

**Committee for Risk Assessment**  
**RAC**

Annex 2  
**Response to comments document (RCOM)**  
to the Opinion proposing harmonised classification and  
labelling at EU level of

Fluoroethylene

**EC Number: 200-832-6**  
**CAS Number: 75-02-5**

CLH-O-0000007333-78-01/F

**Adopted**  
**8 June 2023**

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FLUOROETHYLENE

### COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

ECHA accepts no responsibility or liability for the content of this table.

**Substance name: fluoroethylene**

**EC number: 200-832-6**

**CAS number: 75-02-5**

**Dossier submitter: France**

#### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
17.11.2022	Germany		MemberState	1
Comment received				
<p>Physicochemical properties: The physicochemical properties are summaries in table 5. In this table, the vapour pressure is stated as 1.71mPa at 25°C. In table 17 of the report however the vapour pressure is stated as 2.55 mPa whereas no temperature is given. As neither a reference nor a temperature is given for the latter value, we recommend checking which value is the most appropriate one and state this value consistently in both tables. Annotation: According to "pubchem" the vapour pressure is 2.4 mPa at 21°C. This value is taken from the hazardous substance data bank (HSDB). <a href="https://pubchem.ncbi.nlm.nih.gov/compound/6339#section=Vapor-Pressure">https://pubchem.ncbi.nlm.nih.gov/compound/6339#section=Vapor-Pressure</a></p> <p>Entry in Annex VI: For the entry in Annex VI, the assignment of Note "D" should be considered. With regard to the classification of the substance as Carc. 1A, H350, a read-across approach to chloroethylene (vinyl chloride; CAS No 75-01-4) is chosen due to the structural analogy. Chloroethylene is harmonised classified in Annex VI, Part 3, Table 3 (Index No 602-023-00-7) as Carc. 1A, H350. The substance entry also contains Note "D". Note D states: "Certain substances which tend to polymerise or decompose spontaneously are usually placed on the market in a stabilised form. This is also the form in which they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, occasionally these substances are also placed on the market in a non-stabilised form. In this case, the supplier placing such a substance on the market must indicate on the label the name of the substance followed by the words 'non-stabilised'. As the annotation "D" has been assigned to chloroethylenes, it must be assumed that this substance is capable of spontaneous polymerisation or decomposition.</p>				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FLUOROETHYLENE**

<p>Due to the structural similarity, it can be assumed that fluoroethylenes are also capable of spontaneous polymerisation or decomposition.          From the database " ChemInfo (www.gsbl.de)" it can be seen that fluoroethylene is usually transported in a stabilised state. A possible transport with unstabilised fluoroethylene can therefore not be excluded.          For this reason, Note "D" should be considered for this substance.</p>
<p><b>Dossier Submitter's Response</b></p> <p>Physicochemical properties:          We agree with DE remarks to use the same value for the vapour pressure throughout the CLH report. We propose to replace the estimated value of the vapour pressure (1.71 mPa at 25°C) by measured value of 2.4 mPa at 21 °C, which are actually very close. This latter value comes from the following reference in HSDB: Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V11: 684 (1994)).          Entry in Annex VI:          Due to the structural similarity, we agree with the fact that unstabilised fluorethylene can react spontaneously. So we agree that the note D to the fluoroethylene can be justified.</p>
<p><b>RAC's response</b></p> <p>Information has been reflected in the Opinion Document.</p>

**CARCINOGENICITY**

Date	Country	Organisation	Type of Organisation	Comment number
17.11.2022	Germany		MemberState	2
<b>Comment received</b>				
<p>The proposed classification of Carc. 1A (H350) is supported by DE CA based on read-across to chloroethylene.</p> <p>The criteria for the classification of fluoroethylene as Carc. 1B are considered to be fulfilled, as sufficient evidence of carcinogenicity in experimental animals is demonstrated. A causal relationship between the agent and an increased incidence of malignant neoplasms in two species and a mutagenic mode of action has been established. Remarkable are the dose-related, highly increased incidences of hepatic haemangiosarcomas in male and female rats and mice.</p> <p>There are no epidemiological studies available for fluoroethylene. Nevertheless, the dossier submitter considered also the criteria for Carc. 1A fulfilled for fluoroethylene based on a read-across to the structurally similar monohaloalkene chloroethylene (EC 200-831-0) which bears a harmonised classification of Carc. 1A (H350). Classification of chloroethylene is based on cohort studies in exposed workers in which a substantial increase in the relative risk for angiosarcoma of the liver, an extremely rare tumour type in the general population, was found.</p> <p>DE CA supports the proposed Carc. 1A classification for fluoroethylene based on read-across to chloroethylene for the following reasons: (i) structural similarity, (ii) increased incidence of hepatic haemangiosarcoma in experimental animals treated with fluoroethylene or chloroethylene, consistent with epidemiological data in chloroethylene exposed workers and (iii) positive findings in genotoxicity tests in somatic cells and indications of similar genotoxic mode of action (CYP 2E1 dependent metabolic activation to yield a reactive metabolite and formation of etheno DNA adducts).</p> <p>DE CA agrees that because of the proposed Carc. 1A classification based on read-across, setting an SCL is currently not possible for fluoroethylene.</p>				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FLUOROETHYLENE**

Dossier Submitter's Response
Thank you for your support
RAC's response
Noted and considered for the Opinion Document.

**MUTAGENICITY**

Date	Country	Organisation	Type of Organisation	Comment number
17.11.2022	Germany		MemberState	3
Comment received				
<p>The proposed classification of Muta. 2 (H341) for the substance by the DS is supported by DE CA based on the available information in the dossier.</p> <p>Classification criteria for Muta. Category 2 are considered to be fulfilled as there is a reliable positive in vivo mammalian somatic cell mutagenicity test available for the substance, namely a micronucleus (MN) test (MN according to OECD TG 474 and GLP). The potential of the substance to induce cytogenicity is further supported by positive results in an in vitro mammalian cell chromosomal aberration test.</p> <p>Based on the available data in the CLH dossier there is no evidence that the substance causes mutations in mammalian germ cells. Therefore, classification as Muta Category 1A/1B is not justified.</p>				
Dossier Submitter's Response				
Thank you for your support				
RAC's response				
Noted and considered in the Opinion Document.				