

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

Application Number: 2009-4553
Application: New product – new guarantee, identity and proportion of formulants.
Product: Proxel BD Microbiostat Dispersion
Registration Number: 30230
Active ingredients (a.i.): 1,2-benzisothiazolin-3-one
PMRA Document Number English PDF: 2085576

Purpose of Application

The purpose of this application was to register a new end-use product Proxel BD Microbiostat Dispersion, which contains the active ingredient 1,2-benzisothiazolin-3-one (33.5% guarantee), as a material preservative (Use Site Category 18).

The application was based on the precedent registered product, Proxel BD 20 Microbiostat Dispersion (Registration number 28855, guarantee: 19.3% 1,2-benzisothiazolin-3-one). The use pattern and rate of application for the proposed product is the same as for the registered product.

Chemistry Assessment

Proxel BD Microbiostat Dispersion is a suspension containing 1,2-benzisothiazolin-3-one at a nominal concentration of 33.5%. This end-use product has a specific gravity of 1.15 – 1.17 and pH of 6.38. The chemistry data requirements for Proxel BD Microbiostat Dispersion are complete.

Health Assessments

Proxel BD Microbiostat Dispersion is of moderate acute toxicity via the oral and inhalation routes, and of low acute toxicity via the dermal route in rats. Proxel BD Microbiostat Dispersion is corrosive to the eyes and extremely irritating to the skin of rabbits and is considered a dermal sensitizer in guinea pigs.

A qualitative health assessment has been conducted for Proxel BD Microbiostat Dispersion. Proxel BD Microbiostat Dispersion is within the currently registered use pattern for the active ingredient 1,2-benzisothiazolin-3-one. Therefore, exposure to 1,2-benzisothiazolin-3-one is not expected to increase over the exposure from the currently registered product, Proxel BD 20 Microbiostat Dispersion.

Environmental Assessment

No additional environmental data were required to register the new end-use product, Proxel BD Microbiostat Dispersion. As the precedent product is registered at the same application rates and for the same use pattern, it is expected that the registration of Proxel BD Microbiostat Dispersion will not pose an increased risk to the environment.

Value Assessment

Data used to support the precedent product Proxel BD 20 Microbiostat Dispersion was submitted in support of Proxel BD Microbiostat Dispersion. The formulation of Proxel BD Microbiostat Dispersion was compared to that of Proxel BD 20 Microbiostat Dispersion and effects on the product's efficacy are not expected, thus, the data could be used to support the new product. Aliquots of spoiled latex adhesives, metal working fluids and aqueous based paints were treated with Proxel BD 20 Microbiostat Dispersion. Microbiological plate counts were then performed after 1, 2, 3 and 7 days of incubation. The efficacy studies demonstrated that the label rates were sufficient to eliminate established spoiling organisms in latex adhesives, metal working fluids and aqueous based paints.

Conclusion

The PMRA has completed an assessment of available information for Proxel BD Microbiostat Dispersion and has found the information sufficient to support the full registration of Proxel BD Microbiostat Dispersion.

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PMRA

Document

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