

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2012-1254
Application: B.1.1 - New Source(site) same registrant
Product: A H Marks Fenoxaprop-P-ethyl Technical Ester
Registration Number: 29380
Active ingredients (a.i.): Fenoxaprop-P-ethyl (FPF)
PMRA Document Number : 2222582

Purpose of Application

The purpose of this application was to add an alternate source of manufacture and change the net contents range of A H Marks Fenoxaprop-P-ethyl Technical Ester.

Chemistry Assessment

Common Name: Fenoxaprop-P-ethyl
IUPAC Chemical Name: Ethyl (*R*)-2-[4-(6-chloro-1,3-benzoxazol-2-yloxy)phenoxy] propionate
 OR ethyl (*R*)-2-[4-(6-chlorobenzoxazol-2-yloxy)phenoxy] propionate
CAS Chemical Name: Ethyl (2*R*)-2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy] propanoate

A H Marks Fenoxaprop-P-ethyl Technical Ester has the following properties:

Property	Result
Colour and physical state	Off-white solid
Nominal concentration	97.5%
Odour	Odourless
Specific gravity	1.35
Vapour pressure	5.3×10^{-4} mPa (at 20°C)
pH	Not applicable
Solubility in water	0.7 mg/L at pH 5.8
n-Octanol/water partition coefficient	$\log K_{ow} = 4.58$

The chemistry requirements for A H Marks Fenoxaprop-P-ethyl Technical Ester have been completed.

Health Assessments

Although the new source of A H Marks Fenoxaprop-P-ethyl Technical Ester is not chemically equivalent to the registered source, the small increase in impurity levels in the new source of active ingredient is not expected to pose an additional health risk; therefore, no further toxicological data are required at the present time.

Occupational exposure and food residue assessments were not required for this application.

Environmental Assessment

Additional data were not required to support the registration of the new source of manufacture of A H Marks Fenoxaprop-P-ethyl Technical Ester. Although the technical grade active ingredient sources are not considered to be chemically equivalent due to the presence of impurities, registration of the new source of manufacture of A H Marks Fenoxaprop-P-ethyl Technical Ester is not expected to contribute significantly to the overall environmental loading of Track-1 contaminants.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of an alternate source of manufacture and to change the net contents range of A H Marks Fenoxaprop-P-ethyl Technical Ester.

References

- 2174419 2012, Technical Grade Active Ingredient Chemistry Summary Information and Selected Physical and Chemical Properties, DACO: 2.1,2.12.1,2.13.4,2.14.6,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
- 2174420 2009, Production Chemistry of Fenoxaprop-P-ethyl, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
- 2174421 2012, Fenoxaprop-P-ethyl TGAI, NUP-08089, Appearance and Relative Density, DACO: 2.14.1,2.14.2,2.14.3,2.14.6 CBI
- 2174422 2011, Fenoxaprop-p-ethyl Method Validation - Impurity Content, DACO: 2.13.1,2.13.2 CBI
- 2174423 2011, Fenoxaprop-P-ethyl, NUP-08089, Five Batch Analysis, DACO: 2.13.3 CBI
- 2174427 2010, Fenoxaprop-P-ethyl: Impurities of Toxicological Concern, DACO: 2.13.4 CBI

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