



HAZARD ASSESSMENT OUTCOME DOCUMENT

for

Perylene-3,4:9,10-tetracarboxydiimide

EC No 201-344-6

CAS No 81-33-4

Member State: Belgium

Dated: 1 August 2023

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1. HAZARD SUBJECT TO ASSESSMENT

Perylene-3,4:9,10-tetracarboxydiimide (also known as C.I. Pigment Violet 29 or PV 29) was originally selected for hazard assessment in order to clarify suspected hazard properties:

- PBT/vPvB

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Outcome	Tick box
According to the authority's assessment the substance does not have PBT/vPvB properties based on the currently available information.	
According to the authority's assessment the substance has PBT/vPvB properties.	
According to the authority's assessment further information would be needed to confirm the PBT/vPvB properties but follow-up work is not relevant or carried out at present.	X

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING¹

Based on the currently available information in the registration dossier(s) and considering the various comments that were received in response to a written procedure in the PBT Expert Group, the BE CA can at present not come to a definitive conclusion whether the substance with EC n° 201-344-6 (Pigment Violet 29) meets the PBT criteria. This substance tends to aggregate in solution and to readily form particulates which hampers a reliable execution of any study usually performed to determine the log K_{ow} . In the registration dossier(s) the log K_{ow} is evaluated to be <0.8 based on the separate solubilities in n-octanol and water. There remains some uncertainty on the correctness of this value, but it is noted that this value is also considerably below the screening threshold for bioaccumulation in air-breathers (log K_{ow} >2).

¹ Assessments of PBT properties are based on Annex XIII to the REACH Regulation.

However, as described in the Appendix R7-1 for nanomaterials applicable to ECHA Guidance Chapter R.7a, $\log K_{ow}$ is not sufficient to conclude on the bioaccumulation potential of substances under nanoform. Therefore, based on the available information a conclusion whether Pigment Violet 29 is or is not bioaccumulative for air-breathers and/or for aquatic organisms cannot be made. In the absence of information on the fate descriptors to predict the behaviour and transport of nanoforms in the environment and biological media as alternatives to n-octanol/water partition coefficient (e.g. dispersion stability), the BE CA does not want to pursue the assessment of the bioaccumulation potential of the Substance at this moment.

Another reason for not continuing the evaluation of the bioaccumulation potential at present is the observation that legal bioaccumulation criteria for air-breathers are not yet established in the REACH Regulation. Further there are also no agreed approaches or set quantitative values regarding the bioaccumulation assessment of nano forms. Therefore, the BE CA is of the opinion that for now it is appropriate to cease the evaluation of this substance. Follow-up work on this substance can be considered when more bioaccumulation criteria are clearly enshrined.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not viewed as a commitment by the authority. Any commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
not at present	n.a.	n.a.