Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 3.12 Application

Application Number: 2014-1777
Application: B.2.1 - New Guarantee
B.3.12 - New Site
Product: Mergal K14
Registration Number: 32007
Active ingredients (a.i.): 5-chloro-2-methyl-4-isothiazolin-3-one + 2-methyl-4-isothiazolin-3-one
PMRA Document Number : 2576516

Purpose of Application

The purpose of this application was to register a new material preservative, Mergal K14, to control bacteria and fungi for a variety of uses, including in polymer emulsions, paints and coatings, mineral slurries and dispersions, adhesives, building and construction compositions and inks.

Chemistry Assessment

Mergal K14 is formulated as a solution containing 5-chloro-2-methyl-4-isothiazolin-3-one at 0.51% and 2-methyl-4-isothiazolin-3-one at 0.18%. This end-use product has a desnity of 1.028 g/cm^3 and a pH of 4.96. The chemistry requirements for this product have been fulfilled.

Health Assessments

Mergal K14 is of moderate toxicity via the acute inhalation route and of low toxicity via the acute oral and dermal routes of exposure. It is corrosive to the eye and skin and is a dermal sensitizer.

The use of Mergal K14 fits within the currently registered use patterns for the active ingredients 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one. Therefore, exposure to Mergal K14 is not expected to increase over the exposure from the currently registered products.

Environmental Assessment

Considering the use patterns for Mergal K14, direct environmental exposure to non-target organisms is expected to be negligible. Therefore, the PMRA has no environmental concerns for the registration of this product for the accepted uses.

Value Assessment

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Laboratory studies were conducted to evaluate the ability of Mergal K14 to protect a number of different material samples within each of the material categories (i.e., polymer emulsions, paints/coatings, mineral slurries, 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 K14 is effective against bacterial and fungal growth under representative use conditions.

Conclusion

The PMRA has reviewed the information provided in support of Mergal K14. Based on this review, Mergal K14 is acceptable for full registration.

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