



Evaluation Report for Category B, Subcategory 2.1 (Change in guarantee), 2.3 (Identity of formulants), 2.4 (Proportion of formulants) Application

Application Number: 2005-1258
Application: Category B, subcategory 2.1 (Change in guarantee), 2.3 (Identity of formulants), 2.4 (Proportion of formulants)
Product: Brotab Milk Preservative
Registration Number: 28530
Active ingredients (a.i.): Bronopol & Pimaricin
PMRA Document Number: 1364604

Purpose of Application

Brotab Milk Preservative (PCP 28530) is used to preserve milk samples for testing purposes only. The purpose of this submission is to amend the active ingredient guarantee for both actives, and to change the proportion and identity of the formulants in the product.

Chemistry Assessment

Brotab "10" Milk Preservative is a solid containing the active ingredients bronopol and pimaricin at nominal concentrations of 30% and 1.62% respectively. The chemistry requirements for Brotab "10" Milk Preservative are complete.

Health Assessment

The product label currently contains the most severe hazard labelling statements (ie., Danger Poison, Corrosive to Eyes and Skin, Potential Skin Sensitizer). These statements are a result of the acute toxicity profile of the active ingredient Bronopol. The increase in the concentration of Bronopol in the proposed new formulation, the minor increase in the Pimaricin concentration, and the change in formulants, will not have an impact on the hazard profile for the product. Therefore, acute toxicity studies performed with the new formulation were not required.

Brotab is always handled through a dispenser, and thus there is no operator contact when using this product. The tablets are placed directly into the dispensers by the manufacturer. These dispensers are sent to customers in vacuum-sealed packaging. Since most analytical facilities use sample tubes with pre-dispensed tablets, and other facilities use the supplied dispensers to avoid manipulating the tablets directly, the potential for exposure to bronopol and pimaricin from the use of this product is very low. Exposure is expected to be negligible.

Environmental Assessment

An environmental assessment was not required.

Value Assessment

Data was submitted to support the proposed guarantee amendments of the product. The studies demonstrated that Brotab Milk Preservative could protect milk samples stored at room temperature for up to 10 days as assessed by daily measurements of butter fat stability in the milk samples.

Conclusions

The Agency has completed an assessment of available information for Bronopol Milk Preservative and has found the information sufficient to allow for registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

PMRA 1160219. Brotab 10 Mil Preservative efficacy trials. D&F Control Systems. DACO 10.2.3

1160232 Brotab 10 Milk Preservative Chemistry Data, N/S, N/S, DACO:
0.9.1,3.1.1,3.1.2,3.2.1,3.3.1,3.4

ISSN: 1911-8082

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