

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: 2005-3793
Application: Category B, Subcategory B 1.1 and B 1.3
Product: Maquat MC1416-80%
Registration Number: 21894
Active ingredients (a.i.): Alkyl (5% C₁₂, 60% C₁₄, 30% C₁₆, 5% C₁₈) dimethyl benzyl ammonium chloride [QAL]
PMRA Document Number: 1500237

Background

The product, Maquat MC1416-80%, is a registered Technical Grade Active Ingredient (TGAI) in Canada under PCP 21894. 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 (5% C₁₂, 60% C₁₄, 30% C₁₆, 5% C₁₈) dimethyl benzyl ammonium chloride

Maquat MC 1416-80% has the following properties:

Property	Result
Colour and physical state	white liquid
Nominal concentration	80%
Odour	mild benzaldehyde type odour
Specific gravity	0.91 - 0.95
Vapour pressure	40 mmHg
pH	6-8(10% solution)
Solubility in water	soluble in water
n-Octanol/water partition coefficient	soluble in water

The chemistry requirements for Maquat MC 1416-80% 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

- 1102479 Manufacturing Summary, Maquat MC1416-80%,, DACO: 2.11.1
- 1102480 Description of Starting Materials, DACO: 2.11.2
- 1102481 Standard Manufacturing Procedures, DACO: 2.11.3
- 1102482 Discussion of Formation of Impurities, DACO: 2.11.4
- 1102483 Establishing Certified Limits, DACO: 2.12.1
- 1102484 Detailed Specification for Maquat MMC1416-80%, DACO: 2.13.1
- 1102485 Maquat MC1416-80 Preliminary Analysis;, DACO: 2.13.3,2.13.4
- 1102486 Applicants Name and Office Address, Manufacturers Name and Office Address,, DACO: 2.1,2.2
- 1319173 Material Safety Data Sheet, DACO: 2.11.2
- 1319174 2006, DACO: 2.11.4
- 1319175 DACO: 2.13.1
- 1319176 2004, UV Visible Absorption, 410-184, DACO: 2.14.12
- 1422970 Technical Chemistry file Maquats, DACO: 2.99
- 1449815 2007, Material Safety Data Sheet - Component Breakdown, DACO: 2.11.2

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