

Evaluation Report for Category B, Subcategories 2.1, 2.3, 2.4, 3.1 Application

Application Number: 2022-1353

Application: New End-use Product (Product Chemistry) – Guarantee, Identity

of Formulants, and Proportion of Formulants; New Product

Labels-Application Rate Increase or Decrease

Product: Preventol BM 10

Registration Number: 35207

Active ingredients (a.i.): 1,2-benzisothiazolin-3-one and 2-methyl-4-isothiazolin-3-one

PMRA Document Number: 3572130

Purpose of Application

The purpose of this application was to register a new commercial class material preservative, Preventol BM 10.

Chemistry Assessment

Preventol BM 10 is formulated as a solution containing 1,2-benzisothiazolin-3-one at a concentration of 5.00 % and 2-methyl-4-isothiazolin-3-one at 5.00 %. This end-use product has a density of 1.044 g/mL and a pH of 8.46. The required chemistry data for Preventol BM 10 have been provided, reviewed and found to be acceptable.

Health Assessments

Preventol BM 10 is of low acute toxicity via the oral and dermal routes of exposure, but is of high acute toxicity via the inhalation route of exposure. It is expected to be corrosive to the eye, and it is mildly irritating to the skin. Preventol BM 10 is considered to be a dermal sensitizer.

The use of Preventol BM 10 as a preservative in adhesives, paints, coatings, polymer latex emulsions, household, institutional and industrial cleaning products and pesticide products is not expected to result in potential occupational or bystander exposure over the registered uses of 1,2-benzisothiazolin-3-one and 2-methyl-4-isothiazolin-3-one. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

A dietary exposure assessment was not required for this application.



Environmental Assessment

The uses of Preventol BM 10 are within the currently registered use pattern for the active ingredients. Therefore, no additional risk is expected when Preventol BM 10 is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The comparison of the formulation of Preventol BM 10 to the precedent product and the subsequent comparison of the use patterns demonstrated that the efficacy of Preventol BM 10 should be similar to the precedent product (at the same active ingredient rates). Therefore, Preventol BM 10 has been found to have acceptable value.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Preventol BM 10.

References

PMRA Document	
Number	Reference
3337181	2021, Acute Oral Toxicity Study of Preventol BM 10 in Rats, DACO: 4.6.1
3337182	2021, Acute Dermal Toxicity Study of Preventol BM 10 in Rats, DACO: 4.6.2
3337183	2021, Acute Inhalation Toxicity Study of Preventol BM 10 in Rats, DACO: 4.6.3
3337184	2021, Acute Eye Irritation Study of Preventol BM 10 in Rabbits, DACO: 4.6.4
3337185	2021, Acute Dermal Irritation Study of Preventol BM 10 in Rabbits, DACO: 4.6.5
3337186	2021, Skin Sensitization Study of Preventol BM 10 by Local Lymph Node Assay in Mice, DACO: 4.6.6
3337177	2022, Preventol BM 10 Product Chemistry Supplement to Support PMRA Registration, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.5.4,3.5.5 CBI
3337178	2021, Preventol BM 10 Product Chemistry, DACO: 3.5.1,3.5.2,3.5.3,3.5.6, 3.5.7,3.5.8,3.5.9
3337179	2021, Preventol BM 10 Accelerated Storage Stability with Corrosion Characteristics, DACO: 3.4.1,3.5.10,3.5.14
3337180	2022, Preventol BM 10 Product Chemistry Waiver Requests to Support PMRA Registration, DACO: 3.5.11,3.5.12,3.5.13,3.5.15
3567944	2024, Response to Preventol BM 10, 2022-1353 Chemistry Clarification Request, DACO: 3.5.11 CBI

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