



Evaluation Report for Category B, Subcategory B.2.3, B.2.4, 3.14-S-N-MA Application

Application Number: 2005-3227
Application: Category B, subcategories:
B2.3 Identity of formulants; B2.4 Proportion of formulants;
B3.14 New or changes to product labels-classifications
Product: Bromotril Manufacturing Concentrate
Registration Number: 28864
Active ingredients (a.i.): Bromoxynil
PMRA Document Number: 1539416

Background

The PMRA has received an application to register a new manufacturing concentrate containing the active ingredient bromoxynil, and is classified as a Category B (Identity and Proportion of Formulants, classification).

Purpose of Application

To register a new manufacturing concentrate containing bromoxynil. The product will be used in manufacturing, formulating, or repackaging.

Chemistry Assessment

Bromotril Manufacturing Concentrate is formulated as a solution containing bromoxynil, present as the octanoate ester, at a nominal concentration of 56.2%. This product has a density of 1.16 g/mL and pH of 3.5-5. With the exception of the storage stability study that is currently in progress, the chemistry requirements for Bromotril Manufacturing Concentrate are complete.

Health Assessments

No new toxicological data were submitted nor reviewed for this submission. Bromotril Manufacturing Concentrate is sufficiently similar to currently registered products that the previously reviewed data for those products could be used to generate label statements for this new product. Occupational/bystander exposure and food residue assessments are not required for a manufacturing concentrate.

Environmental Assessment

No environmental studies were required to support the registration of Bromotril Manufacturing Concentrate and EAD does not need additional environmental data. The new identity and proportion of the formulants of this manufacturing concentrate are not expected to pose additional risk to the environment provided that the petroleum distillate used in this product, is utilized alone at the same proposed amount in the TGAI.

Value Assessment

A value assessment is not required for a manufacturing concentrate.

Conclusion

The PMRA has completed an evaluation and determined that Bromotril Manufacturing Concentrate is eligible for full registration with a condition to fulfill the following requirement:
- Submission of a storage stability study (DACO 3.5.10)

References

- 1427279 1998, Reregistration Eligibility Decision (RED) Bromoxynil, List B, Case 2070,EPA 738-R-98-013, 299 p.
- 942828 Summary: Toxicology Profile.
- 942829 Acute Oral Toxicity Study (UDP) in Rats., 8306-04, DACO: 4.6.1
- 942830 Acute Dermal Toxicity Study in Rabbits., 8307-04, DACO: 4.6.2
- 942835 Acute Inhalation Toxicity Study in Rats., 8308-04, DACO: 4.6.3
- 942836 Acute Eye Irritation Study in Rabbits., 8309-04, DACO: 4.6.4
- 942837 Acute Dermal Irritation Study in Rabbits., 8310-04, DACO: 4.6.5
- 942838 Skin Sensitization Study in Guinea Pigs., 7927-03, DACO: 4.6.6
- 1204045 BROMOXYNIL OCTANOATE ACUTE TOXICITY AND IRRITANCY STUDIES, DACO: 4.2.1,4.2.2,4.2.4,4.2.5
- 1204047 BROMOXYNIL ACUTE INHALATION TOXICITY IN RATS 4-HOUR EXPOSURE, DACO: 4.2.3
- 1204048 BROMOXYNIL OCTANOATE DERMAL SENSITIZATION STUDY IN THE GUINEA PIG, DACO: 4.2.6
- 942832 2004, Bromoxynil 2EC Product Properties., 90006606, DACO: 3.2,3.4.1
- 1345054 2006, Product Identification, NS, MRID: NS, DACO: 3.1.1,3.1.2,3.1.3,3.1.4
- 1345055 2006, Formulation Process, NS, MRID: NS, DACO: 3.2.1,3.2.2
- 1345056 2006, Establishing Certified Limits, NS, MRID: NS, DACO: 3.3.1
- 1345058 2006, Chemical and Physical Properties, NS, MRID: NS, DACO: 3.5.1,3.5.10, 3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9
- 1410513 2007, MAKHTESHIM AGAN OF NORTH AMERICA, INC. APPLICATION FOR THE REGISTRATION OF A MUP FOR [CBI Removed], NS, MRID: NS, DACO: 3.4.1

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