



New Source (Site of Manufacture) by Current Registrant and Specifications and Manufacturing Process Evaluation Report for Category B, Subcategories B1.1 and B1.3 Application

Application Number: 2006-0035
Application: New source (site of manufacture) by current registrant (B1.1) and Specifications and manufacturing process (B1.3)
Product: Fludioxonil Technical Fungicide
Registration Number: 24731
Active ingredients (a.i.): Fludioxonil [FLD]
PMRA Document Number: 1418664

Background

Fludioxonil Technical has been registered since October 2, 1996. This product is used in the reformulation of pesticides. It contains the TGAI fludioxonil at 97.6%. Fludioxonil is a member of the phenylpyrrole class of compounds. Fludioxonil is a contact fungicide that is active against a wide range of pathogens that cause a variety of air-, seed- and soil-borne diseases in numerous crops.

Purpose of Application

The purpose of this application was to amend the registration of Fludioxonil Technical in order to add a new manufacturing site and to change the specifications of the TGAI.

Chemistry Assessment

Common Name: Fludioxonil
IUPAC Chemical Name: 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile
CAS Chemical Name: Pyrrole-3-carbonitrile, 4-(2,2-difluoro-benzodioxol-4-yl)-

Fludioxonil Technical Fungicide has the following properties:

Property	Result
Colour and physical state	colourless solid
Nominal concentration	98.1%
Odour	odourless
Density	1.54 g/cc
Vapour pressure	2.9 x 10 ⁻⁹ mmHg (25° C)
pH	n/a
Solubility in water	1.88 ppm
n-Octanol/water partition coefficient	Log Kow = 4.12 (pH 5.9)

The chemistry requirements for Fludioxonil Technical Fungicide are complete.

Health Assessments

With the new manufacturing site, the Fludioxonil Technical Fungicide is considered to be chemically equivalent, but not identical to the precedent chemical as the guarantee has increased from 96.7% Fludioxonil to 98.1% Fludioxonil and process-related impurities have decreased. Therefore, the toxicity profile is not expected to be significantly different and no toxicological data were required.

The food residue risk profile of Fludioxonil Technical is expected to be similar to that of the original registered Fludioxonil Technical as chemistry concluded that both TGAI's were chemically equivalents. Accordingly, no increase in dietary exposure is anticipated.

Environmental Assessment

An environmental assessment was not required under this application.

Value Assessment

A value assessment was not required under this application.

Conclusion

Following the review of all available data, the new fludioxonil TGAI is considered equivalent to the original registered fludioxonil TGAI and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

Chemistry

Studies/Information Provided by Applicant/Registrant

- 1116473 2005, CGA 173506: Chemistry requirements of TGAI, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1116476 2005, CGA 173506: Manufacturing Methods for the TGAI, DACO: 2.11.1,2.11.2,2.11.3
- 1116478 2005, CGA 173506: Chemistry requirements of TGAI., DACO: 2.11.4
- 1116480 2005, CGA 173506: Certification of Limits, DACO: 2.12.1
- 1116481 2005, CGA 173506: Methodology/Validation., DACO: 2.13.1
- 1116483 2005, CGA 173506: Confirmation of Identity, DACO: 2.13.2
- 1116485 2005, CGA 173506: Analysis of Five Representative Batches Produced at Monthey, GLP Testing Facility EZA, DACO: 2.12.1,2.13.3
- 1116486 2005, CGA 173506: Chemical and Physical Properties., DACO: 2.14
- 1268105 1995, CGA 173506 Basic Information on CGA 173506, Ciba-Geigy Canada Ltd., DACO: 2.11.1,2.11.2,2.11.3,2.11.4
- 1268106 1993, CGA 173506: Manufacturing Process, Ciba-Geigy Corporation, PC-92-035, DACO: 2.11.1
- 1268110 1992, CGA 173506: Analytical Method for CGA 173506, Ciba-Geigy Corporation, AW- 156/4, DACO: 2.13.1
- 1268111 1992, CGA 173506: Method Validation for Technical Active Substances, Ciba-Geigy Corporation, AW-156/4, DACO: 2.13.1
- 1268112 1993, CGA 173506: Analytical Method for CGA 173506 By Products in Technical Active Substances, Ciba-Geigy Corporation, AW-156/3, DACO: 2.13.1

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