Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2018-1313
Application: New End-use Product (Product Chemistry) - Identity of Formulants; Proportion of Formulants
Product: T-0034
Registration Number: 33464
Active ingredients (a.i.): Copper (present as copper sulfate pentahydrate); Available chlorine, present as trichloro-S-triazinetrione
PMRA Document Number : 3003893

Purpose of Application

The purpose of this application was to register T-0034, a new end-use product for use as an algaecide/bactericide in swimming pools.

Chemistry Assessment

T-0034 is formulated as a tablet, puck or stick containing available chlorine present as trichloro-s-triazinetrione at 83.25%, and copper present as copper sulfate pentahydrate at 0.25%. This end-use product has a density of 2.2 – 2.3 g/mL and pH of 2.1 – 2.5. The required chemistry data for T-0034 have been provided, reviewed and found to be acceptable.

Health Assessments

T-0034 is highly toxic by the acute oral route, slightly toxic by acute inhalation, and of low acute dermal toxicity. It is extremely irritating to the eyes, severely irritating to the skin, and is considered to be a dermal sensitizer.

Risk to individuals handling and applying T-0034 is acceptable when the product is used according to label directions. Precautionary, personal protective equipment and directions for use statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to exposure.

Bystander and residential exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

As of April 16, 2019, 37 human incident reports and 3 domestic animal incident reports involving copper (present as copper sulfate pentahydrate), available chlorine as trichloro-s-triazinetrione, or trichloro-s-triazinetrione, have been reported to the PMRA. Respiratory exposure to the active ingredients during the application or handling of pool products or pool product containers were frequently reported in the human incidents. The reported respiratory effects (for example, coughing, irritated throat and difficulty breathing) were

minor in nature. The precautionary, personal protective equipment and directions for use statements on the product labels aimed at minimizing potential respiratory exposure to the products are adequate to address these health concerns when the products are used according to label directions. No health risks were identified from the domestic animal reports.

A dietary exposure assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

A study was provided to support the value of T-0034 as a pool sanitizer and algaecide. The study, which was designed and carried out by experienced pool operators to simulate outdoor pool conditions in a controlled environment, demonstrated that T-0034 was sufficient to control green and blue-green algae levels in pools. T-0034 has been shown to have acceptable value as a pool sanitizer and algaecide.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has determined that the registration of the new swimming pool product T-0034 can be supported.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2867003	2018, DACO 3.1.1 - 3.1.4, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4 CBI
2867004	2015, T0034 Group A - Product Identity, Composition, and Analysis, DACO: 3.2.1 CBI
2867005	2018, Guideline: OPPTS 830.1650 Description of Formulation Process, DACO: 3.2.2 CBI
2867006	2018, Guideline: OPPTS 830.1650 Description of Formulation Process (Alternate), DACO: 3.2.2 CBI
2867007	2015, T-0034 Chemical Characterization of a Test Substance to Determine the Amount of Active Ingredient, DACO: 3.3.1 CBI
2867008	2015, T-0034 Group A - Product Identity, Composition, and Analysis, DACO: 3.4.1 CBI
2867009	2018, DACO 3.5, DACO: 3.5, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.5, 3.5.8, 3.5.9 CBI
2867010	2015, T-0034 Product Chemistry, DACO: 3.5.2,3.5.4,3.5.6,3.5.7 CBI
2867011	2016, T-0034 Storage Stability with Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI

2979140	2019, Certified Limits Rationale for Expansion, DACO: 3.3.1 CBI
2979141	2019, T-0034 Group A - Product Identity, Composition and Analysis, DACO: 3.2.1,3.2.2,3.2.3 CBI
2867020	2015, Simulated in-use Data Demonstrating the Effectiveness of T-0034, Against two Species of Swimming Pool Algae when Used According to Label, DACO: 10.2.3.3
2867012	2018, Toxicology Summary of Acute Studies for T-0034, DACO: 4.1, 4.6.4
2867013	2015, Acute Oral Toxicity in Rats, DACO: 4.6.1
2867014	2015, Acute Dermal Toxicity in Rats, DACO: 4.6.2
2867015	2015, Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2867016	2015, Acute Dermal Irritation in Rabbits, DACO: 4.6.5
2867017	2015, T-0034 Skin Sensitization: Lymph Node Assay in Mice, DACO: 4.6.6
2893126	2018, Occupational Exposure Information, DACO: 5.2
2969806	2019, Clarification Response to Dermal Sensitization Study, DACO: 4.6.6

B. Additional Information Considered

Published Information

PMRA Document Number	Reference
2983724	World Health Organization, 2006, Guidelines for Safe Recreational Water Environments Volume 2 Swimming Pools and Similar Environments Chapter 4 Chemical hazards, DACO: 12.5

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