Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.2, 2.3, 2.4, 3.1 and 3.12 Application

Application Number: 2006-4006
Application: New guarantee, form of TGAI, identity and proportion of formulants, change in application rate, as well as a new site
Product: Preventol OF 45
Registration Number: NA
Active ingredients (a.i.): 2-Phenylphenol (present as potassium salt)
PMRA Document Number : 1616376

Purpose of Application

The purpose of this application was to register Preventol OF 45, a new material preservative end-use product containing the active ingredient, 2-phenylphenol (present as potassium salt). Preventol OF 45 is used to prevent the spoiling of calcium carbonate, talcum and titanium dioxide slurries in papermaking processes. The requested use pattern of this product is similar to that of Preventol ON Extra (Reg. No. 27633). For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Preventol OF 45 is a liquid containing the active ingredient 2-phenylphenol (present as potassium salt) at a nominal concentration of 45%. This product has a density of 1.18 - 1.22 g/cm^3 and pH of 14. The chemistry requirements for Preventol OF 45 are complete.

Health Assessments

Preventol OF 45 is of moderate toxicity to rats via the oral route and is expected to be of moderate toxicity via the dermal route and high toxicity via the inhalation route. Preventol OF 45 is not expected to be a dermal sensitizer and is considered to be corrosive to the eyes and skin based on toxicity information for components of the formulation.

A health assessment has been conducted for Preventol OF 45. It is not expected that exposure to handlers will increase over the exposure of currently registered products containing the active ingredient 2-phenylphenol.

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Environmental Assessment

The maximum rate of application is the same as the currently registered product Preventol ON Extra. Although the active ingredient is present as a different type of salt (potassium instead of sodium), the environmental impact is expected to be similar. No additional increase in environmental exposure is expected, therefore, additional environmental data were not required to support the registration of Preventol OF 45. Environmental concerns are mitigated on the existing label.

Value Assessment

Efficacy data was provided in the form of a small-scale study, which examined the ability of Preventol OF 45 to control a range of bacteria within a calcium carbonate slurry. Preventol OF 45 was tested at 300, 400, and 500 ppm and compared to an untreated control over a six week period. The slurry samples were inoculated with a high concentration of mixed bacteria (10^6 to 10^7 CFU/ml) at the start of the test, and at each subsequent week for the duration of the test. The efficacy of Preventol OF 45 was evaluated by regularly sampling and enumerating the viable bacteria from the mineral slurry. A bridging rationale was provided to support the use of Preventol OF 45 for titanium dioxide and talcum slurries, based on the specific mineral in the slurry not acting as a microbial nutrient, and therefore having minimal influence for growth within the slurry. The supported rates for the mineral slurries were 0.030 - 0.045% Preventol OF 45, which matches the concentration of active ingredient for this use in the precedent product Preventol ON Extra.

Conclusion

The PMRA has completed an assessment of available information for Preventol OF 45 and has found the information sufficient to allow for full registration.

References

PMRA Document Number	Reference
1270104	2003. An Acute Oral LD50 Study in the Rat with Preventol OF 45. 02-A12-M1, January 13, 2003. Unpublished. DACO 4.6.1.
1270106	2006. Preventol OF 45 Acute Toxicity Studies - Waiver Request. April 6, 2006. DACO 4.6.2, 4.6.3, 4.6.4, 4.6.5 and 4.6.6.
1522531	2007. Acute Inhalation Study Waiver. December 5, 2007. DACO 4.6.3.
1522533	1992. Chemical Manufacturing Association Antimicrobial Exposure Assessment Study. December 8, 1992. DACO 4.6.6.
1522529	2007. Preventol OF 45 - Letter of Intent - Clarification (Response to Deficiencies). December 6, 2007. DACO 4.6.1, 4.6.3 and 4.6.6.

1280407	Control Product Specification Form.
1270108	2006. Proposed Draft Label. July 1, 2006.
1270100	2003. Formulation Process. DACO: 3.2.1, 3.2.2 CBI.
1270101	2006. Five Batch Analysis. 2006/0028/01. DACO: 3.2.3 CBI.
1270102	2006. Validation of an analytical method for the determination of the main component in Preventol OF 45. 2006/0028/01. DACO: 3.4.1 CBI.
1270103	2006. DACO 3.5 Chemical and Physical Properties. DACO: 3.5.
1352634	2002. Preventol OF 45 (former Preventol TP SP 80005) Storage Stability and Shelf Life. BCH-MPP-TM-IPC. DACO: 3.5.10, 3.5.14.

ISSN: 1911-8082