

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2010-3364
Application: New/Changes to the technical grade active ingredient – new source (site) same registrant
Product: Technical Fenbutatin Oxide
Registration Number: 18594
Active ingredients (a.i.): Fenbutatin oxide (FBT)
PMRA Document Number English PDF: 2049969

Purpose of Application

The purpose of this application was to amend the registration of Technical Fenbutatin Oxide, Registration number 18594, by adding a new alternate manufacturing site and removing two of the currently registered manufacturing sites.

Chemistry Assessment

Common Name: fenbutatin oxide

Chemical Name: bis[tris(2-methyl-2-phenylpropyl)tin] oxide

Technical Fenbutatin Oxide has the following properties:

Property	Result
Colour and physical state	White to off-white solid
Nominal concentration	98.4%
Odour	Odourless
Specific density @ 23°C	1.30 g/mL
Vapour pressure @ 25°C	2.4×10^{-9} Pa
Solubility in water	12.7 ppb

The chemistry requirements for Technical Fenbutatin Oxide have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new manufacturing site for the production of Technical Fenbutatin Oxide is acceptable.

References

- 1427867 1994, Vendex (Fenbutatin Oxide). Product Identity and Composition., DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.16 CBI
- 1937429 2010, Enforcement of Analytical Method - Validation of Analytical Method for the Determination of Fenbutatin Oxide Active Ingredient and its Associated Impurities, DACO: 2.13.1, 2.13.2 CBI
- 1937430 2010, Enforcement of Analytical Method - Validation of Analytical Method for the Determination of Fenbutatin Oxide Active Ingredient and its Associated Impurities - Signature Pages, DACO: 2.13.1, 2.13.2
- 1937431 2010, Preliminary Analyses of Five Representative Production Batches of Fenbutatin Oxide Technical Grade Active Ingredient (TGAI) to Determine % Fenbutatin Oxide and to Quantify its Associated Impurities, DACO: 2.12.1, 2.13.1, 2.13.2, 2.13.3 CBI
- 1968860 2010, Applicant Name and Manufacturing Plant for Technical Fenbutatin Oxide, PCP No. 18594, DACO: 2.1,2.2 CBI

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