

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2016-0509
Application: New Technical Grade Active Ingredient Product Chemistry – New source (site) for a new registrant
Product: NewAgco Bentazone Technical
Registration Number: 32996
Active ingredients (a.i.): Bentazone
PMRA Document Number : 2690796

Purpose of Application

The purpose of this application was to register a new source of bentazone, NewAgco Bentazone Technical (guarantee 98.6% bentazone) by a different registrant. This application is based on a registered precedent technical grade active ingredient.

Chemistry Assessment

Common Name: Bentazone
IUPAC* Chemical Name: 3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide
CAS† Chemical Name: 3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

NewAgco Bentazon Technical has the following properties:

Property	Result
Colour and physical state	Oyster White and Solid
Nominal concentration	98.6%
Odour	Odourless
Density	1.412 g/mL
Vapour pressure	1.79×10 ⁻⁸ Pa (at 20 °C) 5.44 ×10 ⁻⁸ Pa (at 25°C)
pH	2.60 at 25±2°C
Solubility in water	532.0 mg/L (at 20°C)
n-Octanol/water partition coefficient	Log K _{ow} = 0.45

The required chemistry data for NewAgco Bentazon 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 PMRA has completed a review of all available information and found it sufficient to support full registration of NewAgco Bentazone Technical.

References

PMRA Document Number	Reference
2603469	2016, Chemistry Requirements (General Info), DACO: 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9
2603470	2016, Manufacturing Process of Bentazone Technical Grade Active Substance, DACO: 2.11.1, 2.11.2, 2.11.3
2603471	2016, Impurity Profile of Bentazone Technical, DACO: 2.11.4
2603472	2015, Preliminary Analysis and 5-Batch Study of Bentazone TGAI, DACO: 2.12.1, 2.13.1, 2.13.2, 2.13.3
2603473	2015, Preliminary Analysis and 5-Batch Study of Bentazone TGAI - Confidential Attachment, DACO: 2.12.1, 2.13.1, 2.13.2, 2.13.3
2603474	2014, Preliminary Analysis and 5-Batch Study of Bentazone TGAI - Amendment, DACO: 2.12.1, 2.13.1, 2.13.2, 2.13.3
2603475	2015, Physical and Chemical Characterization of Bentazone TGAI, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 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, 2.14.9
2650498	2016, Discussion of Formation of Impurities in Bentazone Technical, DACO 2.11.4

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