

Evaluation Report for Category B, Subcategory 1.1 (new source by same registrant) Application

Application Number: 2006-3555
Application: Evaluation Report for Category B, Subcategory 1.1 (new source by same registrant)
Product: Pyrimethanil Technical Fungicide
Registration Number: 28010
Active ingredients (a.i.): 4,6-dimethyl-N-phenylpyrimidin-2-amine at 98%
PMRA Document Number: 1371429

Background

The original source of Pyrimethanil technical grade active ingredient, “Pyrimethanil Technical Fungicide” (Reg. No. 28010) was first registered in 2005.

Purpose of Application

The purpose of this application is to register a new technical source of pyrimethanil fungicide. This new source of technical grade active ingredient, “Pyrimethanil Technical Fungicide” (Reg. No. 28010) is intended for use in the manufacture, formulating and repackaging.

Chemistry Assessment

Common Name: Pyrimethanil
Chemical Name: 4,6-dimethyl-N-phenylpyrimidin-2-amine

Property	Result
Colour and physical state	white to yellow, crystalline powder
Nominal concentration	98% as determined by HPLC
Odour	No distinguishable odour
Density	1.15 g/cm ³
Vapour pressure	1.1 x 10 ⁻³ Pa at 20°C 2.2 x 10 ⁻³ Pa at 25°C 4.1 x 10 ⁻³ Pa at 30°C
pH	7.9
Solubility in water	0.160 (20°C) g/L at pH 4.2 0.121 (25°C) g/L at pH 6.1 0.099 (20°C) g/L at pH 9.9
n-Octanol/water partition coefficient	log Kow = 2.84

The chemistry requirements for Pyrimethanil have been completed

Health and Environmental Assessment

The health and environmental risk profile of Pyrimethanil Technical Fungicide is expected to be similar to that of the original registered source of Pyrimethanil Technical. However, due to product specific registration (data protection) considerations (see Trade Memorandum T-1-249, “Product-Specific Registration and Proprietary Rights to Data”), the applicant is required to generate the following studies as a condition of registration:

Study description and organism/type		DACO
Human Toxicology		
Acute neurotoxicity	rat	(DACO 4.5.1.3)
Environmental Chemistry and Fate		
Analytical methodology	soil/sediment	(DACO 8.2.2.1/ 8.2.2.2)
Analytical methodology	water	(DACO 8.2.2.3)
Analytical methodology	biota - fish	(DACO 8.2.2.4)
Environmental Toxicology		
Biotransformation in soil	anaerobic soil (flooded) 20-30°C	(DACO 8.2.3.4.4)
Non-target aquatic plants: freshwater vascular plants	<i>Lemna</i> sp	(DACO 9.8.5)

Value assessment

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

Conclusions

The PMRA has completed an evaluation of the subject application and has determined that Pyrimethanil Technical Fungicide is eligible for full registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

- PMRA # 1251749. 2006, Pyrimethanil Technical Fungicide, Bayer CropScience Inc., 06007DC, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- PMRA # 1251751. 1990, Chemical Substances, Water - Volumetric Method, Bayer Inc., 2011-0131301-90E, DACO: 2.13.1
- PMRA # 1251752. 2006, Validation of HPLC-method AM000705DB1, Bayer Industry Services GmbH, VB1-AM000705DB1, DACO: 2.13.1

- PMRA # 1251753. 2006, Validation of HPLC-method AM001005DB1, Bayer Industry Services GmbH, VB1-AM001005DB1, DACO: 2.13.1
- PMRA # 1251754. 2006, Pyrimethanil Technical Grade - Sodium acetate, sodium chloride, anion exchange chromatography, external standard. Analytical Method AM000106DB1, Bayer Industry Services, AM000106DB1, DACO: 2.13.1
- PMRA # 1251755. 2006, Pyrimethanil technical grade: By-products - HPLC, external standard. Analytical Method AM000705DB1, Bayer Industry Services, AM000705DB1, DACO: 2.13.1
- PMRA # 1251756. 2006, Pyrimethanil technical grade: By-products, headspace capillary gas chromatography, internal standard. Analytical Method AM001005DB1, Bayer Industry Services, AM001005DB1, DACO: 2.13.1
- PMRA # 1251757. 2006, Pyrimethanil technical grade: Assay - HPLC, external standard. Analytical Method AM00125DB2, Bayer Industry Services, AM001205DB2, DACO: 2.13.1
- PMRA # 1251758. 2006, Validation of IC-method AM000106DB1, Bayer Industry Services GmbH, VB1-AM000106DB1, DACO: 2.13.1
- PMRA # 1251759. 2006, Validation of HPLC-method AM001205DB2, Bayer Industry Services, VB1-AM001205DB2, DACO: 2.13.1
- PMRA # 1251760. 2006, Material accountability of Pyrimethanil (AE B100309): Analytical Profile of Five Production Batches Manufactured by Bayer CropScience at Dormagen, Bayer Industry Services, 2006/0003/01, DACO: 2.13.2,2.13.3
- PMRA # 1251761. 2006, Composition Statement Technical Material, Bayer CropScience SA, N/A, DACO: 2.12.1
- PMRA # 1252141. 2003, Tier 2 Summary of Identity, Physical and Chemical Properties and Further Information on the Active Substance for Pyrimethanil. Code: AE B100309, Bayer CropScience Inc., B004275, DACO: 2.1,2.10,2.11.1,2.11.2,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- PMRA # 1293595. 2006, Pyrimethanil Technical Material MANUFACTURING PROCESS Description of Materials Used to Produce the Product and Description of Production Process, Bayer CropScience AG, N/A, DACO: 2.11.2

7.1.2 PMRA's Previous Evaluations

PMRA # 1016681. Chemistry Evaluation of Pyrimethanil. PMRA report with Submission number 2003-1079.

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