

Evaluation Report for Category B, Subcategory B.1.2 Application

Application Number: 2011-2904
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Rotam Tribenuron-Methyl Technical
Registration Number: 31903
Active ingredients (a.i.): Tribenuron-methyl
PMRA Document Number : 2549217

Background

The source of tribenuron-methyl used to determine chemical equivalence was Registration Number 22330

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, tribenuron-methyl, by a different Registrant.

Chemistry Assessment

Common Name: Tribenuron-methyl
IUPAC Chemical Name: Methyl 2-[4-methoxy-6-methyl-1,3,5-triazin-2-yl(methyl)carbamoylsulfamoyl]benzoate
CAS Chemical Name: Methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylamino]carbonyl]amino]sulfonyl]benzoate

Rotam Tribenuron-Methyl Technical has the following properties:

Property	Result
Colour and physical state	Off-white, Solid
Nominal guarantee	97.5%
Odour	Slight pungent odour
Relative Density	1.35
Vapour pressure	7.9×10^{-8} Pa
pH	3.92 (1% dilution)
Solubility in water	2.7 g/L (pH 7, 20°C)
n-Octanol/water partition coefficient	Log K_{ow} 0.1(pH 7)

The chemistry requirements for Rotam Tribenuron-Methyl Technical have been fulfilled.

Health and Environmental Assessments

As the new source of tribenuron-methyl is acceptable, the health and environmental risk profiles are expected to be similar to that of the product used to determine equivalence. No additional assessments were required.

Value Assessment

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

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Rotam Tribenuron-Methyl Technical.

References

PMRA Document Number	Reference
2078031	Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities
2119463	Manufacturing Process of TRIBENURON-METHYL Technical
2119465	Discussion of Formation of Impurities in Tribenuron-Methyl Technical
2078032	Preliminary Analysis of Five Representative Production Batches of Tribenuron-Methyl Technical Grade Active Ingredient (TGAI) to Determine % Tribenuron-Methyl and to Quantify Its Associated Impurities
2119466	Mass Spectral Identification
2078033	Determination of Physical/Chemical Properties of Rotam Tribenuron-methyl Technical
2078022	Ambient Temperature Shelf Life with Corrosion Characteristic (1 year) of Tribenuron-Methyl Technical

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