

Evaluation Report for Category B, Subcategory B.1.2 Application

Application Number: 2013-3184
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Mergal OIT Technical Microbicide
Registration Number: 31812
Active ingredients (a.i.): 2-n-octyl-4-isothiazolin-3-one (octhiline)
PMRA Document Number: 2517905

Background

The source of octhiline used to determine chemical equivalency was Registration Number 24126.

Purpose of Application

The purpose of this application was to register a new source of the technical grade active ingredient, octhiline, by a different Registrant.

Chemistry Assessment

Common Name: octhiline
IUPAC Chemical Name: 2-octyl-1,2-thiazol-3(2*H*)-one
or
2-octylisothiazol-3(2*H*)-one
CAS Chemical Name: 2-octyl-3(2*H*)-isothiazolone

Mergal OIT Technical Microbicide has the following properties:

Property	Result
Colour and physical state	Yellow liquid
Nominal guarantee	2-n-octyl-4-isothiazolin-3-one at 99.40% Available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins at 28.6% (limits 27.7-29.5%)
Odour	Very weak sharp smell
Density	1.041 g/mL at 20°C
Vapour pressure	7.3×10^{-2} Pa at 25°C
pH	4.0-7.0
Solubility in water	0.527 mg/L at 23°C

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} 3.45

The chemistry requirements for Mergal OIT Technical Microbicide have been fulfilled.

Health and Environmental Assessments

As the new source of octhiline is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Mergal OIT Technical Microbicide.

References

PMRA Document Number	Reference
2315284	2013, DACO 2.1 to 2.9 Summary document, DACO: 2.0 CBI
2315285	2013, Preliminary Analysis, DACO: 2.11,2.13 CBI
2315286	2012, Enforcement Analytical Method for the Determination of OIT by HPLC, DACO: 2.13.1,2.14 CBI
2315287	2013, DACO 2.14 Summary document, DACO: 2.14 CBI
2315288	2013, Phys-Chem properties (DACO 2.14.5 - 2.14.12), DACO: 2.14 CBI
2315289	2013, OIT: Vapour Pressure, DACO: 2.14.9 CBI
2315290	2013, Letter of Confirmation, DACO: 2.14.13,2.14.14 CBI
2414235	2014, DACO 2.1- 2.9 Revised, DACO: 2.0 CBI
2414236	2014, Mergal OIT Syntesis Scheme, DACO: 2.11.3 CBI
2414237	2012, Certificates of Analysis with Dates, DACO: 2.13.3 CBI
2420413	2014, Mergal OIT Syntesis Scheme, DACO: 2.11.3 CBI

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2015

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.