

Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

Application Number: 2009-1377
Application: TGAI Prod Chemistry – New Source (site) and Changes to Specifications
Product: Thifensulfuron Methyl Technical Herbicide
Registration Number: 21060
Active ingredients (a.i.): Thifensulfuron-methyl (MMM)
PMRA Document Number : 1872656

Purpose of Application

The purpose of this application was to add a new manufacturing site and to amend the specifications of Thifensulfuron Methyl Technical Herbicide which currently has full registration.

Chemistry Assessment

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

Thifensulfuron Methyl Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Off-white solid
Nominal concentration	98.0%
Odour	Odourless
Specific gravity	1.580
Vapour pressure at 25°C	1.7 x 10 ⁻⁵ mPa
pH	4.09 (54.1 mg/L solution)
Solubility in water at 25°C	<u>pH</u> <u>Solubility (mg/L)</u>
	5 223
	7 2240
	9 8830
n-Octanol/water partition coefficient (K _{ow})	<u>pH</u> <u>log Kow</u>
	5 1.06
	7 0.02
	9 0.0079

The chemistry requirements for Thifensulfuron Methyl Technical Herbicide have been completed.

Health Assessments

Based on the chemistry review, the changes in specifications are not expected to cause impurities of human health or environmental concerns. The toxicity profile is not expected to be significantly different and no toxicological data were required.

No new residue data for thifensulfuron-methyl were submitted in support of this registration to amend the specifications of Thifensulfuron Methyl Technical Herbicide and add a new manufacturing site. A review of the proposed label and specification forms was conducted in the framework of this application. As this technical active ingredient will be used to formulate registered end-use products within the existing use pattern, from a food residue exposure point of view, no changes in the magnitude of the residues in food and feed crops are expected and therefore, no increase in dietary exposure is anticipated.

Environmental and Value Assessment

Environmental and value assessments were not necessary for this application.

Conclusion

The PMRA has conducted a review of the available information for this application and has determined that the requested changes are acceptable.

References

Studies/Information Provided by Applicant/Registrant

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- 1745312 2009, Determination of Thifensulfuron Methyl (DPX-M6316) in Technical Grade Thifensulfuron Methyl, DACO: 2.13.1, 2.13.2 CBI
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- 1745315 2009, Description and Validation of the Analytical Methods for Determination of Impurities in Technical Grade Thifensulfuron Methyl (DPX-M6316) Confidential Attachment, DACO: 2.13.1, 2.13.2 CBI
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- 1745320 2007, Toxicological Significance of [CBI Removed] as a Trace Impurity in Thifensulfuron Methyl, DACO: 2.13.4 CBI
- 1745321 2003, Thifensulfuron Methyl (DPX-M6316): Analysis of Technical Material Used in Toxicology Testing (Confidential Attachment), DACO: 2.16 CBI
- 1745322 2003, Thifensulfuron Methyl (DPX-M6316): Analysis of Technical Material Used in Toxicology Testing, DACO: 2.16 CBI
- 1745324 2009, Justification for Thifensulfuron Methyl (DPX-M6316) Certified Limits, DACO: 2.12.1 CBI
- 1856151 2010, DuPont Response to PMRA Clarification Notice (Part 2 - Chemistry), DACO: 2.0 CBI
- 1856152 2010, DuPont Response to PMRA Clarification Notice (Part 2 - Chemistry) - ATTACHMENT 1, DACO: 2.0 CBI
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