

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2006-7396
Application: Category B, subcategory 1.1 (new source by same registrant)
Product: Bromotril Technical
Registration Number: 27675
Active ingredient (a.i.) contained in product:
- Bromoxynil (present as octanoate ester) at 66.1%
PMRA Document Number: 1432688

Background

The original source of Bromotril Technical was registered in 2004.

Purpose of Application

The purpose of this application is to add an alternate manufacturing site for Bromotril Technical.

Chemistry Assessment

Common Name: Bromoxynil octanoate
IUPAC Chemical Name: 2,6-dibromo-4-cyanophenyl octanoate
CAS Chemical Name: 2,6-dibromo-4-cyanophenyl octanoate

Bromotril Technical has the following properties:

Property	Result
Colour and physical state	brown waxy solid
Nominal concentration	66.1% as determined by HPLC
Odour	Faint odour (fatty acid)
Density	1.4823 g/mL
Vapour pressure	0.86 mPa
pH	2.91
Solubility in water	0.003 g/ L
n-Octanol/water partition coefficient	Log K _{OW} = 5.43 (pH 6.1)

The chemistry requirements for Bromotril Technical are complete.

Health and Environmental Assessments

The health and environmental risk profile of the new source of Bromotrilo Technical is expected to be similar to that of the original registered source.

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 the new manufacturing site for Bromotrilo Technical is eligible for registration.

References

- 1326093 2006, BROMOTRIL (Bromoxynil Octanoate) TECHNICAL - PRODUCT PROPERTIES, NS, MRID: NS, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
- 1326095 2006, Bromoxynil Octanoate Technical - Five Lots Analysis and Method Validation, 06-03/8, MRID: NS, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
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- 1326098 2006, Bromoxynil Octanoate Physical and Chemical Characteristics, 19851, MRID: NS, DACO: 2.14.1,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8

ISSN: 1911-8082

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