3,3-hexafluoroprop-1-ene
Index number in Annex VI of the CLP Regulation	602-061-00-4
Molecular formula:	C ₃ F ₆
Molecular weight or molecular weight range:	150.0225
Synonyms/Trade names:	1-Propene, 1,1,2,3,3,3-hexafluoro-

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

Classification		Labelling	
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Pictograms, Signal Word Code(s)
Liq. Gas (<i>Note U</i>)	H280	H280	GHS07 Wng
Acute Tox. 4	H332	H332	
STOT SE 3	H335	H335	

2.2 Self classification

- In the registrations

The joint submission and one of the individual registrants have given the following self classifications in addition to the ones in Annex VI:

STOT SE 2; H371: May cause damage to organs.

STOT RE 2; H373: May cause damage to organs through prolonged or repeated exposure.

For both: Affected organs: Kidneys
Route of exposure: Inhalation

- In addition are the following hazard class notified to the C&L Inventory:

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input checked="" 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 checked="" type="checkbox"/> Confidential
There are also two individual registrations as intermediate, for which the tonnage is confidential.			
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
PC 0: Other: flame retardant agent (UCN B45000) - fire extinguisher powder (UCN B50000) PC 19: Intermediate ; PC 32: Polymer preparations and compounds SU 9: Manufacture of fine chemicals ; SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compounding and conversion			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 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 disruptor
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

4.3 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 checked="" type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>Italy CA assessed the substance under OECD activities on hazardous chemicals and concluded that the reproductive/developmental toxicity endpoint was not fulfilled. At the SIAM it was concluded that in order to evaluate the developmental toxicity, a reproductive/developmental test is needed for this chemical. Based on similarity of chemical structure and comparable repeat dose toxicity data it was recommended that this data gap could be filled by using information on a surrogate chemical – tetrafluoroethene (TFE) before the conduct of additional animal experiments. However since SIAM 10, no information have been made available for TFE for this end-point.</p>		

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

Furthermore in the REACH registration dossier the available information are not sufficient to conclude on developmental toxicity and on carcinogenicity. Indeed waivers are reported for these two end-points.

However, the potential carcinogenicity of hexafluoropropene was assessed with the OECD (Q)SAR Toolbox by IT CAs. The chemical contains a "Structural alert for nongenotoxic carcinogenicity (Trichloro (or fluoro) ethylene and Tetrachloro (or fluoro) ethylene". The chemical was subsequently subjected to a preliminary Read-Across, that confirmed the suspicion for carcinogenic activity.

4.4 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 checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
ITCA has assessed the substance under OECD activities on HPVC (see above).	

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input 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)
Testing on carcinogenicity and developmental toxicity.	

4.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)