

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2010-1382
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Fluroxypyr Agrogill Technical Grade Active Ingredient
Registration Number: 30335
Active ingredients (a.i.): Fluroxypyr (present as 1-methylheptyl ester)
PMRA Document Number English PDF: 2118676

Background

The source of fluroxypyr used to determine chemical equivalence was Registration Number 24814.

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, fluroxypyr, by a different Registrant.

Chemistry Assessment

Common Name: Fluroxypyr-meptyl
 Chemical Name: (RS)-1-methylheptyl 4-amino-3,5-dichloro-6-fluro-2-pyridoxyacetate

Fluroxypyr Agrogill Technical Grade Active Ingredient has the following properties:

Property	Result
Colour and physical state	White solid (powder)
Nominal concentration	68% (fluroxypyr)
Odour	Musty
Density	1.256-1.265 at 20°C
Vapour pressure	$< 4.4 \times 10^{-4}$ Pa
pH	6.10
Solubility in water	N/A due to hydrolysis
n-Octanol/water partition coefficient	Log K_{ow} = 7.02

The chemistry requirements for Fluroxypyr Agrogill Technical Grade Active Ingredient have been completed.

Health and Environmental Assessments

As the new source of fluroxypyr is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Fluroxypyr Agrogill Technical Grade Active Ingredient.

References

PMRA Document Number	Reference
1889144	Applicant's Name and Office address, DACO: 2.1
1889145	Name and address of manufacturer, DACO: 2.2
1889146	Product Trade Name, DACO: 2.3
1889147	Common name, DACO: 2.4
1889148	Chemical Name, DACO: 2.5
1889153	Chemical Abstracts Registry Number, DACO: 2.6
1889154	Structural Formula, DACO: 2.7
1889155	Molecular formula, DACO: 2.8
1889156	Molecular weight, DACO: 2.9
1889159	Manufacturing summary, DACO: 2.11.1 CBI
1889161	Description of starting materials, DACO: 2.11.2 CBI
1889162	Material Safety Data Sheet, DACO: 2.11.2 CBI
1889164	Material Safety Data Sheet, DACO: 2.11.2 CBI
1889165	Material Safety Data Sheet, DACO: 2.11.2 CBI
1889166	Material Safety Data Sheet, DACO: 2.11.2 CBI
1889167	Material Safety Data Sheet, DACO: 2.11.2 CBI

- 1889168 Material Safety Data Sheet, DACO: 2.11.2 CBI
- 1889169 Material Safety Data Sheet, DACO: 2.11.2 CBI
- 1889170 Material Safety Data Sheet, DACO: 2.11.2 CBI
- 1889171 Material Safety Data Sheet, DACO: 2.11.2 CBI
- 1889172 Material Safety Data Sheet, DACO: 2.11.2 CBI
- 1889173 2.11.3 Detailed Production Process , DACO: 2.11.3 CBI
- 1889174 2.11.4 Discussion on Formation of Impurities , DACO: 2.11.4 CBI
- 1889175 DACO 2.12.1 / 830.1750 Certification of Limits , DACO: 2.12.1
- 1889177 2007, High Performance Liquid Chromatographic determination of Fluroxypyr Meptyl in technical material and formualtions, DACO: 2.13.1,2.13.2 CBI
- 1889178 2007, Validation of analytical method M616, DACO: 2.13.1,2.13.2 CBI
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- 1889180 2007, Validation of analytical method M617, DACO: 2.13.1,2.13.2 CBI
- 1889181 2007, Gas Chromatographic determination of Octanol and [CBI removed] impurities in technical Fluroxypyr Meptyl, DACO: 2.13.1,2.13.2 CBI
- 1889183 2007, Validation of analytical method J16277D, DACO: 2.13.1,2.13.2 CBI
- 1889184 2009, Analysis of 5 Batches of Technical Fluroxypyr Meptyl, DACO: 2.13.3 CBI
- 1889185 2010, Fluroxypyr Meptyl Physical Chemical tests, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
- 1889187 DACO: 2.15
- 1967928 Manufacturing dates for the 5 Batches used in the Batch analysis, DACO: 2.13.3
- 1967929 2007, Validation of Anaytical Method M616 for Technical Fluroxypyr Meptyl, DACO: 2.14.12 CBI
- 1979336 MSDS, DACO: 2.11.2 CBI
- 1979337 Revised Production Process STEP D.pdf, DACO: 2.11.3 CBI

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