

Referral to the Coordination Group under Article 35 of Regulation (EU) No 528/2012

Executive summary

Type of referral: Referral to the Coordination Group of a disagreement on Mutual recognition (MR) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR).

Product name in the rMS: Acticide C1

Case type: Mutual recognition in parallel (MR-P)

Reference Member State (rMS): FR

Initiating concerned Member State (icMS): NL, DE

Other Concerned Member States (cMSs): AT, BE, BG, HR, CY, CZ, DK, EE, FI, EL, HU, IE, IT, MT, NO, PL, PT, RO, SK, SI, ES, SE, CH, UK

Product type(s): 6

Active substance(s): 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT)

Brief summary of the points of disagreement:

1. Both flammability and auto-ignition should be supported by test results because according to the CLP regulation, the flammability cannot be waived based on the flashpoint of ingredients and the auto-ignition cannot be waived based on the water content of the product.
2. No safe outdoor use was identified (Use 2) and the proposed risk mitigation measure (RMM) to mitigate the risk from a direct rainwater discharge "*Do not apply the preserved paint where release to drains cannot be prevented*" is not enforceable. Therefore, a restricting RMM allowing indoor use only should be implemented.
3. Phrases, such as RMMs, concerning treated articles should not be included at the product authorisation level, except if they were laid down during the active substance approval. The proposed RMMs cannot be accepted and unacceptable risk remains for the uses 2, 3 and 7. Thus, these uses should not be authorised.

In addition, the following sentences: "*The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties*" and "*The person responsible for the placing on the market of articles for non-professional users shall ensure that the concentration of C(M)IT in treated*

articles do not exceed the threshold value set for sensitizing properties" for the uses 1 and use 2 should be removed from the SPC.

4. The provided test does not sufficiently address corrosiveness to metals according to the CLP requirements due to the applied deviations from the test manual.

Outcome of the discussion within the Coordination Group (CG):

No agreement was reached by the CG members on 26 March 2020 on the following points of disagreement:

2. No safe outdoor use was identified (Use 2) and the proposed RMM to mitigate the risk from a direct rainwater discharge "*Do not apply the preserved paint where release to drains cannot be prevented*" is not enforceable. Therefore, a restricting RMM allowing indoor use only should be implemented.
3. Phrases, such as RMMs, concerning treated articles should not be included at the product authorisation level, except if they were laid down during the active substance approval. The proposed RMMs cannot be accepted and unacceptable risk remains for the uses 2, 3 and 7. Thus, these uses should not be authorised.

The refMS FR will refer the aforementioned disagreement points to the Commission in accordance with provisions of the Article 36 of the BPR.

The CG members agreed by consensus on 26 March 2020 that:

1. The applicant submitted new study reports addressing flammability and auto-ignition properties of the product. The product should not be classified as flammable and it has no auto-ignition properties.
3. The sentences: "*The person responsible for the placing on the market of articles for professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties*" for the uses 1 and use 2 and "*The person responsible for the placing on the market of articles for non-professional users shall ensure that the concentration of C(M)IT in treated articles do not exceed the threshold value set for sensitizing properties*" for the general section of the SPC can be included in the SPC.
4. The applicant submitted amended version of the report addressing corrosiveness. Thus the product should not be classified as corrosive to metals.

This formal referral is therefore closed.