Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2020-4339
Application: Changes to Technical Grade Active Ingredient Product Chemistry - Specifications
Product: Trinexapac-Ethyl Technical
Registration Number: 26988
Active ingredient (a.i.): Trinexapac-ethyl
PMRA Document Number: 3294879

Purpose of Application

The purpose of this application was to amend the manufacturing process for Trinexapac-Ethyl Technical.

Chemistry Assessment

Common Name: Trinexapac-Ethyl Technical
IUPAC* Chemical Name: Ethyl (1RS,4EZ)-4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate
CAS† Chemical Name: Ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Trinexapac-Ethyl Technical has the following properties:

Property	Result
Colour and physical state	Yellow to red-brown liquid
Nominal concentration	97%
Odour	Slightly sweet
Density	1.215 g/mL
Vapour pressure	2.16 x 10^{-3} Pa at 25°C
pH	3-4 (1% in water)
Solubility in water	1.1 g/L at pH 3.55; 2.8 g/L at pH 4.9; 10.2 g/L at pH 5.5; and 21.2 g/L at pH 8.2

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Property	Result
n-Octanol/water partition coefficient	Log Kow = 1.60 at pH 5.3 and 25°C

The required chemistry data for Trinexapac-Ethyl Technical have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the amendment to the manufacturing process for Trinexapac-Ethyl Technical.

References

PMRA Document Number	References
2227139	Description of Production Process, DACO: 2.11.2 CBI
2227140	Description of Starting Materials, DACO: 2.11.2 CBI
2227141	Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2227143	1999, Analytical Method AK-151/3, DACO: 2.13.1 CBI
2227144	1991, Analytical Method AW-151/2, DACO: 2.13.1 CBI
2227145	2000, Confirmation of structures of by-products for CGA 163935 by mass spectroscopy, DACO: 2.13.2 CBI
2227146	2011, Trinexapac-Ethyl Analysis of five representative batches produced at [PRIVACY INFO REMOVED], DACO: 2.13.3 CBI
3154972	2020, Trinexapac-ethyl Technical (CGA163935) - Manufacturing Process Description and Supporting Data (Addendum to PMRA Document Numbers 1243413 and 1243415), DACO: 2.11,2.11.1 CBI