

ETAD Information Notice

Diarylide pigments and the PBT/vPvB issue

Introduction

There is growing regulatory momentum to categorize many organic substances, amongst which are organic pigments, as substances of concern with respect to PBT characteristics, i.e. **P**ersistent, **B**ioaccumulative, **T**oxic.

There is a lack of regulatory harmonisation: Several countries (EU member states, USA, Canada) have prepared working lists of substances, which they are concerned could cause long-term environmental effects due to persistence (P), bioaccumulation (B) and/or toxicity (T). Very few organic pigments meet the criteria for toxicity (T). To fulfil their technical function in most applications, they need to be persistent (P). In the EU approach for screening substances, they are listed if they meet criteria for "very persistent" (vP) **and** "very bioaccumulative" (vB) even if they are not toxic (T): otherwise the criteria for P and B and T must be met. (T meaning Chronic NOEC (No Observable Effect Concentration) < 0.01 mg/l or CMR (Carcinogenic, Mutagenic or Reprotoxic) or endocrine disrupting effects.

The EU list includes a few pigments, including some which belong to the important diarylide pigments group.

This information notice summarizes the current state of knowledge and the steps being taken to address this issue with reference to the diarylides.

Some facts

- The EU list addresses 5 diarylide pigments (C.I. Pigment Yellow 12, 13, 14 and 83; C.I. Pigment Orange 13).

Whereas the EU model predicts high bioaccumulation potential for these pigments, the model used by the US Environmental Protection Agency predicts that they are not bioaccumulative. Fish bioaccumulation tests on two of the pigments (C.I. Pigment Yellow 12 and C.I. Pigment Orange 13) have indicated "not bioaccumulative", however the robustness of the test procedure cannot be assigned.

- Other evidence indicates that it is most unlikely that these pigments would bioaccumulate.
 - non-bioavailability after oral and dermal administration of C¹⁴-labelled C.I. Pigment Yellow 12 in Fischer 334 rats.
 - The pigments have molecular sizes larger than the size predicted to be able to penetrate cell membranes and therefore cannot be bioaccumulative.
 - Solubility in n-octanol
 N-octanol serves as a surrogate for fish lipid and if a substance has a reduced solubility in n-octanol, a reduced bioaccumulation may be concluded.
 A rationale developed for the **T**echnical **C**ommittee of **N**ew and **E**xisting **S**ubstances (TC NES) predicts that bioaccumulation can be excluded in case the measured n-octanol solubility is < 0.002 * Molecular Weight [mg/L] (assuming base line toxicity).
 For the 5 Diarylide pigments the measured n-octanol solubilities are significantly below the indicated solubility limit.

Conclusions and future approach

The very low octanol solubilities together with the large size of the molecules indicate that these pigments will not bioconcentrate to a level of concern.

ETAD is currently conducting more experimental work in order to resolve the issue conclusively for other categories of pigments.