

Didecylmethylpoly(oxyethyl)ammonium propionate: Candidate for Substitution

We as Kurt Obermeier GmbH & Co KG as a wood preservative manufacturer object to the proposal of the RMS to list Didecylmethylpoly(oxyethyl)ammonium propionate for a potential candidate for substitution. We doubt the legality of the procedure as well as the correctness of the PBT assessment.

Regarding the legality of the procedure:

The rapporteur member state Italy has proposed Didecylmethylpoly(oxyethyl)ammonium propionate for a potential candidate for substitution according to article 10 (1d) BPR.

According to Article 8(1) BPR prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

We have been informed by the applicant (Lonza) that no finalised assessment report including the PBT assessment has been provided prior to submission of the conclusions to the Agency. In fact, the conclusion taken by the RMS Italy in the last Rapporteur Member State Assessment Report for PT08 as shared with Lonza was that “Bardap 26 can definitely be considered not to fulfil the P criteria”.

Therefore, conflicting information has been sent out by RMS Italy on the PBT criteria and no comments of the applicant could be taken into account before finalising the evaluation. The public consultation for potential candidates of Substitution shall take place after the rapporteur member state has finalised its evaluation. For Didecylmethylpoly(oxyethyl)ammonium propionate the requirements of regulation 528/2012 have not been fulfilled. The substance has been identified as potential Candidate for substitution without providing an appropriate commenting period for the applicant. Therefore this case should be checked in order to verify the correct proceeding.

Regarding the correctness of the PBT assessment:

Due to the rapporteur member state Didecylmethylpoly(oxyethyl)ammonium propionate is considered as Toxic (T) and persistent (P).

According to the information from Lonza no evidence for the criteria T (toxic) and P (persistent) Didecylmethylpoly(oxyethyl)ammonium propionate has been shown by the submitted data. Didecylmethylpoly(oxyethyl)ammonium propionate does not meet the criteria for P and T.

Toxicity

A substance fulfils the toxicity criterion (T-) when:

- the long-term no-observed effect concentration (Noec) for marine or freshwater organisms is less than 0,01 mg/l, or
- the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications:

T, R48, or Xn, R48 according to Directive 67/548/EEC.

Regarding the Toxicity criterion:

Didecylmethylpoly(oxyethyl)ammonium propionate is considered as Toxic due to the the long-term no-observed effect concentration (Noec) for marine or freshwater organisms.

The most sensitive species is *Daphnia magna* where the NOEC for the long-term 21 d study is **not** < 0.01 mg/l, but = 0.01 mg/l. Therefore the criterion for Toxicity according to Annex XIII to Regulation (EC) No 1907/2006 is not fulfilled for Didecylmethylpoly(oxyethyl)ammonium propionate.

Furthermore, Didecylmethylpoly(oxyethyl)ammonium propionate is not a CMR and all the other information on acute and chronic ecotoxicity shows significantly higher (less toxic) values. Consequently, it does not fulfil the “T” criteria.

Persistence

A substance fulfils the persistence criterion (P-) when:

- the half-life in marine water is higher than 60 days, or
- the half-life in fresh- or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh- or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

Regarding the Persistence criterion:

Although, the substance is termed as being not readily biodegradable (34% mineralisation after 28 days, as CO₂ according to an OECD 301B study) such a conclusion from a single screening test in which the study design was never intended to assess biodegradability of substances with biocidal properties against (activated) sludge microorganisms cannot be relied upon. A more recent C¹⁴-die away STP test with Didecylmethylpoly(oxyethyl)ammonium propionate itself shows rapid elimination and complete mineralisation (86% CO₂ evolution after 28 days).

The conclusion that the substance is NOT inherently biodegradable is also not agreed in the recently submitted REACH dossier, where it is concluded that the T^{1/2} is less than 40 days as the substance reached 80% elimination (23% elimination, 57% biodegradation).

Didecylmethylpoly(oxyethyl)ammonium propionate cannot be considered as being Persistent and so does not fulfil the P criteria. In fact, this conclusion was also taken by the RMS Italy in the last Rapporteur Member State Assessment Report for PT08 as shared with Lonza (as applicant for Didecylmethylpoly(oxyethyl)ammonium propionate) who concluded that “*Bardap 26 can definitely be considered not to fulfil the P criteria*”.