

POSITION PAPER CHLOROPHENE

April 5, 2017

Justification for the approval of the active substance Chlorophene (CAS 120-32-1) which is currently being evaluated as part of the EU Review programme according to Regulation 528/2012 for use in product types 2 and 3.

Sir / Madam

The harmonized classification for the biocidal active substance chlorophene includes Carc. Cat. 2 and Repr. Cat. 2. Chlorophene therefore fulfils the interim criteria of Regulation 528/2012 (BPR) as an active substance with endocrine disrupting properties and hence the exclusion criteria of the BPR would apply to the substance.

We object to the proposal of the eCA for non-approval of this active. Please consider our statements below:

a) Legal point of view

The interim ED criteria of the BPR are planned to be replaced in due course by the legislators. From a legal point of view it can thus be questioned if they should now be applied to chlorophene. According to the current EChA timetable, the BPC opinion for chlorophene can be expected at the end of 2017. This opinion and the publication of a decision for the substance could thus overlap with the planned EU regulation on endocrine disruptors. Considering this situation, we consider that one appropriate way forward is to put the dossier evaluation on hold and re-evaluate once the final ED criteria have entered legally into force.

b) Scientific point of view

The interim ED criteria are scientifically unjustified for identification of an endocrine disrupting substance. Their application can lead to either false negative or to false positive decisions on substances.

The toxicological assessment of studies and other available information for chlorophene has shown that the substance is not an endocrine disruptor (reference: attachment 1).

Summary: Overall, whereas the screening assays on endocrine activity showed some positive results the observed activity was consistently weak and therefore does not indicate a specific endocrine activity. This conclusion is in line with the available in vivo toxicological studies, which indicated only weak (or even questionable) isolated observations in a two generation reproductive toxicity study without evidence of a specific and relevant endocrine activity.

The kidney is the main target organ of toxicity.

The recently agreed classification (RAC/EChA) confirms this view: STOT RE 2 (related to kidney damage). Carc 2 (based on transitional cell carcinoma in rats and the renal neoplasms in male mice). Repr. 2 (H361f- suspected of damaging fertility; no indication of a mechanistic explanation). Thus, based on all available toxicity, data chlorophene is not an endocrine disruptor. Application of the interim ED criteria would lead to an incorrect decision and the unjustified removal of an active substance from the market.

c) Essential uses

Chlorophene is a fungicidal and bactericidal active which is efficacious against target organisms as *Aspergillus spp.*, *Pseudomonas aeruginosa* and Mycobacteria. Its intended uses include disinfection of animal housing as well as applications in health care units. It can be used under heavy duty conditions (high organic load).

Based on its efficacy profile, Chlorophene is an important disinfection management tool which is essential for disease prevention.

Medical treatments against infectious diseases as tuberculosis and to a lower extent also aspergillosis seem to fail in an increasing number of especially vulnerable patient groups. Development of resistant strains against medical treatments is one of the major reasons for that (reference: Global tuberculosis report 2016, WHO.) Mycobacteriosis may occur also in animals. In commercial animal production the disease can result in economic losses, such as reduced animal production. Generally, spreading of mycobacterium infections in animals could be prevented by using medical antibiotic treatments, however, this is not a good option due to possible occurrence of resistance with possible impact also on human health, high treatment costs and prolonged keeping of animals, as highlighted by heightened concerns on antimicrobial resistance to antibiotics.

As a consequence, hygiene management is a very important tool to reduce the risk of disease transmission to both humans and animals. Disinfection is one of the main biosecurity measures. A sufficient number of disinfection actives must be available on the market. The complete picture of suitable substances for a specific application is however only available once all substances have been evaluated and sufficient biocidal products are available on a market.

Properties to consider and to compare include:

- Suitable application techniques for the disinfection of a specific surface
- Intended uses
- application type
- Target organisms
- Physico-chemical properties of a product (eg is a product corrosive to a specific surface material it is going to be applied on?)
- Efficacy under the specific intended use conditions
- Possible resistance development

Our comparison identified only a limited number of actives which could cover similar use conditions as chlorophene.

Please refer to our statement (attachment 2).

Yours sincerely


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