Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2006-3034
Application: Category B, Subcategory 4.1 (Conversion or Extensions to Ltd. or Term-Conversion)
Product: Triallate Technical II
Registration Number: 28120
Active ingredients (a.i.): Triallate (TRL)
PMRA Document Number: 1333407

Purpose of Application

The purpose of this application is to convert the product from temporary registration to full registration and in so doing to update the guarantee of the active ingredient. The guarantee is being updated to 96.6% from 96%.

Chemistry Assessment

Common Name: Triallate
Chemical Name: *S*-2,3,3-trichloroallyl di-isopropyl(thiocarbamate)

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Triallate Technical II has the following properties:

Property	Result
Colour and physical state	crystal white
Nominal concentration	96.6% as determined by GC
Odour	none
Bulk density	0.87 kg/L
Vapour pressure at 25°C	1.1×10^{-4} mm Hg
pH	4.2 (1% solution in water)
Solubility in water at 25°C	3 ppm
n-Octanol/water partition coefficient	log K_{ow} = 4.54

The chemistry requirements for Triallate Technical II have been completed.

Health Assessments

A Health Assessment is not required for conversion applications.

Environmental Assessment

An Environmental Assessment is not required for conversion applications.

Value Assessment

A Value Assessment is not required for conversion applications.

Conclusion

Since the Chemistry requirements have been fulfilled in this application, the product has been granted full registration, and the active ingredient guarantee has been changed to 96.6%.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

PMRA # 1201171. (1985) "Product Chemistry Data for Manufacturing-use Product Triallate S-(2,3,3-Trichloroallyl)-N,N-Diisopropylthiocarbamate", vol 1 of 1, page 23-27.

PMRA# 1288607. Statement of Product Specification Form dated 2006/08/04.

PMRA # 1201165. (2004) “Triallate Technical: Description of Beginning Materials and Manufacturing Process at an Alternate Site and Discussion of Formation of Impurities”, vol 1, page 7.

PMRA # 1201171. (1985) “Product Chemistry Data for Manufacturing-use Product Triallate S-(2,3,3-Trichloroallyl)-N,N-Diisopropylthiocarbamate”, vol 1 of 1, page 15.

PMRA # 1216826. (2006) “Analysis and Certification of Product Ingredients in Five Batches of Technical Triallate Manufacturing Use Product (MUP)” in Part 2 Chemistry, vol 1, page 16.

PMRA # 1216826. 2003/07/23, “Triallate Technical - Determination of Purity of Five Technical Batches”, Part 2 Chemistry, P26-33.

PMRA # 1216826. 2006/02/28, “Method Validation and Five Batch Analysis of Triallate in Triallate Technical”, Part 2 Chemistry, P6-24.

PMRA # 1216826. 2006/2/28, “Method Validation for the Analysis of Volatile Impurities and Moisture in Triallate Technical”, Part 2 Chemistry, P44-104.

PMRA # 1216826. 2006/02/28, “Analysis and Certification of Product Ingredients in Five Batches of Technical Triallate Manufacturing Use Product (MUP): Impurity Analysis of High Boiling Impurities”, Part 2 Chemistry, P105-142.

PMRA # 1216826. 2006/02/28, “Method Validation and Five Batch Analysis for the N-Nitrosodiisopropylamine”, Part 2 Chemistry, P143-159.

ISSN: 1911-8082