

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2011-1423
Application: Changes to product label – New site or host
Product: Proxel GXL Microbiostat Solution
Registration Number: 14683
Active ingredients (a.i.): 1,2-Benzisothiazolin-3-one
PMRA Document Number : 2196756

Background

Proxel GXL Microbiostat Solution (guarantee of 19.3% 1,2-benzisothiazolin-3-one; Registration number 14683) was first registered in 1982 for industrial use only as an in-can preservative for latex, casein/rosin emulsions, emulsion paints, and metal working fluids. The active ingredient 1,2-benzisothiazolin-3-one is also used as a formulant in a variety of other pesticide products as a material preservative.

These uses of benzisothiazolin-3-one were re-evaluated in 2008 and were determined to be acceptable for continued registration (Proposed Re-evaluation Decision PRVD2008-13, *Benzisothiazolin-3-one*; Re-evaluation Decision RVD2008-25, *Benzisothiazolin-3-one*).

Purpose of Application

The purpose of this application was to amend the product label of Proxel GXL Microbiostat Solution to include new material preservative uses for household/institutional cleaning products at 0.03-0.25%.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The inclusion of additional uses on the product label of Proxel GXL Microbiostat Solution does not impact the toxicological profile of this product.

A quantitative risk assessment was conducted for the proposed Proxel GXL Microbiostat Solution. No increase in exposure from this use expansion is expected over the exposure from currently registered uses.

Environmental Assessment

Additional environmental data were not required to support the use expansion of Proxel GXL Microbiostat Solution to include use in aqueous-based cleaning products. Increase in the environmental loading of Track-1 dioxins and furans from the proposed expansion is considered unlikely to be above background levels, and environmental exposure to 1,2-benzisothiazolin-3-one is expected to be minimal compared to current registered uses.

Value Assessment

Data from four laboratory trials were provided testing a range of different aqueous-based cleaning products and wipes. The studies were scientifically valid and representative of the proposed new use. Proxel GXL Microbiostat Solution was found to be an effective material preservative in these materials against bacteria, but not against fungi at the rates proposed.

Conclusion

The PMRA has completed an assessment of available information for Proxel GXL Microbiostat Solution and has found the information sufficient to amend the label to include new material preservative uses for household/institutional cleaning products.

References

PMRA #	Reference
2063556	Health & Hygiene Preservative Efficacy Challenge Test for Wipe Formulations, DACO 10.2.3.2
2063557	Health & Hygiene Preservative Efficacy Challenge Test, DACO 10.2.3.2
2061144	Evaluation of Preservative Efficacy of Proxel GXL in Customers Wipes, DACO 10.2.3.2
2061146	Evaluation of Preservative Efficacy of Proxel GXL in Customers Floor Cleaner Product, DACO 10.2.3.2
2061152	Evaluation of Preservative Efficacy of Proxel AQ in Customers Neutral Cleaner Product, DACO 10.2.3.2

ISSN: 1911-8082

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