



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2014-1776
Application: B.2.6 - New combination of TGAIs
Product: Mergal 758
Registration Number: 31968
Active ingredients (a.i.): 1,2-benzisothiazolin-3-one + 2-methyl-4-isothiazolin-3-one + 5-chloro-2-methyl-4-isothiazolin-3-one
PMRA Document Number : 2599684

Purpose of Application

The purpose of this application was to register Mergal 758, a material preservative product for use in a number of materials, containing the currently registered active ingredients 1,2-benzisothiazolin-3-one, 2-methyl-4-isothiazolin-3-one and 5-chloro-2-methyl-4-isothiazolin-3-one.

Chemistry Assessment

Mergal 758 is formulated as a solution containing 1,2-benzisothiazolin-3-one at 10.1%, 5-chloro-2-methyl-4-isothiazolin-3-one at 0.49%, and 2-methyl-4-isothiazolin-3-one at 0.17%. This end-use product has a density of 1.06 g/cm³ and a pH of 3.87. The chemistry requirements for this product have been fulfilled.

Health Assessments

Mergal 758 is of slight toxicity via the oral route and of low toxicity via the dermal and inhalation routes. It is corrosive to the eyes and skin and is considered a dermal sensitizer.

The use of Mergal 758 fits within the currently registered use patterns for the active ingredients. Therefore, exposure to Mergal 758 is not expected to increase over the exposure from the currently registered products.

Environmental Assessment

Based on the use rates and use patterns, the use of Mergal 758 will not result in unacceptable risk to the environment. One of the active ingredient in Mergal 758, 1,2-benzisothiazoline-3-one, contains low levels of dioxins and furans. These are being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP.

Value Assessment

Laboratory studies were conducted to evaluate the ability of Mergal 758 to protect a number of different material samples each within the proposed material categories (i.e.,

polymer emulsions, paints/coatings, mineral slurries, latices, adhesives, building materials (i.e., joint compounds, sealants, stucco), inks, floor wax, floor cleaner and buffing compound. The studies were conducted with various materials and used bacterial and fungal inoculum simulating real-life contamination possibilities. The data demonstrated that Mergal 758 is effective against bacterial and fungal growth under representative use conditions.

Conclusion

PMRA has reviewed information provided in support Mergal 758. Based on this review Mergal 758 is acceptable for full registration.

References

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