Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2014-3351
Application: Changes to TGAI Chemistry – New Source Same Registrant
Product: Penthiopyrad Technical Fungicide
Registration Number: 30330
Active ingredients (a.i.): Penthiopyrad
PMRA Document Number : 2535508

Purpose of Application

The purpose of application was to register a new manufacturing site (same registrant) for Penthiopyrad Technical Fungicide (Registration Number 30330).

Chemistry Assessment

Common Name: Penthiopyrad
IUPAC Chemical Name: (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl) pyrazole-4-carboxamide
CAS Chemical Name: N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-
pyrazole-4-carboxamide

Penthiopyrad Technical Fungicide has the following properties:

Property	Result
Colour and physical state	White solid
Nominal guarantee	99.5%
Odour	Odourless
Density	1.256
Vapour pressure	6.43 mPa (at 25°C)
pH	5.9
Dissociation Constant	10.0 ± 0.16
Solubility in water	7.53 mg/L (20°C, pH 7)
n-Octanol/water partition coefficient	Log K_{ow} = 4.62 (20°C, pH 7)

With the exception of the five-batch commerical production data, the chemistry requirements for Penthiopyrad Technical Fungicide have been fulfilled.

Health, Environmental, and Value Assessments

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

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Conclusion

Following review of the application a new manufacturing site for Penthiopyrad Technical Fungicide has been approved. The submission of five-batch commerical production data is a condition of full registration.

References

PMRA Document Number	Reference
1839200	1999, Determination of the Melting Point/Melting Range of MTF-753, DACO: 2.14.4 CBI
1839201	1999, Determination of the Boiling Point/Boiling Range of MTF-753, DACO: 2.14.5, 2.14.13 CBI
1839211	2008, Storage Stability and Corrosion Characteristics of MTF-753, DACO: 2.14.14 CBI
1839212	2006, Screening of the Thermal Stability in Air of MTF-753, DACO: 2.14.13
1839213	2007, Determination of the Relative Density and the Bulk Density of MTF-753, DACO: 2.14.6 CBI
1839216	1999, Determination of the Vapour Pressure of MTF-753, DACO: 2.14.9
1839218	2008, Color of Pentiopyrad Technical (MTF-753), DACO: 2.14.1, 2.14.2
1839219	2008, Color of Purified Active Substance, Penthiopyrad (MTF-753), DACO: 2.14.1, 2.14.2 CBI
1839221	2008, Physical State of Penthiopyrad Technical (MTF-753), DACO: 2.14.1, 2.14.2 CBI
1839222	2008, Physical State of Purified Active Substance, Penthiopyrad (MTF-753), DACO: 2.14.1, 2.14.2 CBI
1839223	2008, Odour of Penthiopyrad Technical (MTF-753), DACO: 2.14.3 CBI
1839224	2008, Odour of Purified Active Substance, Penthiopyrad (MTF-753), DACO: 2.14.3 CBI
1839225	2007, Determination of the NMR-, IR-, UV/VIS Absorption and Mass Spectra of MTF-753, DACO: 2.13.2, 2.14.12 CBI
1839228	2008, Determination of the Water Solubility of MTF-753 Including Effect of pH and Temperature, DACO: 2.14.7 CBI
1839229	1999, Determination of the Solubility of MTF-753 in Water and in Organic Solvents, DACO: 2.14.7, 2.14.8 CBI
1839234	2008, Deternination of the Partition Coeffcient (N-Octanol/Water) of MTF-753 Including Effect of pH and Temperature, DACO: 2.14.11 CBI
1839239	1999, Determination of the Dissociation Constant of MTF-753 in Water, DACO: 2.14.10 CBI
1839243	Validation of Analytical Method (Analytical Method for Determination of Active Ingredientand Impurities in Penthiopyrad Technical Product), DACO: 2.13.1, 2.13.3, 2.13.4 CBI
1927497	2010, Analysis and Certification [CBI removed] of Penthiopyrad in Six Batches of Technical Penthiopyrad, DACO: 2.13.1, 2.13.3 CBI

1927500 2010, Analysis and Certification [CBI removed] of Penthiopyrad in Six Batches of Technical Penthiopyrad, DACO: 2.13.1, 2.13.3 CBI

2106889 1999, Determination of The Partition Coefficient (N-Octanol / Water) of MTF-753, DACO: 2.14.11 CBI

2449934 2014, Five Batch Analysis of Penthiopyrad Technical Product, DACO: 2.12.1, 2.13.3 CBI

2503523 2015, Penthiopyrad Active Substance: Information on the Active Ingredient - Response to PMRA Request Dated 12JAN15 for Submission 2014-3351, DACO: 2.11 CBI

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