

**AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
PYRENE**

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

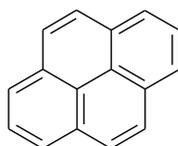
Substance name: Pyrene

EC number: 204-927-3

CAS number: 129-00-0

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

France presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (29 August 2018, submission number SPS-014398-18) on identification of *Pyrene* 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):

***Pyrene* 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 and bioaccumulation

The assessment of the PBT/vPvB properties in the present dossier and the conclusion that pyrene fulfils the criteria in Article 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. This information was considered together in a weight-of-evidence approach.

Persistence

The available experimental information shows that pyrene degrades very slowly in soils exhibiting half-lives between 127 to 320 days, higher than 180 days (vP criteria according REACH Annex XIII). The soil experimental study conducted under field conditions and the predicted half-life support the low degradation in soils.

It is also assumed that pyrene meets the P and vP criterion in sediment, as in the available simulation study with phenanthrene the observed 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 pyrene should meet P and vP in sediment as well.

Thus, pyrene fulfils the criteria for P and vP of REACH Annex XIII for soils and sediments.

Bioaccumulation

BCF values higher than 5 000 L/kg (vB criteria according REACH Annex XIII) have been measured in four studies with molluscs (6 430 to 77 000 L/kg), two studies with crustacean (12 300 to 166 000 L/kg) and one study with an oligochaete species (6 688 L/kg).

Thus, pyrene fulfils the B and vB criteria of REACH Annex XIII.

Toxicity

Based on the available information from long-term studies with aquatic organisms, the lowest EC10 value was reported for the mollusc *Crassostrea gigas* exposed to UV radiation. The resulting EC10 of 0.5 µg/L shows that pyrene fulfils the T criteria (NOEC or EC10 for marine or freshwater organisms is less than 0.01 mg/L) of REACH Annex XIII.

In conclusion, *pyrene* meets the criteria for a PBT and vPvB substance according to Article 57 (d) and (e) of REACH Regulation by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

References:

Support Document (Member State Committee, 12 December 2018)

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