



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2015-4206
Application: Changes to TGAI Product Chemistry – New Source (site) same registrant
Product: Paclobutrazol Technical Plant Growth Regulator
Registration Number: 28550
Active ingredients (a.i.): Paclobutrazol
PMRA Document Number : 2642363

Purpose of Application

The purpose of this application was to add a new site of manufacture for Paclobutrazol Technical Plant Growth Regulator, containing the active ingredient paclobutrazol.

Chemistry Assessment

Common Name: paclobutrazol
IUPAC* Chemical Name: *rac*-(2*R*,3*R*)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1*H*-1,2,4-triazol-1-yl)pentan-3-ol
CAS† Chemical Name: (*αR*,*βR*)-*rel*-*β*-[(4-chlorophenyl)methyl]-*α*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Paclobutrazol Technical Plant Growth Regulator has the following properties:

Property	Result
Colour and physical state	White powder
Nominal concentration	99.3%
Odour	Faint almond
Specific gravity	1.22 at 20°C
Vapour pressure	1.7×10^{-7} Pa (at 25°C)
pH	6.2 (1% aqueous solution)
Solubility in water	25.9 mg/L (20°C)

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} = 3.18 at room temperature

The required chemistry data for Paclobutrazol Technical Plant Growth Regulator have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

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

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the addition of a new site of manufacture for Paclobutrazol Technical Plant Growth Regulator.

References

PMRA Document Number	References
2559220	2015, Manufacturers Name and Office Address and Manufacturing Plants Name and Address, DACO: 2.2 CBI
2559221	2015, Manufacturing Summary, DACO: 2.11.1 CBI
2559222	2015, Description of Starting Materials, DACO: 2.11.2 CBI
2559223	2015, Detailed Production Process Description, DACO: 2.11.3 CBI
2559224	2015, Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2559225	2015, Establishing Certified Limits, DACO: 2.12.1 CBI
2559227	2015, Methodology/Validation, DACO: 2.13.1 CBI
2559228	2015, Confirmation of Identity, DACO: 2.13.2 CBI
2559229	2015, Batch Data, DACO: 2.13.3 CBI
2559240	2014, Paclobutrazol - Analytical Method Validation of [CBI removed], DACO: 2.13.1 CBI
2559241	2014, Paclobutrazol - Analytical Method Validation for Assay by High Performance Liquid Chromatography, DACO: 2.13.1 CBI
2559242	2013, LCMS Examination of Paclobutrazol, DACO: 2.13.1 CBI
2559243	2015, Five Batch Characterisation of Paclobutrazol, DACO: 2.13.2,2.13.3 CBI
2637203	2013, LCMS Examination of Paclobutrazol, DACO: 2.13.2 CBI
2637204	2016, NMR Assignment for [CBI removed] in Paclobutrazol, DACO: 2.13.2 CBI

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