

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2007-7657

Application: B.4.1 Conversion To Full Registration Without Consultation

Product: KathonTM DC-886 Technical Microbicide

Registration Number: 28330

Active ingredients (a.i.): 2-Methyl-4-isothiazolin-3-one

5-chloro-2-methyl-4-isothiazolin-3-one

PMRA Document Number: 1786382

Purpose of Application

The purpose of this application is to convert Kathon TM DC-886 Technical Microbiocide (Reg. No. 28330) from conditional to full registration.

Chemistry Assessment

Common Name: No ISO common name assigned

Chemical Names: 2-Methyl-4-isothiazolin-3-one (ISL)

5-Chloro-2-methyl-4-isothiazolin-3-one (IST)

Kathon TM DC-886 Technical Microbiocide has the following properties:

Property	Result
Colour and physical state	Yellow to Yellow /Orange semi-solid at 25 °C
Nominal concentration	5-Chloro-2-methyl-4-isothiazolin-3-one (present as the hydrochloride salt) 2-Methyl-4-isothiazolin-3-one (present as the hydrochloride salt) 20.1 %
Odour	Weakly sweet and pungent at 25 °C
Specific gravity	1.420 at 25 °C
Vapour pressure	ISL 8.2 Pa (20 °C) IST 2.4 Pa (20 °C)
рН	2.12 (5% in water)
Solubility in water	ISL: ≥226 g/L (25 °C) IST: ≥660 g/L (25 °C)
n-Octanol/water partition coefficient	ISL: $\log K_{ow} = -0.486$ IST: $\log K_{ow} = 0.401$

The chemistry requirements for Kathon TM DC-886 Technical Microbiocide are complete.



Health Assessments

No toxicology data were required for the conversion of this technical grade active ingredient to full registration. As a result, the toxicity profile is not expected to change.

Environmental Assessment

An environmental assessment was conducted on KathonTM DC-886 Technical Microbicide (containing 20.1 % of 2-Methyl-4-isothiazolin-3-one and 58.3% of 5-chloro-2-methyl-4-isothiazolin-3-one). The environmental hazard statements on the label are adequate.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has completed the assessment of available information and has found the information sufficient to support the conversion of the conditional registration of KathonTM DC-886 Technical Microbicide to full registration.

References

PMRA No	Title
1491175	2007, KATHON(TM) DC-886 TECHNICAL MICROBICIDE (Reg. No. 28330) Sample Collection Process, DACO: 2.13.3 CBI
1491174	2007, Five Batch Analysis for Active Ingredient, Impurities and Residual Process Solvents, DACO: 2.13.3, 2.14.1, 2.14.2 CBI
1259306	2005, Pest Management Regulatory Agency Product Chemistry, Part 2 Product Identity, Composition, and Analysis of Kathon LX-1400 ISP Biocide from [CBI removed] DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.3 CBI
1491174	2007, Five Batch Analysis of RH-886.HCl for Active Ingredient, Impurities and Residual Process Solvents, DACO: 2.13.3,2.14.1, 2.14.2 CBI
1681032	2003, GLP Validation of CIS Analytical Test Method #01-76-01, DACO: 2.13.1 CBI
1491177	1992, PRODUCT CHEMSISTRY-SERIES 63 SF-886 TECH TECHNICAL GRADE OF ACTIVE INGREDIENT, DACO: 2.14.10, 2.14.11, 2.14.13, 2.14.4, 2.14.6, 2.14.7, 2.14.8, 2.14.9
1491181	1993, CHARACTERIZATION OF TEST SUBSTANCE: KATHON(R) 886F, AN MUP, TO BE USED FOR SUBMISSION TO REGULATORY AGENCIES IN EUROPE, DACO: 2.14.12

ISSN: 1911-8082

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