

**AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
FLUORANTHENE
AS A SUBSTANCE OF VERY HIGH CONCERN**

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹**

Adopted on 12 December 2018

This agreement concerns

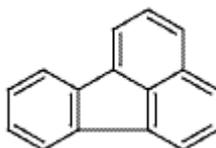
Substance name: Fluoranthene

EC number: 205-912-4

CAS number: 206-44-0

Molecular formula: C₁₆H₁₀

Structural formula:



¹Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Belgium presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (24 August 2018, submission number SPS-013907-17) on identification of *Fluoranthene* as a substance of very high concern due to its persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties.

The Annex XV dossier was circulated to Member States on 4 September 2018 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 19 November 2018 and discussed in the meeting on 10-14 December 2018 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

***Fluoranthene* is identified as a substance meeting the criteria of Article 57 (d) and (e) of Regulation (EC) 1907/2006 (REACH) as a substance, which is:**

- **persistent, bioaccumulative and toxic (PBT), and**
- **very persistent and very bioaccumulative (vPvB)**

both in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN

Persistence, bioaccumulation and toxicity (PBT)

An assessment of the PBT and vPvB properties in the present dossier and the conclusion that fluoranthene fulfils the criteria in Articles 57 (d) and (e) were based mainly on the information in the MSC Support Document on CTPHT (ECHA, 2009)² and supplemented with information from newer studies that are presented as further evidence in a weight of evidence approach. The newly available information however do not trigger a need to modify the conclusions taken by authorities earlier on and therefore allows compact assessment of the substance properties with a focus on PBT/vPvB properties.

Persistence

The available experimental information shows that fluoranthene degrades very slowly in soil with half-life > 180 days. Study performed under field conditions demonstrated half-life of more than 7.8 years in soil.

It is assumed that fluoranthene meets the P and vP criterion in sediment, as in the available simulation study with phenanthrene the obtained half-life meets the P and vP criterion. Considering that the biodegradation rates decrease with increasing number of aromatic rings and the half-lives of PAHs in sediment are proportionally related to the octanol-water partition coefficient (Kow), the half-life of fluoranthene should meet the P and vP criterion in sediment as well.

Therefore, the P and vP criteria according to REACH Annex XIII are fulfilled for fluoranthene for soil and sediments.

Bioaccumulation

Data on the bioaccumulation potential of fluoranthene were reported in the EU Risk Assessment report on CTPHT (European Commission, 2008)³. The bioaccumulation factors in different species (fish, molluscs, polychaeta and crustacea) range from 180 L/kg (*Crangon septemspinosa*) to 14 836 L/kg (*Pimephales promelas*).

Bioaccumulation potential of fluoranthene can differ between organisms due to their ability to metabolise PAHs (biotransformation).

High BCF values have been reported especially for fish (2772 L/kg) and molluscs (range of 4 120 - 5 920 L/kg).

Fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH Regulation since several of the experimentally obtained BCF values (in fish and molluscs) were above 2000 and 5 000 L/kg respectively.

Toxicity

Fluoranthene appears to be extremely phototoxic when organisms are exposed in parallel to ultraviolet radiation, such as in sunlight. The acute L(E)C50 values of fluoranthene are comparable to the obtained chronic NOEC or L(E)C10 values.

Numerous long term studies with a range of species representing various taxonomic groups (fish, aquatic invertebrates and algae) report NOEC or EC10 values for fluoranthene below 10 µg/L.

A 31-day *Mysidopsis bahia* study was given the highest weight, as it provided the lowest reliable NOEC (reproduction) value of 0.6 µg/L.

² ECHA (2009): Support Document for identification of Coal Tar Pitch, High Temperature as a SVHC because of its PBT and CMR properties. <http://echa.europa.eu/documents/10162/73d246d4-8c2a-4150-b656-c15948bf0e77>

³ European Commission (2008): European Union Risk Assessment Report, Coal Tar Pitch High Temperature, CAS No: 65996-93-2, EINECS No: 266-028-2.

Therefore, fluoranthene fulfils the T criterion according to Annex XIII 1.1.3 a) of REACH Regulation.

In conclusion, *fluoranthene* meets the criteria for the identification of a PBT and vPvB substance according to Article 57 (d) and (e) of the REACH Regulation, based on a weight-of-evidence approach.

Reference:

Support Document (Member State Committee, 12 December 2018)