

9.12.2021

Tukes 10709/04.01.04/2021

BPC-41: Minority Opinion of the Finnish Competent Authority on BPC Opinion on Alkyl (C12-16) dimethylbenzyl ammonium chloride, Product type 2

Finnish CA raises concerns that approval is proposed for the active substance Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC) despite of an unacceptable risk is identified for soil in the environmental risk assessment.

The risk assessment of active substance ADBAC/BKC has been performed according to the current Emission Scenario Document for Product Type 2¹ (ESD for PT 2). Emission scenarios for calculating releases of disinfectants used for sanitary purposes based on an average consumption and annual tonnage were applied. The tonnage approach represented the worst-case estimation, since calculated emissions were higher compared to the average consumption approach. Thus, according to the current guidance (ESD for PT 2) the emissions based on tonnage were selected for the environmental exposure and risk assessment. In addition, the tonnages of two applicants were summed up per same use as requested also before in case of multiple applicants. According to the Technical Agreements for Biocides, Environment² (entry 188) an active substance approval for a specific product-type is not an individual application but an approval of the substance in the EU and should consider all biocidal uses in one product-type.

The unacceptable risk was identified for soil. The risk was considered acceptable due the following reasons:

- The consumption-based approach did not show an unacceptable risk
- In the tonnage-based approach the risk characterisation ratio only slightly exceeded one
- Dissipation/disintegration during use and transport in the sewer to the sewage treatment plant (STP) was not assumed, which stands as a worst-case consideration
- ADBAC/BKC is readily biodegradable and not persistent
- ADBAC/BKC is highly absorptive: it is likely that it will absorb in the sewer to larger particles, which may be removed in the first filtering step at the STP and disposed of

¹ [Emission scenario documents - ECHA \(europa.eu\)](https://echa.europa.eu)

² [S-CIRCABC - TAB - Technical Agreements for Biocides \(europa.eu\)](https://echa.europa.eu)

The consumption-based approach was considered as a best-case approach during the exposure assessment. Therefore, it cannot be used as a justification for approval of the active substance. The risk characterisation ratio ■ indicates an unacceptable risk as it is above 1. Dissipation/disintegration during use and transport in the sewer is not typically assumed, and so far it has been accepted only for oxidizing substances that degrade rapidly in the sewer in the presence of organic matter. Even though the active substance is readily biodegradable, not persistent and highly adsorptive, the unacceptable risk was identified when the risk assessment was performed according to the valid ESD and guidance³.

Finnish CA is of the opinion that approval should not have been proposed for ADBAC/BKC in PT 2 before either refinement of the risk assessment or risk mitigation measures are proposed that would allow a safe use.

³ [Biosidilainsäädäntöä koskevat ohjeet - ECHA \(europa.eu\)](https://echa.europa.eu) (Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C))