

**SUMMARY OF DECISION OF 15 JANUARY 2019 OF THE BOARD OF APPEAL OF
THE EUROPEAN CHEMICALS AGENCY****Case number: A-004-2017**

*(Substance evaluation – PBT assessment – Grounds for concern – Bioaccumulation –
Proportionality – Error of assessment – Annex XIII)*

Factual background

The appeal concerns a decision on the substance evaluation of UVASORB HEB (EC No 421-450-8, CAS No 154702-15-5; the 'UVASORB HEB').

Following an evaluation by the German competent authority, the Appellant was required to provide information on an EU C.24/OECD TG 308 sediment simulation study and further information on uses and environmental emissions of UVASORB HEB.

The Appellant requested the Board of Appeal to annul the contested decision requiring that information.

Main findings of the Board of Appeal

- Simulation testing in aquatic sediment system (OECD TG 308)

The contested decision requests the appellant to perform an OECD TG 308 study, primarily to identify the transformation and/or degradation products of the UVASORB HEB. The Agency considered that such a study is needed because of the indications that UVASORB HEB may pose a risk to the environment due to the potential persistent, bioaccumulative and toxic ('PBT') or very persistent and very bioaccumulative ('vPvB') properties of its predicted transformation and/or degradation products.

The Appellant claims that the measure imposed is disproportionate because it is unnecessary and inappropriate. It argued that further testing is not necessary because, even if UVASORB HEB were to transform or degrade in the environment, none of the predicted transformation and/or degradation products would be bioaccumulative, and therefore they cannot be PBT or vPvB.

The Appellant also argued that the OECD TG 308 study is not appropriate to achieve the objective pursued because the study is required to be performed at an unrealistic temperature, namely 20 °C.

The Board of Appeal found that the Agency had established, using quantitative structure-activity relationship ('QSAR') models, that UVASORB HEB may form transformation and/or degradation products in the environment and some of those transformation and/or degradation products may be PBT or vPvB.

The Agency and the Appellant used different QSAR data to support their arguments as regards the potential bioaccumulative properties of the transformation and/or degradation products of UVASORB HEB. The Board of Appeal found that the Agency had established, by use of QSAR calculated octanol-water coefficient values, that the predicted transformation and/or degradation products of UVASORB HEB may be bioaccumulative.

The potential persistence and toxicity of the transformation and/or degradation products

was not disputed. The Board of Appeal found that the Agency had established the concern that the predicted transformation and/or degradation products of UVASORB HEB may be PBT and pose a potential risk to the environment. Clarifying the uncertainty by requesting a study aiming at identifying the transformation and/or degradation products was therefore necessary.

The Board of Appeal also found that 20 °C is an appropriate temperature to perform the OECD TG 308 study aiming at identifying the transformation and/or degradation products of UVASORB HEB. According to Annex XIII, PBT assessment of substances must be based on data obtained under '*relevant conditions*'. The Board of Appeal found that '*relevant conditions*' means conditions that allow for an objective assessment of the PBT/vPvB properties of a substance instead of particular environmental or realistic conditions.

The Board of Appeal found that the requirement for the OECD TG 308 study is proportionate and consequently dismissed the appeal as regards this requirement.

- Further information on uses and environmental emissions

The Appellant argued that if UVASORB HEB is not identified as PBT or vPvB, the Agency had no grounds for requesting further information on uses and environmental emissions of UVASORB HEB.

The Board of Appeal found that the Agency had not demonstrated the necessity and appropriateness of the requested information on uses and environmental emissions of the UVASORB HEB.

The Board of Appeal consequently annulled the contested decision as regards the requirement to submit further information on uses and environmental emissions of UVASORB HEB.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

Unofficial document, not binding on the Board of Appeal

*The full text of the decision is available on the Board of Appeal's section of ECHA's website:
<http://echa.europa.eu/about-us/who-we-are/board-of-appeal>*