

Evaluation Report for Category B, Subcategory 1.1 & 1.3 Application

Application Number: 2009-1211

Application: New TGAI Prod Chemistry-New Source same registrant, and

Specifications

Product: Hoegrass Technical Herbicide

Registration Number: 19514

Active ingredients (a.i.): Diclofop-methyl [DPP]

PMRA Document Number: 1828298

Purpose of Application

The purpose of this application was to register a new source of the technical diclofop-methyl (99.4% guarantee) to replace the currently registered source of the active ingredient (93.7% guarantee) for Hoegrass Technical Herbicide.

Chemistry Assessment

Common Name: Diclofop-methyl

IUPAC Chemical Name: Methyl (*RS*)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionate CAS Chemical Name: Methyl 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoate

Hoegrass Technical Herbicide has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	99.4%
Odour	No characteristic odour
Density	$1.30 \text{ g/cm}^3 \text{ (at } 28.5^{\circ}\text{C)}$
Vapour pressure	0.25 mPa (at 20°C); 7.7 mPa (at 50°C)
pН	Not applicable
Solubility in water	0.8 mg/L (at pH 5.7)
n-Octanol/water partition	P = 37800
coefficient	$\log P = 4.58$

The chemistry requirements for Hoegrass Technical Herbicide have been completed.



Health Assessments

The Hoegrass Technical Herbicide produced at the new source of manufacture is considered to be similar to that of the currently registered source. Therefore, the toxicology profile is not expected to be significantly different and no toxicology data were required.

Environmental Assessment

Diclofop-methyl degrades rapidly to diclofop acid in the environment. Combined residues of diclofop-methyl and diclofop acid are highly toxic to fish and aquatic invertebrates. Aquatic hazards must be identified on the Hoegrass Technical Herbicide label with a prohibition on discharging effluent into aquatic systems.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has conducted a review of the available information and can support a full registration of the new source to replace the currently registered source of the technical diclofopmethyl for Hoegrass Technical Herbicide (Registration Number 19514).

References

Studies/Information Provided by Applicant/Registrant

PMRA#	Reference
1742891	1989, Static acute 48-hour toxicity of diclofop-methyl (HOE 023408 00 ZD93 0002) to <i>Daphnia magna</i> , DACO 9.3.2
1742889	1989, Static acute 96-hour toxicity of diclofop-methyl (HOE 023408 00 ZD93 0002) to rainbow trout, DACO 9.5.2.1
1740508	2002, Validation of the analytical method AL016/97-2 for the determination of the organic impurities in AE F023408 technical grade active ingredient Code: AE F023408, DACO: 2.13.1 CBI
1740509	2007, Analytical Method: Determination of organic impurities in pure and technical grade AE F023408 (diclofop-methyl) by [CBI REMOVED], DACO: 2.13.1 CBI
1740510	2007, 1. Amendment to the validation report PA01/021 - Validation of the analytical method AM012106FP1 (follow-up version of AL016/97-2) for the determination of organic impurities in pure and technical grade AE F023408 (diclofop-methyl) by [CBI REMOVED], DACO: 2.13.1 CBI
1740511	2007, Analytical method - Determination of AE F023408 (diclofop-methyl) in technical grade and pure active ingredient by [CBI REMOVED] - Code: AE F023408, DACO: 2.13.1 CBI
1740512	2007, 1. Amendment to the validation report OE03/045 - Validation of the analytical method AM017307FP2 (follow-up version of AL115/96-3) for the determination of AE F023408 (diclofop-methyl) in technical grade and pure active ingredient by [CBI REMOVED], DACO: 2.13.1 CBI
1740513	2003, Validation of the Analytical Method AL115/96-2 for the Determination of AE F023408 (Diclofop-methyl) in Technical Grade and Pure Active Ingredient by [CBI REMOVED], DACO: 2.13.1 CBI
1740514	2008, Material accountability of diclofop-methyl (AE F023408) Manufactured by [CBI REMOVED] - Five Batches of Technical Grade Diclofop-methyl (AE F023408), DACO: 2.12.1,2.13.2,2.13.3 CBI
1740515	2008, Diclofop-methyl technical material - manufacturing process used by [CBI REMOVED], DACO: 2.11.1,2.11.2,2.11.3 CBI
1740516	2008, Diclofop-methyl technical material manufactured by [CBI REMOVED] - Discussion of the formation of impurities, DACO: 2.11.4 CBI
1740517	2009, Diclofop-methyl technical herbicide, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1742922	2002, Physical characteristics color, appearance and odor Diclofop-methyl substance pure, substance technical Code: AE F023408, DACO: 2.14.1,2.14.2,2.14.3
1814183 1814184	Material Safety Data Sheet - Description of Starting Materials, DACO: 2.11.2 2009, Diclofop-methyl Technical Material: Manufacturing Processes used by [CBI REMOVED], DACO: 2.11.3 CBI
1814185	2009, Determination of [CBI REMOVED] in 5 batches of Diclofop-methyl (AE F023408) manufactured by [CBI REMOVED], DACO: 2.13.4

1814186	1994, The Determination of the Stability of Diclofop-methyl Technical,
	DACO: 2.14.13
1837828	2009, Validation of Linearity and Accuracy for the Determination of [CBI
	REMOVED] in 5 batches of Diclofop-methyl (AE F023408) manufactured by
	[CBI REMOVED], DACO: 2.11.4 CBI
1840928	2009, Diclofop-methyl Technical Material Manufacturing Process Used by [CBI
	REMOVED], DACO: 2.11.3 CBI
1848561	2010, Diclofop Technical Manufacturing Process used by [CBI REMOVED],
	DACO: 2.11.3 CBI

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