

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2013-1961
Application: New / Changes TGAI or ISP Prod Chemistry-New Source(site)
same registrant
New / Changes TGAI or ISP Prod Chemistry-Specifications
Product: PyGanic Refined Technical
Registration Number: 31787
Active ingredients (a.i.): Pyrethrins
PMRA Document Number : 2513794

Purpose of Application

The purpose of this application is to register a new source of the Technical Grade Active Ingredient.

Chemistry Assessment

Common Name: Pyrethrins
IUPAC* Chemical Name: **Pyrethrin I:** (1*S*)-2-methyl-4-oxo-3-[(2*Z*)-penta-2,4-dien-1-yl]cyclopent-2-en-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropane-1-carboxylate
Cinerin I: (1*S*)-3-[(2*Z*)-but-2-en-1-yl]-2-methyl-4-oxocyclopent-2-en-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropane-1-carboxylate
Jasmolin I: (1*S*)-2-methyl-4-oxo-3-[(2*Z*)-pent-2-en-1-yl]cyclopent-2-en-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropane-1-carboxylate
Pyrethrin II: (1*S*)-2-methyl-4-oxo-3-[(2*Z*)-penta-2,4-dien-1-yl]cyclopent-2-en-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxoprop-1-en-1-yl]-2,2-dimethylcyclopropane-1-carboxylate
Cinerin II: (1*S*)-3-[(2*Z*)-but-2-en-1-yl]-2-methyl-4-oxocyclopent-2-en-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxoprop-1-en-1-yl]-2,2-dimethylcyclopropane-1-carboxylate
Jasmolin II: (1*S*)-2-methyl-4-oxo-3-[(2*Z*)-pent-2-en-1-yl]cyclopent-2-en-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxoprop-1-en-1-yl]-2,2-dimethylcyclopropane-1-carboxylate
CAS† Chemical Name: **Pyrethrins:** pyrethrins
Pyrethrin I: (1*S*)-2-methyl-4-oxo-3-(2*Z*)-2,4-pentadien-1-yl-2-cyclopenten-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate

Cinerin I: (1*S*)-3-(2*Z*)-2-buten-1-yl-2-methyl-4-oxo-2-cyclopenten-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate

Jasmolin I: (1*S*)-2-methyl-4-oxo-3-(2*Z*)-2-penten-1-yl-2-cyclopenten-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate

Pyrethrin II: (1*S*)-2-methyl-4-oxo-3-(2*Z*)-2,4-pentadien-1-yl-2-cyclopenten-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxo-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate

Cinerin II: (1*S*)-3-(2*Z*)-2-buten-1-yl-2-methyl-4-oxo-2-cyclopenten-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxo-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate

Jasmolin II: (1*S*)-2-methyl-4-oxo-3-(2*Z*)-2-penten-1-yl-2-cyclopenten-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxo-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate

* International Union of Pure and Applied Chemistry; only the preferred IUPAC name (PIN) is included here

† Chemical Abstracts Service

PyGanic Refined Technical has the following properties:

Property	Result
Colour and physical state	Brown liquid
Nominal concentration	49.2%
Odour	Sweet
Density	1.013 g/cm ³
Vapour pressure	3.13 × 10 ⁻⁵ Pa for mixture (estimate)
pH	4.5 for a 5% dilution
Solubility in water	Immiscible with water
n-Octanol/water partition coefficient	Log K _{ow} = 4.1 to 5.9 (pH 4 - 10) for mixture

The chemistry requirements for PyGanic Refined Technical have been fulfilled.

Health Assessment

The new source of technical pyrethrins is considered to have an improved toxicological profile when compared to the existing registered source.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support this new source of PyGanic Refined Technical.

References

PMRA Document Number	Reference
2290175	2013, Establishing Certified Limits, DACO: 2.12.1 CBI
2290177	2001, Method Validation for Pyrethrins, and Piperonyl Butoxide by RP-HPLC, DACO: 2.13.1 CBI
2290178	2011, Storage Stability Evaluation of Pyrethrum Refined Concentrate, DACO: 2.14.13,2.14.14 CBI
2290179	1996, Storage Stability of 52% Pyrethrum Concentrate 7428, DACO: 2.14.14 CBI
2290181	2013, Chemistry Requirements for the Registration of Technical Grade Active Ingredients, DACO: 2.1,2.11,2.11.4,2.13,2.13.1,2.13.2,2.13.3,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2290182	2013, Description of the Manufacturing Process, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI
2290183	2004, [CBI REMOVED] for Impurities in MGKÂ® Refined Pyrethrin Concentrate, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2392030	2013, Product Chemistry of Pyganic concentrate, DACO: 2.14 CBI
2409849	2013, Product Chemistry of Pyganic concentrate, DACO: 2.14 CBI
2409850	2014, 5 Lot Analysis for Pyrethrins and Other Plant Extract in Refined Pyrethrum Concentrate, DACO: 2.13.1,2.13.3 CBI
2409853	2013, Description of the Formulation Process, DACO: 2.11.2 CBI
2412497	2014, 5 Lot Analysis for Pyrethrins and Other Plant Extract in Refined Pyrethrum Concentrate (revised version), DACO: 2.13.1,2.13.3 CBI
2438768	2013, Specification, DACO: 2.11.2 CBI
2438771	2014, MSDS_Specification, DACO: 2.11.2 CBI
2438772	2004, Specification, DACO: 2.11.2 CBI
2438774	2004, Specification, DACO: 2.11.2 CBI
2438775	2013, MSDS_Specification, DACO: 2.11.2 CBI
2438776	2013, MSDS_Specification, DACO: 2.11.2 CBI
2438780	2008, UV/Visible Spectrum of Individual Pyrethrin Esters by RP-HPLC-DAD, DACO: 2.14.12 CBI
2438783	2014, 5 Lot Analysis for Pyrethrins and Other Plant Extracts in Refined Pyrethrum Concentrate, DACO: 2.13.1,2.13.3 CBI
2438784	2014, 2.13.3, DACO: 2.13.3 CBI
2438785	2009, Pyrethrum Extracy (Refined Pyrethrum Extract) Physico-Chemical Properties, DACO: 2.14.11,2.14.5 CBI
2438787	2008, Calculation of Vapour Pressure for Pyrethrins at 20C, DACO: 2.14.9 CBI
2289387	1991, Acute Oral Toxicity, LD50 - Rats, DACO: 4.6.1
2289389	1991, Acute Dermal Toxicity, Single Level- Rabbits, DACO: 4.6.2

2289390	1991, An Acute Inhalation Toxicity Study of Pyrethrum Extract in the Rat, DACO: 4.6.3
2289393	1991, Primary Eye Irritation - Rabbits, DACO: 4.6.4
2289396	1991, Primary Skin Irritation - Rabbits, DACO: 4.6.5
2289398	1991, Guinea Pig Dermal Sensitization - Modified Buehler Method, DACO: 4.6.6

ISSN: 1911-8082

© 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.