

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2009-1809
Application: New TGAI chemistry: new source, new registrant
Product: Pathene MB
Registration Number: 30693
Active ingredient (a.i.): 3-(trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride
PMRA Document Number: 2168015

Background

All registered uses of the active ingredient 3-(trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride were re-evaluated in 2010 and were proposed for continued registration (Proposed Re-evaluation Decision PRVD2010-09, *3-Trimethoxysilyl propyldimethyl octadecyl ammonium chloride*).

Purpose of Application

The purpose of this application was to register a new technical grade active ingredient based on chemical equivalency to the precedent product AEM 5772-TA Antimicrobial (Registration Number 23388, Aegis Environmental Management Inc). The precedent product AEM 5772-TA Antimicrobial was registered in 1994.

Chemistry Assessment

IUPAC Name: 3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride
CAS Name: 1-Octadecanaminium, N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride (1:1)

Pathene MB has the following properties:

| Property | Result |
|---------------------------|-----------------------|
| Colour and physical state | Pinkish orange liquid |
| Nominal concentration | 71.2% |
| Odour | Mild-sweet soap odour |
| Specific gravity | 0.96 |
| Vapour pressure | Not available |
| pH | 5-8 |
| Solubility in water | Completely soluble |

| Property | Result |
|--|---|
| n-Octanol/water partition coefficient (K_{ow}) | Not applicable since the PAI is 100% miscible in water and alcohols |

The chemistry requirements for Pathene MB have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA conducted an evaluation of the subject application and determined that Pathene MB is chemically equivalent to the precedent product AEM 5772-TA Antimicrobial and is acceptable for registration.

References

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- 1920833 1999, Preliminary analysis, DACO: 2.13 CBI
- 1920834 1999, Certified limits, DACO: 2.12.1 CBI
- 1920839 1999, Determination of the boiling point, DACO: 2.14.5 CBI
- 1920843 1999, Product identity and disclosure of ingredients, description of beginning materials and manufacturing process, and discussion of the formation of impurities, Volume 2, DACO: 2.11.2 CBI
- 1920844 1999, Product identity and disclosure of ingredients, description of beginning materials and manufacturing process, and discussion of the formation of impurities, Attachment to volume 2, DACO: 2.11.2 CBI
- 2028078 2011, Batch data, DACO: 2.13.3 CBI
- 2116911 2011, Product identity and disclosure of ingredients, description of beginning materials and manufacturing process, and discussion of the formation of impurities, Attachment to volume 2, DACO: 2.11.2, 2.11.3, 2.11.4, 2.13.4, 3.2.1, 3.2.3, 3.4.2 CBI
- 2116912 1999, Product chemistry testing for an end-use product following product properties test guidelines series 830, Volume 5, DACO: 2.12.1, 3.3.1 CBI
- 2116914 2011, Methodology/validation, batch data, DACO: 2.13.1, 2.13.3, 3.6 CBI
- 2116939 1997, Discussion of formation of impurities, DACO: 2.11.4 CBI
- 2116944 2011, Stability testing, DACO: 2.14.14, 8.4.1 CBI
- 2116946 2011, Summary of chemistry information required to satisfy Canadian data requirements, DACO: 2.0 CBI

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