Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.1, 3.11, 3.12 Application

Application Number: 2018-0547
Application: B.2.1: Guarantee
B.2.3: Identity of Formulants
B.2.4: Proportion of Formulants
B.2.6: New Combination of Technical Grade Active Ingredients
B.3.1: Application Rate Increase or Decrease
B.3.11: Pests
B.3.12: Site or Host
Product: BioLab T-0041
Registration Number: 33486
Active ingredients (a.i.): Copper sulfate pentahydrate (CUS), Poly [oxyethylene(dimethylimino) ethylene(dimethylimino)ethylene dichloride] (POD)
PMRA Document Number: 3090451

Purpose of Application

The purpose of this application was to register a domestic class product containing a new combination of active ingredients. BioLab T-0041 for use as an algaecide in swimming pools.

Chemistry Assessment

BioLab T-0041 is formulated as a solution containing poly[oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride] at 6.5% and copper, present as copper sulfate pentahydrate, at 3.3%. This end-use product has a density of 1.234 g/mL and pH of 3.56. The required chemistry data for BioLab T-0041 have been provided, reviewed and found to be acceptable.

Health Assessments

BioLab T-0041 was of low acute toxicity to rats via the oral, dermal, and inhalation routes of exposure. It was mildly irritating to the eye and corrosive to the skin of rabbits, and was a skin sensitizer in mice according to the Local Lymph Node Assay.

BioLab T-0041 for use in swimming pools to control algae fits within the registered use pattern for poly (oxyethylene dimethylimino) ethylene-(dimethylimino) ethylene dichloride and copper sulfate. The potential exposure for residential handlers and bathers is not expected to exceed the current exposure to registered products. No health risks of concern are expected for individuals handling BioLab T-0041 provided that the label directions are followed and they wear the recommended PPE.

Canada

Environmental Assessment

Environmental assessment was not required for this application.

Value Assessment

Value information was submitted to demonstrate the ability of BioLab T-0041to prevent algae growth in swimming pool water. A small-scale efficacy trial was provided that tested the product against three species of algae known to grow in swimming pools. As this product is for the control of algae in the pool, it is necessary to use with a registered pool or spa sanitizer. BioLab T-0041was found to have acceptable value as a swimming pool algaecide.

Conclusion

The PMRA has reviewed the information provided in support of the new product. Based on the results of that review, BioLab T-0041 is acceptable for registration.

References

2847872	2018, FORMULATING PLANT'S NAME AND ADDRESS, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2847873	2016, DESCRIPTION OF STARTING MATERIALS, DACO: 3.2.1,3.2.2,3.3.1 CBI
2847874	2016, ENFORCEMENT ANALYTICAL METHOD, DACO: 3.4.1 CBI
2847875	2016, EXPLODABILITY, DACO: 3.5.12,3.5.13,3.5.15,3.5.8 CBI
2847876	2018, CORROSION CHARACTERISTICS, DACO: 3.5.10,3.5.14,3.5.4,3.5.5 CBI
2847877	2016, PH, DACO: 3.5.11,3.5.2,3.5.6,3.5.7,3.5.9 CBI
2848338	2016, CORROSION CHARACTERISTICS, DACO: 3.5.10,3.5.14 CBI
2847886	2018, Value Summaries and Information, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.3.1,10.3.2
2847887	2017, Biolab T-0041: Simulated In-Use Data Demonstrating the Effectiveness Against The Swimming Pool Algae Phormidium autumnale (blue-green algae), Chlorella pyrenoidosa (green algae) and Eustigmatos vischeri (mustard algae) when used according to label directions, DACO: 10.2.3.3
2847878	2016, T-0041: Acute Oral Toxicity - Up-and-Down Procedure in Rats, DACO: 4.6.1
2847879	2016, T-0041: Acute Dermal Toxicity in Rats, DACO: 4.6.2
2847880	2016, T-0041: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2847881	2016, T-0041: Primary Eye Irritation in Rabbits, DACO: 4.6.4
2847882	2016, T-0041: Primary Skin Irritation in Rabbits, DACO: 4.6.5
2847883	2016, T-0041: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6

ISSN: 1911-8082