

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin Federal Institute for Occupational Safety and Health

Minority opinion of the German CA regarding the Union authorisation application "EuLA oxi-lime 23" discussed at BPC-43

The German Competent Authority agrees with the quantitative assessment for the "Disinfection of indoor floor surfaces of animal accommodations and transportation" and the scenario "Disposal of small bags".

The quantitative assessment indicates exceedance of the agreed Acceptable Exposure Concentration (AEC_{inhalation}) for the active substance and thus unacceptable risks for the professional user.

However, we object to the qualitative assessment as it considers a 100% efficacy of the stipulated respiratory protective equipment, as this is not a realistic assumption.

We have no doubts on the appropriateness of the AEC_{inhalation} derived during the active substance approval. In our opinion the AEC_{inhalation} is not too conservative and the results of the quantitative assessment are reliable.

We do not agree with the final conclusion considering only the qualitative assessments made and ignore the unacceptable risks identified in the quantitative assessments.

In summary, there are unacceptable risks for the professional user for the "Disinfection of indoor floor surfaces of animal accommodations and transportation" (use 3) and the scenario "Disposal of small bags". This use should not be proposed for authorisation.