

Evaluation Report for Category B Subcategory 1.1 Application

Application Number: 2009-1127
Application: New/Changes to the technical grade active ingredient – new source (site) same registrant
Product: Ethofumesate Technical Herbicide
Registration Number: 20364
Active ingredients (a.i.): Ethofumesate [ETS]
PMRA Document Number : 1888022

Purpose of Application

The purpose of this application was to add a new source of the active ingredient ethofumesate to the currently registered product, Ethofumesate Technical Herbicide, Registration number 20364, by the same registrant.

Chemistry Assessment

Common Name: Ethofumesate
Chemical Name: (R,S)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate

Ethofumesate Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Light brown crystalline solid
Nominal concentration	97.7%
Odour	Mild Aromatic Odour
Density	1.29 g/mL
Vapour pressure	0.12 to 0.65 mPa(s)
pH	N/A
Solubility in water	50 mg/mL
n-Octanol/water partition coefficient	Log K_{ow} = 2.7 (pH 6.5-7.6)

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new source for the production of Ethofumesate Technical Herbicide is acceptable.

References

- 1738036 2009, BCS DER- Product Chemistry Summary- Ethofumesate Technical Herbicide, DACO: 2.0,2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1, 2.13,2.13.1,2.13.2,2.13.3,2.2, 2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
- 1738037 2008, Ethofumesate technical material manufacturing process used by [CBI Removed], DACO: 2.11.2,2.11.3 CBI
- 1738038 2009, Ethofumesate technical material - Discussion of the formation of impurities in ethofumesate manufactured by [CBI Removed], DACO: 2.11.4 CBI
- 1738039 2008, Determination of [CBI Removed] (AE C639174) and [CBI Removed] (AE C639170) in technical grade ethofumesate (AE B049913) manufactured at [CBI Removed] - Five batches of technical grade ethofumesate (AE B049913), DACO: 2.12.1 CBI
- 1738040 2003, Validation of the analytical method AL056/02-0 for the determination of the organic impurity AE C508291 in ethofumesate technical material, DACO: 2.13.1 CBI
- 1738041 2008, Analytical method - Determination of traces of AE C639174 [CBI Removed] and AE C639170 [CBI Removed] in technical grade AE B049913 (ethofumesate) by gas chromatography - mass spectrometry applying selected-ion-monitoring (GC-MS/SIM), DACO: 2.13.1 CBI
- 1738042 2008, Validation of the analytical method AM018807FP1 for the determination of AE C639174 [CBI Removed] and AE C639170 [CBI Removed] in technical grade AE B049913 (ethofumesate) by gas chromatography - mass spectrometry applying selected-ion-monitoring (GC-MS/SIM), DACO: 2.13.1 CBI
- 1738043 2008, Analytical method - Determination of the impurities in technical grade and pure AE B049913 by high performance liquid chromatography (HPLC), DACO: 2.13.1 CBI
- 1738044 2008, Validation of HPLC-method AM020008FP1 Determination of the impurities in technical grade and pure Ethofumesate (AE B049913) by high performance liquid chromatography (HPLC), DACO: 2.13.1 CBI
- 1738045 2008, Analytical method - Determination of AE B049913 (Ethofumesate) in technical grade and pure active substance by high performance liquid chromatography (HPLC), DACO: 2.13.1 CBI
- 1738046 2008, Validation of HPLC-method AM022208FP1 - Determination of AE B049913 (Ethofumesate) in technical grade and pure active substance by high performance liquid chromatography (HPLC), DACO: 2.13.1 CBI

- 1738047 2008, Analytical method - Determination of AE C508291 in pure and technical grade ethofumesate AE B049913 by gas chromatography, DACO: 2.13.1 CBI
- 1738048 2008, First Addendum to the Validation Report PA02/071: Validation of the analytical method AL056/02-0 for the determination of the organic impurity AE C508291 in ethofumesate technical material - Validation of analytical method AM022108FP1 regarding confirmatory techniques, DACO: 2.13.1 CBI
- 1738049 2008, Material accountability of ethofumesate (AE B049913) manufactured at [CBI Removed]- Analytical profile of production batches, DACO: 2.12.1,2.13.2,2.13.3 CBI

References

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