Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.1.2 Application

Application Number: 2011-2932
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Rotam Thifensulfuron-Methyl Technical
Registration Number: 31905
Active ingredients (a.i.): Tribenuron-methyl
PMRA Document Number : 2549305

Purpose of Application

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

Chemistry Assessment

Common Name:	Thifensulfuron-methyl
IUPAC Chemical Name:	methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate
CAS Chemical Name:	methyl 3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate

Rotam Thifensulfuron-Methyl Technical has the following properties:

Property	Result
Colour and physical state	Light yellow, Solid
Nominal guarantee	97.0%
Odour	No characteristic odour
Relative Density	1.51
Vapour pressure	$< 1.0 \times 10^{-5}$ Pa
pH	3.6 (dilution in water)
Solubility in water	7.29 g/L (pH 7, 25°C)
n-Octanol/water partition coefficient	Log K_{ow} 0.58

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

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Health and Environmental Assessments

As the new source of thifensulfuron-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 Thifensulfuron-Methyl Technical.

References

PMRA Document Number	Reference
2078829	Jiangsu - Manufacturing Process of Thifensulfuron-methyl Technical
2078787	Tianjin - Product Identity and Disclosure of Ingredient, Including Manufacturing Process and Discussion of Formation of Impurities
2131520	Manufacturing Process and Flow Chart RRL 0206 - Jiangsu
2131523	Manufacturing process and Flow Chart Anadiag RA 6133 - Tianjin
2137037	Manufacturing Process and Flow Chart RRL 0206 - Jiangsu
2131524	Discussion of Formation of Impurities RRL 0206 - Jiangsu
2078830	Jiangsu - Purity Profile for Five Batches of Thifensulfuron-Methyl Technical
2078832	Jiangsu - Declaration of Composition
2078788	Tianjin - Product Chemistry (Group A) Product Identity and Composition Preliminary Analysis Rotam Thifensuluron-methyl Technical
2078789	Tianjin - Determination of Physical and Chemical Properties of Thifensulfron Methyl Technical
2131525	Batch Data Manufacturing Dates (Tianjin)
2078790	Tianjin - Product Chemistry (Group B) Physical/Chemical Properties Rotam Thifensulfuron-methyl Technical
2078833	Jiangsu - Safety Data Sheet
2078827	Tianjin - Rotam Thifensulfuron methyl Technical Ambient Temperature Shelf Life
2078837	Jiangsu - Ambient temperature Shelf Life of Thifensulfuron Methyl Technical

ISSN: 1911-8082