

**AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
BENZO[K]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

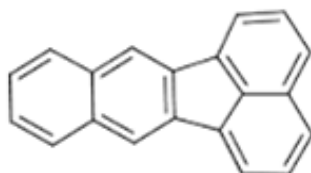
Substance name: Benzo[k]fluoranthene (BkFA)

EC number: 205-916-6

CAS number: 207-08-9

Molecular formula: C₂₀H₁₂

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-013908-17) on identification of *Benzo[k]fluoranthene* as a substance of very high concern due to its carcinogenic (CMR), 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):

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

- **meets the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen category 1B² in accordance with Regulation (EC) No 1272/2008³, and**
- **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).**

² Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances [as amended and adapted to technical and scientific progress by Commission Regulation (EC) No 790/2009, OJ No L 235, p. 1, 5.9.2009].

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN

Carcinogenicity:

Benzo[k]fluoranthene is listed by index number 601-036-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH Regulation.

Persistence, bioaccumulation and toxicity (PBT)

An assessment of the PBT and vPvB properties in the present dossier and the conclusion that benzo[k]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)⁴ 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 benzo[k]fluoranthene degrades very slowly in soil with half-life > 180 days. Study performed under field conditions demonstrated a half-life of more than 8.7 years in soil.

It is also assumed that benzo[k]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 (K_{ow}), the half-life of benzo[k]fluoranthene will meet the P and vP criterion in sediment as well.

Therefore, the P and vP criteria according to Annex XIII of REACH Regulation are fulfilled for benzo[k]fluoranthene for soil and sediment.

Bioaccumulation

Limited data on the bioaccumulation potential of benzo[k]fluoranthene were reported in the EU Risk Assessment Report on CTPHT (European Commission, 2008)⁵ and in the Support Document for identification of CTPHT as SVHC (ECHA, 2009).

The obtained BCF value for *Daphnia magna* was 13 225 L/kg for benzo[k]fluoranthene.

Thus, benzo[k]fluoranthene has a high bioaccumulation potential at lower trophic levels, which could contribute to a constant high exposure of

⁴ 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>

⁵ European Commission (2008): European Union Risk Assessment Report, Coal Tar Pitch High Temperature, CAS No: 65996-93-2, EINECS No: 266-028-2.

benzo[k]fluoranthene to predators for which the effects are unpredictable due to the absence of sufficient data.

Benzo[k]fluoranthene meets the criteria for B and vB, in accordance to Annex XIII of REACH Regulation since the experimentally obtained BCF value for *Daphnia magna* was above 5 000 L/kg.

Toxicity

A 42-day Early Life Stage study with *Brachydanio rerio* was given the highest weight. It provided an EC₁₀ value (weight) of 0.31 µg/L and an EC₁₀ value (length) of 0.17 µg/L. Length was the most sensitive endpoint.

Therefore, benzo[k]fluoranthene fulfils the T criterion according to Annex XIII 1.1.3 (a) of REACH Regulation.

In addition, benzo[k]fluoranthene is classified in the hazard class Carc. 1B according to Regulation (EU) No. 1272/2008. Thus, the T criterion according to Annex XIII 1.1.3 (b) of REACH Regulation is also fulfilled.

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

Reference:

Support Document (Member State Committee, 12 December 2018)