Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.1.1 Application

Application Number: 2007-0278
Application: New TGAI -New Source(site) same registrant
Product: Sevin Brand Technical Carbaryl Insecticide
Registration Number: 18463
Active ingredients (a.i.): Carbaryl
PMRA Document Number: 1694501

Purpose of Application

The purpose of this category B.1.1-S-A-TGAI is to register a new source of active ingredient by the same registrant

Chemistry Assessment

Common Name: Carbaryl
Chemical Name: 1-naphthalenyl methylcarbamate

Sevin Brand 99% Technical Carbaryl Insecticide has the following properties:

Property	Result
Colour and physical state	Colourless to light tan crystalline solid
Nominal concentration	99.5 %
Odour	essentially odourless
Bulk Density	0.7842 g/mL
Vapour pressure	4.16×10^{-5} Pa (23.5 °C)
pH	4 – 7 (as a 1 % aqueous dispersion)
Solubility in water	9.4 mg/L at 20°C (pH 4) 9.1 mg/L at 20°C (pH 7) 7.2 mg/L at 20°C (pH 9)
n-Octanol/water partition coefficient	log K_{ow} = 2.36 at 23 °C

In support of this submission, the applicant has provided full and recent batch data for both sites of production. At the request of the PMRA, the applicant has changed the guarantee of the product from a minimum to a nominal.

Conclusion

The chemistry requirements for Sevin Brand 99% Technical Carbaryl Insecticide are complete.

References

7.1.1 **Studies/Information Provided by Applicant/Registrant**

PMRA No. Title

1519682 2007 Carbaryl Manufacturing Process (source: [**Privacy information removed]**) of the Technical Active Substance, DACO: 2.11.2 CBI

1519684 2007 Impurities of Carbaryl Technical Material Description, Formation & Justification, Spec. No: 102000002972, UVP 05931533, Code : AE F054158, DACO: 2.11.4 CBI

1519690 1999 Carbaryl Determination by HPLC analysis in formulation EXP05671B (WP); ROO4459; Study No: 99-39, C-989-02-99; R&D/CRLDA4N/9915257, DACO: 2.13.1 CBI

1519689 2006 Analytical method Determination of the organic Impurities in Carbaryl Technical Materials by High Performance Liquid Chromatography, AM008205FP2, DACO: 2.13.1 CBI

1519693 2002 Validation of the Analytical Method C-989-02-99 for the Determination of Carbaryl in Carbaryl Technical Material and WP Formulated Products, PA01/051, DACO: 2.13.1 CBI

1519697 2002 The analytical profile of technical grade Carbaryl Code AEF054158 Carbaryl (Technical Grade Active Ingredient), PA01/061, DACO: 2.13.3 CBI

1519696 2007 Chromatographic and Spectral Data in Support of Document M-206778-01-1 (Study PA01/061) AE F054158 (Carbaryl) Technical Material, AFO7/124, DACO: 2.13.3 CBI

1519692 2002 Validation of the Analytical Method LM 040/01-0 for the Determination of Impurities in Carbaryl Technical Material, C018831; PA01/050, DACO: 2.13.1 CBI

1519691 1993 Method Validation for Analysis of Carbaryl, 3521 -F, DACO: 2.13.1 CBI

1519694 2005 First Addendum to the Validation Report PA01/050: "Validation of the Analytical Method for the Determination of Impurities in Carbaryl Technical Product" Validation of the Analytical Method AM008205FP1 (formerly AL040/01-1) Regarding Confirmatory Techniques, DACO 2.13.2, 2.14.12 CBI

1367016 Material Accountability of AE F054158 (CARBARYL) TECHNICAL MATERIAL Analytical Profile of Five Production Batches from [**Privacy information removed]**, PA05/11, DACO: 2.13.2, 2.13.3 CBI

1519680 FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES CARBARYL 1-naphthyl methylcarbamate, DACO: 2.11.2, 2.14.4, 2.14.5, 2.14.7, 2.14.9, 2.14.10, 2.14.11, 2.14.13

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