

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.12 Application

Application Number: 2017-1746
Application: B.2.1: New Guarantee
B.2.3: New Identity of Formulants
B.2.4: New Proportion of Formulants
B.3.12: New Site or Host
Product: Acticide M 10
Registration Number: 33231
Active ingredients (a.i.): 2-Methyl-4-isothiazolin-3-one
PMRA Document Number : 2920333

Purpose of Application

The purpose of this application was to register Acticide M10, an in-can preservative for use in a number of aqueous-based materials and based on 2-methyl-4-isothiazolin-3-one as the sole active ingredient.

Chemistry Assessment

Acticide M 10 is formulated as a solution containing 2-methyl-4-isothiazolin-3-one at a concentration of 9.50%. This end-use product has a density of 1.020-1.050 g/cm³ and pH of 4.4. The required chemistry data for Acticide M 10 have been provided, reviewed and found to be acceptable.

Health Assessments

Acticide M 10 is considered to be slightly acutely toxic by the oral and inhalation routes and of low acute toxicity via the dermal route based on studies in rats, and corrosive to the eye and slightly irritating to the skin based on studies in rabbits. Acticide M 10 is a potential dermal sensitizer based on results of a local lymph node assay in mice.

The application and post-application exposures and risks from the use of Acticide M 10 for the control of bacteria, mold and yeast in polymer emulsions/solutions, paints and coatings, adhesives, inks/ink components, fountain solutions, building materials, concrete admixtures, dispersed pigments/mineral slurries, and household consumer, industrial and janitorial products were assessed. No risks of concern are expected from these uses when the maximum use rates for paints (including other uses that would be covered by the paints exposure scenario such as polymer emulsions/solutions, coatings, adhesives, inks/ink components, fountain solutions, building materials, concrete admixture, dispersed pigments/mineral slurries) and cleaning products do not exceed 75 and 30 ppm ISL, respectively.

Environmental Assessment

The uses are within the currently registered use pattern of the active ingredient 2-methyl-4-isothiazolin-3-one (ISL) as a material preservative.

The label includes the statement “DO NOT apply to any body of water.” under ENVIRONMENTAL HAZARDS.

No additional environmental risk is expected from the use of Acticide M10.

Value Assessment

Laboratory studies were conducted to evaluate the ability of Acticide M10 to protect a number of different material samples each within the material categories (i.e., polymer emulsions, paints/coatings, adhesives, inks, fountain solutions, building materials (i.e., joint compounds, sealants, etc.), concrete admixtures, mineral slurries, and industrial/janitorial products. The studies were conducted with various materials and used bacterial and fungal inoculum simulating real-life contamination possibilities. The data demonstrated that Acticide M10 is effective against bacterial and fungal growth under representative use conditions.

Conclusion

The PMRA has reviewed the information provided to register Acticide M10. Based on the results of this review, Acticide M10 is acceptable for registration.

References

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