

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

Minority opinion of the German CA regarding the Union authorisation application "Chlorocresol based products - CID LINES NV"

The German Competent Authority does not agree with the BPC opinion and Summary of Product Characteristics (SPC) in the present form.

For use 7.7 ("Use 7.7 PT3 – Concentrated animal skin disinfectants"). the default maximum residue limit (MRL) for the active substance established for plant protection products was exceeded. No conclusion on acceptability was drawn for use 7.7 in the BPC opinion because of ongoing discussions at the CA-meeting about the consequences of an exceedance of the default MRL for chlorocresol.

The use is not included in the SPC, which would be an anticipated non-authorisation decision for use 7.7.

Still, it is neither clear whether the default MRL for plant protection products is applicable at all nor whether an exceedance of the MRL leads to a non-authorisation decision.

From our point of view, it is not possible to conclude about an application, when the decision about one use is still pending.

In addition, as the specific instruction for use and risk mitigation measures for use 7.7 have not been included in the SPC, they have never been agreed upon between member states, accordingly. Hence, the use cannot simply be included subsequently in the authorisation if required due to a future decision on the MRL topic.

As a way forward we would propose waiting with finalization of the BPC opinion and the SPC until Commission has presented its opinion on this issue at the CA-meeting.