Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4Application

Application Number: 2017-0869
Application: B.2.3: New Identity of Formulants
B.2.4: New Proportion of Formulants
Product: Mergal 530
Registration Number: 33131
Active ingredients (a.i.): 2,2-DIBROMO-3-NITRILOPROPIONAMIDE
PMRA Document Number: 2870401

Purpose of Application

The purpose of this application was to register the end-use product, Mergal 530 which has slimicide and material preservative uses.

Chemistry Assessment

Mergal 350 is formulated as a solution containing 2,2-dibromo-3-nitrilopropionamide at a concentration of 20%. This end-use product has a specific gravity of 1.24 and pH of 4.35. The required chemistry data for Mergal 530 have been provided, reviewed and found to be acceptable.

Health Assessments

Mergal 530 is of moderate acute toxicity via the oral route of exposure, of low acute toxicity via the dermal route, and of slight acute toxicity via the inhalation route of exposure. It is considered corrosive to the eyes and skin. Mergal 530 was not a skin sensitizer when tested using the Buehler Method.

The use pattern of Mergal 530, for material preservation and treatment of industrial process fluids to control against microbial contamination, fits within the registered use pattern for 2,2-dibromo-3-nitrilopropionamide. The potential exposure for mixers, loaders, applicators and postapplication re-entry workers is not expected to exceed the current exposure to registered products.

Environmental Assessment

The use pattern for Mergal 530 is within the registered use pattern of other products containing 2,2,Dibromo-3-nitriloproprionamide. Therefore, there are no additional environmental risks expected with the use of Mergal 530.

Canada

Value Assessment

Value data was provided and reviewed. This review has determined Mergal 530 will provide acceptable value.

Conclusion

The PMRA has reviewed information provided in support of registration of Mergal 530. Based on the results of this review, Mergal 530 is acceptable for registration.

References

2729102	4.2.1 Actute Oral Toxicity
2729103	4.2.2 Acute Dermal Toxicity - Mergal 530
2729104	4.2.3 Acute Inhalation Study - Mergal 530
2729105	4.2.5 Primary Skin Irritation
2729106	4.2.6 Dermal Sensitization Study in Guinea Pigs (Buehler Method) Mergal 530
2729107	4.2.4 Primary Eye Irritation Data Waiver
2729091	2017, DACO 3.1 Product Identification - Mergal 530, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4 CBI
2729092	2017, DACO 3.2 Formulation Process, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI
2729093	2017, DACO 3.3 Specifications - Mergal 530, DACO: 3.3.1 CBI
2729094	2017, DACO 3.4 Product Analysis - Mergal 530, DACO: 3.4,3.4.1,3.4.2 CBI
2729095	2017, DACO 3.5 Chemical and Physical Properties - Mergal 530, DACO: 3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2729098	2014, Mergal 530 Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
2729099	2014, [CBI removed] Analytical Method for he Determination of, DACO: 3.4.1 CBI
2729100	2012, Physical and Chemical Characteristics of Mergal 530, DACO: 3.5,3.5.11,3.5.6,3.5.7,3.5.9 CBI
2729101	2014, Mergal 530 Product Chemistry Data, DACO: 3.7 CBI

ISSN: 1911-8082