

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2005-0990
Application: New / Changes TGAI or ISP Prod Chemistry-New Source(Site)
Product: Paclobutrazol Technical Plant Growth Regulator
Registration Number: 28550
Active ingredients (a.i.): Paclobutrazol 99.3%
PMRA Document Number: 1709309

Background

The original source of paclobutrazol technical grade active ingredient, "Paclobutrazol Technical" (Reg. No.19535) was first registered in 1995.

Purpose of Application

The purpose of this application is to register a new technical source of paclobutrazol.

Chemistry Assessment

Common Name: Paclobutrazol
IUPAC Chemical Name: (2*RS*,3*RS*)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1*H*-1,2,4-triazol-1-yl)pentan-3-ol
CAS Chemical Name: (**R*,**R*)-*rel*-*-[(4-chlorophenyl)methyl]-*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol

Paclobutrazol Technical Plant Growth Regulator has the following properties:

Property	Result
Colour and physical state	white fine powder
Nominal concentration	99.3%
Odour	faint almond
Specific Gravity	1.22
Vapour pressure	1.7×10^{-7} Pa
pH	6.2, for 1% aqueous solution
Solubility in water	25.9 ± 1.6 mg/L (20°C)
n-Octanol/water partition coefficient	Log Kow = 3.18

The chemistry requirements for Paclobutrazol Technical Plant Growth Regulator are complete.

Health and Environmental Assessment

The health and environmental risk profile of Paclobutrazol Technical Plant Growth Regulator is expected to be similar to that of the original registered source, Paclobutrazol 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:

Table 1: Environmental data requested to supplement the PAZ database

Protocol/DACO	Study	Point Value
OECD 201	Paclobutrazol effects on algal growth (blue/green algae)	28
OECD Draft Guideline October 2000 (OECD 221)	Paclobutrazol effects on aquatic higher plants	28
OECD Draft Guideline October 2000 (OECD 221)	Ketone metabolite effects on aquatic higher plants	28
8.2.4.2	Paclobutrazol Absorption/Desorption	35
Total point value		119

Value assessment

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

Conclusion

The PMRA has completed its evaluation of the subject application and has determined that Paclobutrazol Technical Plant Growth Regulator is eligible for full registration with the condition of fulfilling the following requirements:

- submission of above mentioned studies as required under product specific registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

- 1346248 Part 2 - Product Chemistry - Paclobutrazol Technical Plant Growth Regulator, N/S, N/S, DACO: 2.1,2.2,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1346249 Manufacturing Summary, N/S, N/S, DACO: 2.11.1
- 1346250 Description of Starting Materials, N/S, N/S, DACO: 2.11.2
- 1346251 FINE Agrochemicals Limited, Detailed Production Process Description: Product Identity and Composition, Description of Beginning Materials, Production Process, Discussion of Formation of Impurities, and Certified Limits, N/S, N/S, DACO: 2.11.3
- 1346252 from Gairola, I. 2003, Discussion of Formation of Impurities, N/S, N/S, MRID: N/S, DACO: 2.11.4

- 1346253 Specifications. Establishing Certified Limits., N/S, N/S, MRID: N/S, DACO: 2.12.1
- 1346254 2000, Validation of Analytical Method M501 'Gas Chromatographic Determination of Paclobutrazol in Technical Material and Formulations' Final Report J13317/A., G.C. Laboratories Ltd., N/S, MRID: N/S, DACO: 2.13.1
- 1346255 2000, Gas Chromatographic Determination, at the 0.05 to 0.5% Level, of Five Impurities Known to Occur in Paclobutrazol Technical Material, G.C. Laboratories Ltd., N/S, MRID: N/S, DACO: 2.13.1
- 1346256 2003, Confirmation of Identity: Paclobutrazol Characterization of Test Substance., Huntingdon Life Sciences Ltd., N/S, MRID: N/S, DACO: 2.13.2
- 1346257 2001, Analysis of Five Batches of Technical Paclobutrazol. Final Report (Amendment 2) EPA Format., G.C. Laboratories Ltd., N/S, MRID: N/S, DACO: 2.13.3
- 1346258 Impurities of Toxicological Concern, N/S, N/S, MRID: N/S, DACO: 2.13.3
- 1346259 Summary of Chemical and Physical Properties, N/S, N/S, DACO: 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, 2.14.7,2.14.8,2.14.9,2.16
- 1346260 2001, Paclobutrazol (Technical Grade) Physico-Chemical Properties., Huntingdon Life Sciences Ltd., N/S, MRID: N/S, DACO: 2.14.1,2.14.2,2.14.3
- 1346261 2001, Paclobutrazol (Pure Grade) Physico-Chemical Properties., Huntingdon Life Sciences Ltd., N/S, MRID: N/S, DACO: 2.14.4
- 1346262 Summary - Chemical Properties (2.14.5 - 2.14.14), N/S, N/S, DACO: 2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9
- 1346263 2001, Paclobutrazol (Technical Grade) Determination of pH., Huntingdon Life Sciences Ltd., N/S, MRID: N/S, DACO: 2.16
- 1346264 Other Studies / Data / Reports: Oxidizing Properties (Solids), Flammability (Solids), Explosive Properties, Relative Self-Ignition Temperature for Solids, Surface Tension., N/S, N/S, MRID: N/S, DACO: 2.16

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