



Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2016-7191
Application: New TGAI Product Chemistry - New Source, New Registrant
Product: Pyrithione 40 MUP
Registration Number:
Active ingredients (a.i.): sodium omadine
PMRA Document Number : 2770396

Purpose of Application

The purpose of the application was to register a new source of sodium omadine by a new registrant.

Chemistry Assessment

Common Name: Sodium pyrithione
IUPAC* Chemical Name: sodium 2-thioxopyridin-1(2*H*)-olate
OR
sodium pyridine-2-thiolate 1-oxide
CAS† Chemical Name: 2(1*H*)-pyridinethione, 1-hydroxy-, sodium salt (1:1)
OR
2-pyridinethiol, 1-oxide, sodium salt (1:1)

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Pyrithion 40 MUP has the following properties:

Property	Result
Colour and physical state	Clear yellow liquid
Nominal concentration	40.3%
Odour	Odourless
Density	1.222 g/mL
Vapour pressure	9×10^{-8} Pa at 22°C
pH	7.69
Solubility in water	547 g/L
n-Octanol/water partition coefficient	Log K_{ow} = - 2.64

The required chemistry data for Pyrithione 40 MUP have been provided, reviewed, and found to be acceptable.

Health, Environmental, and Value Assessments

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

Conclusion

The PMRA has conducted a review of the available information in support of this application and has determined that registration of this new source of the technical is acceptable.

References

PMRA#	Reference
2698163	2013, DACO 2.1-2.0 Summary, DACO: 2.0 CBI
2698164	2013, Sodium Pyrithione Manufacturing Process, DACO: 2.11 CBI
2698165	2012, Preliminary Analysis, DACO: 2.13,2.13.2,2.13.3 CBI
2698166	2012, Enforcement Analytical Method for the Determination of Sodium Pyrithione [CBI removed], DACO: 2.13.1 CBI
2698168	2012, Preliminary Analysis Confidential Attachment, DACO: 2.13.4 CBI
2698169	2013, Sodium Pyrithione Tech DACO 2.14, DACO: 2.14 CBI
2698170	2012, Physical and Chemical Characteristics: Stability to Normal and Elevated Temperature - Metals and Metal Ions, Miscibility, pH, UV/Visible Absorption, Boiling Point and Density/Bulk Density, DACO: 2.14 CBI
2698171	2013, Storage Stability and Corrosion Characteristics, DACO: 2.14.13,2.14.14 CBI
2725995	2017, Manufacturers Name and Address and Plant Address clarification, DACO: 2.2 CBI
2725996	2017, 2.11.4 Discussion of Formulation of Impurities, DACO: 2.11.4 CBI
2726023	2016, Certificate of Analysis - 5 Commercial Scale Batches, DACO: 2.13.3 CBI
2763749	2017, Revised DACO 2.1 - 2.9, DACO: 2.0,2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2763750	2017, Revised DACO 2.14 - 2.14.14, DACO: 2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI

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