



Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2016-3033
Application: New TGA I Product Chemistry – New Source (site) New Registrant
Product: NewAgco Spirodiclofen Technical
Registration Number: 32938
Active ingredient (a.i.): Spirodiclofen
PMRA Document Number : 2788952

Purpose of Application

The purpose of this application was to register a new source of the active ingredient spirodiclofen by a new registrant.

Chemistry Assessment

Common Name: Spirodiclofen
IUPAC* Chemical Name: 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate
CAS† Chemical Name: 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

NewAgco Spirodiclofen Technical has the following properties:

Property	Result
Colour and physical state	White powder
Nominal concentration	99.2%
Odour	No characteristic odour
Density	0.6139 g/mL
Vapour pressure	$<3 \times 10^{-7}$ Pa (at 20°C)
pH	6.50
Solubility in water at 20°C	0.05 mg/L (pH 4), 0.19 mg/L (pH 7)
n-Octanol/water partition coefficient	Log K_{ow} = 5.1 (pH 7), 5.8 (pH 4)

The required chemistry data for NewAgco Spirodiclofen Technical 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 information provided and has found the information sufficient to support the registration of NewAgco Spirodiclofen Technical.

References

PMRA Document Number	References
2649740	2016, Chemistry of TGAI, DACO: 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2649742	2014, 5-Batch Analysis of Spirodiclofen TGAI in Accordance with International Regulatory Requirements, DACO: 2.12.1, 2.13.2, 2.13.3 CBI
2649743	2014, Analysis of [CBI removed] in 5 Batches of Spirodiclofen TGAI with Validation of Analytical Methodology in Accordance with International Regulatory Requirements, DACO: 2.13.3 CBI
2649744	2014, Development and Validation of Analytical Method for Active Ingredient Analysis of Spirodiclofen TC, DACO: 2.13.1 CBI
2649745	2016, Justification of impurities, DACO: 2.11.4, 2.13.4 CBI
2649746	2016, Manufacture process Of Spirodiclofen Technical, DACO: 2.11.1, 2.11.2, 2.11.3 CBI
2649749	2015, Accelerated Storage Stability of Spirodiclofen TC and Determination of Physical Chemical Properties, DACO: 2.14.1, 2.14.11, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8 CBI
2649750	2014, Dissociation Constant of Spirodiclofen TC, DACO: 2.14.10 CBI
2649751	2014, Spectral Analysis (IR, UV, MASS and NMR) of Spirodiclofen TC, DACO: 2.14.12 CBI
2649752	2014, Vapour Pressure of Spirodiclofen TC, DACO: 2.14.9 CBI
2755110	2017, Manufacture process of Spirodiclofen Technical Revised, DACO: 2.11.3 CBI
2759257	2017, Manufacture process of Spirodiclofen Technical Revised, DACO: 2.11.3 CBI
2779480	2016, Manufacture process of Spirodiclofen Technical (Revised), DACO: 2.11.1, 2.11.3 CBI

ISSN: 1911-8082

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