

Short communication on the PBT-status of Pigment Yellow 110

(CAS number: 5590-18-1, EC number: 226-999-5)

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Key information:

- Pigment Yellow 110 was included in November 2019 in the SIN List (Sunbtitute It Now), with the motivation that it is a PBT substance (Persistant, Bioaccumulative and Toxic).
- A REACH dossier for the substance has been submitted in 2016 and subsequently updated, and contains a specific evaluation of the PBT-status of Pigment Yellow 110.
- Although the colorant is classified as persistant, all available data do not support either bioaccumulation or toxicity.
- Therefore, the classification as PBT in the SIN-List is an unsupported claim, in clear contradiction with the conclusions drawn in accordance to the REACH criteria and accepted approaches.
- Pigment Yellow 110 is not a PBT substance and should not be part of any list dealing with this specific hazard classification.

Background information

Since November 2019, Pigment Yellow 110 has been added to the SIN List of the organisation ChemSec. This list contains substances which, due to their toxicity profile, come into the chemical classes which the organisation advices to substitute, since they are seen as particularly dangerous for human health and/or the environment.

In the specific case of Pigment Yellow 110, according to the List, the colorant was added because it is “Persistent, Bioaccumulative and Toxic”, i.e. it is considered a PBT-substance.

As Pigment Yellow 110 is a substance manufactured/imported in the EU in the tonnage band 10-100 t/y, a specific registration dossier was submitted in 2016 according to the requirements in Annex VIII of the REACH regulation. The dossier was updated in 2017, 2018 and 2019.

Since the substance is manufactured/imported in more than 10 t/y, a a specific PBT assessment is also required and is available under <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/17483/2/3>. The results of this assessment are summarised in the following sections.

PBT assessment of Pigment Yellow 110

A PBT assessment is composed of the three parts persistence, bioaccumulation and toxicity and, in order for a substance to be classified as PBT, **the requirements for all three endpoints have to be fulfilled** as specified in Annex XIII of the REACH regulation. For Pigment Yellow 110, following conclusions have been reached in the corresponding REACH-dossier:

Persistence assessment

All available information about the substance indicates that Pigment Yellow 110 can be considered not readily biodegradable in water and thus likely to be **persistent**.

Bioaccumulation assessment

The estimated BCF value was determined to range from 1905.0 to 1916.0, based on all available information and on specific models. If this chemical is released into the aquatic environment, there should be a low risk for the chemical to bioaccumulate in fish and food chains. The substance is **not bioaccumulative**.

Toxicity assessment

- Mammals

The tested chemical is not classified for carcinogenicity, mutagenicity and reprotoxicity. Further, there is no evidence of chronic toxicity, as identified by the classifications STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume).

- Aquatic organisms

As the substance is very insoluble in water (solubility: < 0.01 mg/L at 25° C), testing for this end point is scientifically unjustified. The low solubility indicates that aquatic toxicity is unlikely to occur. Pigment Yellow 110 is therefore not considered hazardous to aquatic environments.

As a result of the two sets of information above, the substance is **not toxic**.

Result of the PBT assessment

Based on critical, independent and collective evaluation of information summarized in the previous sections, Pigment Yellow 110 fulfils the P criterion but does not fulfil the B and T criterion and has therefore **not been classified as a PBT compound within Annex XIII**.

Conclusion

The PBT assessment in the REACH dossier of Pigment Yellow 110 follows the corresponding REACH requirements and is based on all relevant information available to the registrants¹. This information is sufficient to conclude that Pigment Yellow 110 is not a PBT substance.

Therefore, **the inclusion of the colorant into any list of PBT substances is unjustified and provides a wrong information to the general public**.

¹ It also has to be noted that, in case an alternative assessment was actually based on new information which justifies a different conclusion than the one reached by the registrants, the owners of this information would be considered REACH “data-owners”. As such, they would be expected to communicate the information to the registrants for evaluation within the framework of the REACH data-sharing.