

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2018-1312
Application: New End-use Product (Product Chemistry) - Identity of Formulants; Proportion of Formulants
Product: T-0035
Registration Number: 33463
Active ingredients (a.i.): Copper (present as copper sulfate pentahydrate); Available chlorine, present as trichloro-S-triazinetrione
PMRA Document Number : 3003655

Purpose of Application

The purpose of this application was to register T-0035, a new end-use product for use as an algaecide/bactericide in swimming pools.

Chemistry Assessment

T-0035 is formulated as a tablet, puck or stick containing available chlorine present as trichloro-s-triazinetrione at 85.5%, and copper present as copper sulfate pentahydrate at 0.25%. This end-use product has a density of 2.0 – 2.4 g/mL and pH of 2.0 – 2.4. The required chemistry data for T-0035 have been provided, reviewed and found to be acceptable.

Health Assessments

T-0035 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 and skin, and is considered to be a dermal sensitizer.

Risk to individuals handling and applying T-0035 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-0035 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-0035 was sufficient to control mustard algae levels. T-0035 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-0035 can be supported.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2866967	2018, DACO 3.1.1 - 3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2866968	2015, T-0035 Product Identity, Manufacturing Process and Analytical Method, DACO: 3.2.1, 3.2.2, 3.4.1 CBI
2866969	2015, T-0035 Chemical Characterization of a test Substance to Determine the Amount of Active Ingredient, DACO: 3.3.1, 3.5.2 CBI
2866970	2018, DACO 3.5, DACO: 3.5, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2866971	2015, T-0035 Product Chemistry, DACO: 3.5.6, 3.5.7 CBI
2866972	2016, T-0035 Storage Stability with Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
2979147	2019, Certified Limits Rationale for Expansion, DACO: 3.3.1 CBI
2979148	2019, T-0035 Group A - Product Identity, Composition and Analysis, DACO: 3.2.1, 3.2.2, 3.2.3 CBI
2867019	2017, T-0035: Simulated in-use Data Demonstration the effectiveness Against the Swimming Pool Algae <i>Eustigmatos vischeri</i> (Mustard Algae) when used According to Label Directions, DACO: 10.2.3.3

2866973	2018, Toxicology Summary of Acute Studies for T-0035, DACO: 4.1, 4.6.4
2866974	2015, T-0035 Acute Oral Toxicity in Rats, DACO: 4.6.1
2866975	2015, T-0035 Acute Dermal Toxicity in Rats, DACO: 4.6.2
2866976	2015, T-0035 Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2866977	2015, T-0035 Acute Dermal Irritation in Rabbits, DACO: 4.6.5
2889432	2015, T-0035 Skin Sensitization: Local 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

ISSN: 1911-8082

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