

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.13 Applications

Application Number: 2008-3981
Application: Amendment of the formulation and updating the label
Product: Frontiersman Xtra Bear Attack Deterrent
Registration Number: 28410
Active ingredients (a.i.): Capsaicin
PMRA Document Number : 1966797

Purpose of Application

The purpose of this application was to amend the formulation, update the label precautions and increase the efficacy range.

Chemistry Assessment

Frontiersman Xtra Bear Attack Deterrent is formulated as a solution containing capsaicin at a nominal concentration of 1.0% and related capsaicinoids at a nominal concentration of 0.84%. This end-use product has a density of 0.9878 g/cm³ and a pH of 4.5. The chemistry requirements for Frontiersman Xtra Bear Attack Deterrent are complete.

Health Assessments

There is no change in the technical grade active ingredient (TGAI), therefore the current database with respect to capsaicin is considered to be adequate. No additional toxicological information is required for the TGAI.

Two new formulants were added to the end-use product (EP), one from List 4B and one from List 2. Although one of the formulants is on List 2, it was reassessed by the EPA and is scheduled to be moved from List 2 to List 4B. Two formulants were removed from the formulation of the EP, one of which was on list 2, and as such, precautionary statements pertaining to these formulants were removed from the label of the product. The proportion of another formulant was increased, resulting in label changes to reflect the effective spray range of the EP.

No change in exposure is likely as a result of the formulation changes of the EP. Negligible exposure is expected to applicators and bystanders if the precautionary label statements are observed, as the product is to be applied in the same manner, and there is no change in the TGAI.

Environmental Assessment

The change in formulation of Frontiersman Xtra Bear Attack Deterrent is acceptable from an environmental perspective, as the quantity of the active ingredient (capsaicin) has not changed from the currently registered label (PCP 28410), and there are no environmental concerns associated with the new formulants. Proposed environmentally-related label statements are acceptable.

Value Assessment

Three trials were submitted to demonstrate the shot integrity (i.e., height and width of spray) of canisters containing 222g, 260g and 325g respectively of the new formulation. Canisters were sprayed at a target 9 feet high and 12 feet wide, from distances of 15, 20, 25, 30 and 35 feet (4.5, 6, 7.5, 9 and 10.5 m respectively). Time required for each canister to empty was recorded. Each canister size demonstrated consistent spray heights and widths at distances of 10-12 m from the target. The spray heights and widths recorded at 10-12m were approximately the same or greater than the values obtained at shorter distances. As a result, the shot integrity at the tested distances was demonstrated. The canister emptying time of 5.6-8.2 seconds and was supported.

Conclusion

The PMRA has completed an assessment of the subject application and has determined that the amendments to Frontier Xtra Bear Attack Deterrent are acceptable.

References

- 1647954 2008, Details of Frontiersman Shelf Life Test performed at Time = 6 Months, DACO: 3.5.10 CBI
- 1906788 2008, CFBAD (CBI Removed) Chromatograms - Shelf-life testing - 2008, DACO: 3.5.10 CBI
- 1933040 2010, Chromatograms - Sample blanks- June, 2010, DACO: 3.4.1 CBI
- 1933069 2009, Shelf Life Test - Frontiersman Bear Repellent - 12 Month Report, DACO: 3.5.10 CBI
- 1933040 2010, Chromatograms - Sample blanks- June,2010, DACO: 3.4.1 CBI
- 1933069 2009, Shelf Life Test - Frontiersman Bear Repellent - 12 Month Report, DACO: 3.5.10 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.