

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2014-0425

Application: Changes to TGAI product chemistry specification.

Product: Tembotrione Technical Herbicide

Registration Number: 29657

Active ingredients (a.i.): Tembotrione PMRA Document Number: 2433912

Purpose of Application

The purpose of this application was to amend the manufacturing process.

Chemistry Assessment

Common Name: tembotrione

Chemical Name: 2-{2-chloro-4-mesyl-3-[(2, 2, 2, 2-

trifluoroethoxy)methyl]benzoyl}cyclohexane-1, 3-dione

or

2-[2-chloro-4-(methylsulfonyl)-3-[(2, 2, 2-

trifluoroethoxy)methyl]benzoyl]-1, 3-cyclohexanedione

Tembotrione Technical Herbicide has the following properties:

Property	Result
Colour and physical state	beige powder
Nominal concentration	tembotrione at 97.8%
Odour	no characteristic odour
Density	1.56 g/cm ³ at 20°C
Vapour pressure	Temperature (°C) Vapour pressure (hPa) 20 1.1×10^{-10} 25 2.9×10^{-10} 50 2.6×10^{-8}
рН	50 2.6×10^{-8} $3.63 (1\% solution)$
Solubility in water	<u>pH</u> <u>Solubility (g/L)</u> 4 0.22
	6.2 28.30



Property	Result
n-Octanol/water partition coefficient	<u>pH</u> <u>log Kow</u> 2 2.16 7 -1.09 9 -1.37

The chemistry requirements for Tembotrione Technical Herbicide have been fulfilled.

Health Assessments

The changes to the product specifications for Tembotrione Technical Herbicide result in a product that is chemically equivalent to the previous product specifications. Subsequently, no toxicological data were reviewed or are required.

Residue and exposure assessments were not required for this application.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The changes to the manufacturing process were approved by the PMRA.

References

PMRA Document Number	Reference
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2389626	2014, Tembotrione (AE 0172747) Description of the Manufacturing Process of the Technical Grade Active Substance (Specification No. 102000017602), DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 3.2.3, 830.1600, 830.1620, 830.1670 CBI.
2389627	2013, Material accountability of technical Tembotrione (AE 0172747), DACO: 2.13.1, 2.13.2, 2.13.3, 2.15, 3.6, 830.1700, 830.1900 CBI.
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- 2389629 2013, Analytical Method: Determination of (CBI removed) in Tembotrione (AE 0172747) by Photometry, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14.8, 3.4.1, 3.4.2, 830.1000, 830.1700, 830.1800 CBI.
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- 2414265 2009, Validation of GC-Method AM010305FP2 Determination of (CBI removed) in AE 0172747 (Tembotrione) Technical Material by Gas Chromatography (GC), DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 8.3.
- 2414266 2009, Validation of HPLC method AM008005FP2 Determination of tembotrione (AE 0172747) in technical grade and pure active substance by high performance liquid chromatography (HPLC), DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14.8, 3.4.1, 3.4.2, 830.1000, 830.1700,830.
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- 2421969 2014, Statement about Tembotrione TGAS New Manufacturing Process For USA and Canada, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 3.2.3, 830.1600, 830.1620, 830.1670 CBI.

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