

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2015-5321
Application: New TGAI Product Chemistry - New Source (Site) New Registrant
Product: NewAgco Mesotrione Technical Herbicide
Registration Number: 34981
Active ingredients (a.i.): Mesotrione
PMRA Document Number: 2704121

Purpose of Application

The purpose of this application was to register a new source of mesotrione by a new registrant based on a precedent product.

Chemistry Assessment

Common Name: Mesotrione
IUPAC* Chemical Name: 2-[4-(methanesulfonyl)-2-nitrobenzoyl]cyclohexane-1,3-dione
CAS† Chemical Name: 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

NewAgco Mesotrione Technical has the following properties:

Property	Result		
Colour and physical state	Pale yellow solid		
Nominal concentration	98.92%		
Odour	Odourless		
Density	0.83 g/L (Pour Density) 0.92 g/L (Tap Density)		
Vapour pressure	$<5.69 \times 10^{-3}$ mPa (20°C)		
pH	3.78		
Solubility in water	Water Solubility g/L	pH	T °C
	0.4	3.78	25.2
	20.521	5.50	25.4
	39.231	7.04	26.0
n-Octanol/water partition coefficient at 25.0°C	pH	$\log K_{ow}$	
	3.61	0.23	
	7.06	-2.41	

The chemistry requirements for NewAgco Mesotrione Technical Herbicide have been fulfilled.

Health Assessments

The proposed source was considered chemically and toxicologically equivalent to the precedent registered source. No new toxicological data were reviewed or required for the purpose of this application.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the available information in support of this application and has determined that the registration of a new source of mesotrione can be supported.

References

PMRA #	Title
2569300	2015, Applicant's Name and Office Address, Formulating Plant and address and Trade Name for NewAgco Mesotrione Technical, DACO: 2.1,2.2,2.3
2569301	2015, Applicant's Name and Office Address, Formulating Plant and address and Trade Name for NewAgco Mesotrione Technical, DACO: 2.1,2.2,2.3 CBI
2569302	2015, Manufacturing Process and quality control of Mesotrione Technical, DACO: 2.11.1,2.11.2,2.11.3 CBI
2569303	2015, Discussion of the presence of impurities of Mesotrione Technical, DACO: 2.11.4 CBI
2569304	2014, Determination of Active Content and Impurity Profile of Mesotrione, DACO: 2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2569305	2014, Determination of Physical-chemical properties of Mesotrione, DACO: 2.14.1,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7, 2.14.8,2.14.9,2.4,2.5,2.6,2.7,2.8,2.9,830.7000
2569306	2015, Physical Chemical Properties Test of Mesotrione TC: Dissociation constant, DACO: 2.14.10
2569307	2015, Preliminary Analysis of Active Ingredient and [CBI Removed] in Mesotrione TGAI, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2569308	2015, Preliminary Analysis of Active Ingredient and [CBI Removed] in Mesotrione TGAI, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2569309	2015, Validation of Analytical Methodology for the Assay of [CBI Removed] in Mesotrione TGAI, DACO: 2.13.1,2.13.2 CBI
2696655	2016, Determination of [CBI Removed] in mesotrione, DACO: 2.13.4

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