MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

European Chemical Agency
Biocidal Product Committee
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BPC 37 - Minority opinion on the application for approval of the active substance: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

During the 37th BPC meeting discussion that took place 2 December 2020 the representative of the Czech Republic (CZ) voted against the adoption of BPC opinon on the active substance: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CZ). In particular, CZ did not agree with the BPC conclusion on non-approval of this substance as CZ holds that safe use for this substance was identified. The CZ position is explained in the following text.

Rationale for the CZ minority position:

According to Article 4 (1) the REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products (the BPR) an active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). It was primarily the compliance of the assessment with the condition stipulated in Article 19 (2 a), that was disputed in the BPC discussion by a majority of the members. Article 19 (2a) reads : „ The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors: (a) realistic worst case conditions under which the biocidal product may be used“.

Two possibilities acceptable for CZ as realistic worst case conditions and leading to a safe use, even when applied separately, were presented during the discussion :

1. Calculating the operator exposure during the vacuum pressure treatment for 2 cycles ensured by appropriate labelling (as was originally done by the evaluating CA) rather than factoring in the default number of 3 cycles. The CZ does not agree with the

BPC majority argument that 3 cycles represent the realistic worst-case and must therefore be used, and that two cycles are difficult to be enforced. The meaning of the word default means lack; want; absence. This implies that default values or conditions should only be applied in the absence of other realistic and more suitable options. The CZ insists that 2 cycles specified in the labelling represent realistic and enforceable scenario suitable for operator exposure assessment. The CZ considers labelling as an effective tool for ensuring compliance with the conditions determined in the risk assessment of uses of biocidal products. This applies in particular for the use by professionals and industrial users. Arguing that labelling it is not sufficient to ensure the compliance with safe use conditions by industrial users undermines this tool in general. Thus, such argument should be used only exceptionally, in well justified cases, such as technically not feasible scenarios etc. This is, however, not the case of the proposed use of diamine.

1. Decreasing the working solution a.s. concertation from 0.025% to 0.02 %. This leads to decrease in the a.s. dose taken up by the wood to 2.3 kg/m3 . However, it was confirmed also by the chair of efficacy WG that this dose ensures sufficient efficacy. Simple calculation than reveals that this decrease prevents unacceptable risk and thus ensures a safe use of the representative product.

Risk management

In conclusion, a safe use has been identified[1] and diamine should be approved for use as wood preservative.

[1] CZCA considers the above possibilities as risk mitigation measures (RMMs) and therefore within the remit of the BPC rather than WG, who should decide on more technical issues. Therefore, the 37th BPC meeting has been the only forum that could decide on these RMMs. This implies that these options should not have been refused on the grounds of time delay. In fact option 1) was originally used in the risk assessment and changed, to the best of our knowledge, only after the HHWG (ad-hoc follow up) advised to use 3 cycles (HHWG cannot decide on RMMs). Regarding the option 2) we are not sure why this was refused, as this is a very straightforward and simple way to reduce risk to an acceptable level.

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