



Evaluation Report for Category B, Subcategory 1,2 Application

Application Number: 2015-0899
Application: New TGAI, Prod Chemistry-New Source(Site) New Registrant
Product: Sharda S-Metolachlor Technical Herbicide
Registration Number: #####
Active ingredients (a.i.): S-Metolachlor and R-Enantiomer
PMRA Document Number : 2603483

Purpose of Application

The purpose of this application was to register Sharda S-Metolachlor Technical Herbicide, a new source of S-metolachlor and R-enantiomer by a new registrant.

Chemistry Assessment

Common Name: S-Metolachlor
IUPAC* Chemical Name: Mixture of 80-100% 2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide and 20-0% 2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*R*)-2-methoxy-1-methylethyl]acetamide
OR
Mixture of 80-100% 2-chloro-6'-ethyl-*N*-[(1*S*)-2-methoxy-1-methylethyl]acet-*o*-toluidide and 20-0% 2-chloro-6'-ethyl-*N*-[(1*R*)-2-methoxy-1-methylethyl]acet-*o*-toluidide
CAS† Chemical Name: 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Sharda S-Metolachlor Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Yellow-red viscous liquid
Nominal concentration	98.34%
Odour	Faintly aromatic
Density	1.111 g/mL
Vapour pressure	2.19×10^{-3} Pa (at 25°C)
pH	7.1

Property	Result
Solubility in water	493 mg/L (20°C, pH 7.1)
n-Octanol/water partition coefficient	Log K _{ow} = 3.1 (pH 7.0)

The required chemistry data for Sharda S-Metolachlor Technical Herbicide have been provided, reviewed, and found to be acceptable.

Health Assessments

The new source of S-metolachlor is toxicologically equivalent to the current source. Subsequently no toxicological data were required.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

Following the review of the application, Sharda S-Metolachlor Technical Herbicide was registered.

References

PMRA

Document

Number	Reference
2508869	2015, Manufacturing Process and Quality Control of S-Metolachlor Technical, DACO: 2.11.1, 2.11.2, 2.11.3 CBI
2508870	2015, Discussion of Impurities Presence in S-metolachlor Technical, DACO: 2.11.4 CBI
2508871	2014, Determination of Active Content and Impurity Profile of S-metolachlor, DACO: 2.12.1, 2.13.2, 2.13.3, 2.13.4 CBI
2508872	2014, Validation Of Analytical Method For Determination Of S-metolachlor TC Active Ingredient Concentration, Homogeneity And Stability In Dose Formulation, DACO: 2.13.1 CBI
2508873	2015, Confirmation of the Source of the Batches Manufacturer for Study, DACO: 2.13.3 CBI
2508874	2014, Determination of Physical-Chemical Properties of S-metolachlor, 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, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, CBI
2508875	2014, Determination of Dissociation Constant of S-Metolachlor Technical, DACO: 2.14.10, CBI
2587178	2015, Manufacturing Process and Quality Control of S-metolachlor Technical DACO: 2.11.3 CBI

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