



Evaluation Report for Category B, Subcategory B 1.1 [New source (site of manufacture) by current registrant] and B 1.3 (Specifications or manufacturing process) Application

Application Number: 2005-3791
Application: Category B, Subcategory B 1.1 and B 1.3
Product: Maquat MC 1412-50%
Registration Number: 21724
Active ingredients (a.i.): Alkyl (40% C₁₂, 50% C₁₄, 10% C₁₆) dimethyl benzyl ammonium chloride [QAC]
PMRA Document Number: 1525152

Background

The product, Maquat MC 1412-50%, is a registered Technical Grade Active Ingredient (TGAI) in Canada under PCP 21724. This product is used in the formulation of sanitizers, disinfectants and water treatment microbiocides.

Purpose of Application

The purpose of this application is to replace the manufacturing site with a new site (same registrant) and to change the manufacturing specifications. The application is classified as a Category B 1.1 and B 1.3.

Chemistry Assessment

Common Name: N/A
Chemical Name: Alkyl (40% C₁₂, 50% C₁₄, 10% C₁₆) dimethyl benzyl ammonium chloride

Maquat MC 1412-50% has the following properties:

Property	Result
Colour and physical state	white liquid
Nominal concentration	50%
Odour	mild benzaldehyde type odour
Density	0.94 g/mL
Vapour pressure	38 mmHg
pH	7-8(10% solution)
Solubility in water	soluble in water
n-Octanol/water partition coefficient	soluble in water

The chemistry requirements for Maquat MC 1412-50% are complete.

Health Assessments

There is no expected change to the toxicological profile of the active ingredient since the chemistry review indicated the active ingredient at the new manufacturing site to be chemically equivalent to the registered source.

Environmental Assessment

Not applicable.

Value Assessment

Not applicable.

Conclusion

The PMRA has completed an evaluation of the application and has found the information sufficient for a new manufacturing site and changing manufacturing specifications.

References

- 1102527 Applicants Name and Office Address, Manufacturers Name and Office Address, DACO: 2.1,2.2
- 1102528 Manufacturing Summary, DACO: 2.11.1
- 1102529 Description of Starting Materials, DACO: 2.11.2
- 1102530 Standard Manufacturing Procedures, DACO: 2.11.3
- 1102531 Discussion of Formation of Impurities, DACO: 2.11.4
- 1102532 Establishing Certified Limits,, DACO: 2.12.1
- 1102533 Detailed Specification for Maquat MC1412-50%, DACO: 2.13.1
- 1102534 Maquat MC1412-50% Preliminary Analysis;, DACO: 2.13.2,2.13.3
- 1319139 Material Safety Data Sheet, DACO: 2.11.2
- 1319140 2006, DACO: 2.11.4
- 1319141 DACO: 2.13.1
- 1319142 2004, UV Visible Absorption, 410-183, DACO: 2.14.12
- 1418028 Material Safety Data Sheet with Percentage Breakdown, DACO: 2.11.2
- 1422965 Technical Chemistry file - Analysis of Quaternary Benzyldimethylalkonium Salts by High Performance Liquid Chromatography, DACO: 2.9

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