Health Canada Santé Canada

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: 2006-0475
Application: New source (site of manufacture) by current registrant (B1.1) and Specifications and manufacturing process (B1.3)
Product: Oxamyl Technical
Registration Number: 24949
Active ingredients (a.i.): Oxamyl [OXB]
PMRA Document Number: 1402559

Background

Oxamyl Technical has been registered since May 7, 1997. This product is used in the reformulation of pesticides. It contains the TGAI oxamyl at 24%. Oxamyl, a carbamate, is a cholinesterase inhibitor which acts as a contact and systemic insecticide, acaricide and nematicide.

Purpose of Application

The purpose of this application was to amend the registration of Oxamyl Technical in order to update the manufacturing specifications and to establish a Statement Product Specification Form.

Chemistry Assessment

Common Name:	Oxamyl
IUPAC Chemical Name:	Methyl 2-(dimethylamino)-N-{[(methylamino)carbonyl]oxy}-2-oxoethanimidothioate
CAS Chemical Name:	N,N-Dimethyl-2-methylcarbamoyloxyimino-2-(methylthio) acetamide

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Oxamyl Technical has the following properties:

Property	Result
Colour and physical state	green solid
Nominal concentration	24.0%
Odour	Aromatic with slight sulfurous odour
Density	0.98 g/mL (0.96-0.99)
Vapour pressure	0.051 mPa
pH	3.0 (2.7-3.6)
Solubility in water	280 g/L
n-Octanol/water partition coefficient	logKow = -0.44 Kow = 0.36

The chemistry requirements for Oxamyl Technical are complete.

Health Assessments

A complete toxicological database for Oxamyl was previously reviewed. In brief, Oxamyl has been shown to have extremely high acute toxicity with oral administration in both mice and rats, with females being slightly more sensitive. Via inhalation, Oxamyl is moderately toxic. With acute dermal exposure, Oxamyl is slightly to moderately toxic, depending on species and vehicle used. Oxamyl is considered to be mildly irritating to both eye and skin, and is not considered to be a dermal sensitizer.

Changes in the impurity profile of the new source of Oxamyl were noted and assessed. These impurities were determined to be not of toxicological concern and are present at low levels. The changes to the impurity profile is not expected to alter the toxicological properties of this new source of Oxamyl. The change of guarantee noted from a minimal to a nominal guarantee is not toxicologically relevant. No new toxicological data is required.

The food residue risk profile of Oxamyl Technical is expected to be similar to that of the original registered Oxamyl Technical as chemistry concluded that both TGAIs 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 oxamyl TGAI is considered equivalent to the original registered oxamyl TGAI and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

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1135157 2004, Technical Grade Active Ingredient Oxamyl (DPX-D1410) Analysis and Certification of Product Ingredients for Vydate L Produced at the LaPorte Manufacturing Facility, Exygen Research, DuPont-14981;Exygen P806, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4

1135158 Determination of Nitrosamines in Vydate L End-Use Product, Covance Laboratories Inc., 6915-105, DACO: 2.13.4

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