Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Decision Document RDD2006-03

Imiprothrin

The active ingredient imiprothrin and the associated manufacturing concentrate Pralle® Manufacturing Use Product (both from Sumitomo Chemical Company) as well as the manufacturing concentrate Multicide® Intermediate 2734 and the end-use product Multicide® Pressurized Roach Spray 27341 (both from McLaughlin Gormley King Co.) are eligible for full registration under the Pest Control Products Regulations.

These products were originally proposed for registration in the Proposed Regulatory Decision Document PRDD2005-02, *Imiprothrin*, providing a summary of data reviewed. This Regulatory Decision Document outlines this stage of the Pest Management Regulatory Agency's regulatory decision-making process for the domestic control of cockroaches, ants and other household pests.

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1.0 Introduction

This Regulatory Decision Document completes the Pest Management Regulatory Agency's regulatory decision-making process concerning the use of the active ingredient imiprothrin and the associated manufacturing concentrate Pralle® Manufacturing Use Product as well as the manufacturing concentrate Multicide® Intermediate 2734 and the end-use product Multicide® Pressurized Roach Spray 27341 for the domestic control of cockroaches, ants and other household pests.

2.0 Background

Health Canada's Pest Management Regulatory Agency (PMRA) carried out an assessment of available information in accordance with the Pest Control Products Regulations. The assessment found that there was sufficient information to allow a determination of the safety, merit and value of imiprothrin and the associated manufacturing concentrate Pralle® Manufacturing Use Product (both from Sumitomo Chemical Company Limited) as well as the manufacturing concentrate Multicide® Intermediate 2734 and the end-use product Multicide® Pressurized Roach Spray 27341. The PMRA concluded that the use of imiprothrin in accordance with the label accompanying each intermediate and end-use product has merit and value consistent with the Pest Control Products Regulations and does not entail an unacceptable risk of harm.

These products were proposed for registration in PRDD2005-02, *Imiprothrin*. Comments received by the PMRA concerning PRDD2005-02 are addressed in Appendix I.

3.0 Regulatory Decision

Based on the considerations outlined above, the active ingredient imiprothrin and the associated manufacturing concentrate Pralle® Manufacturing Use Product as well as the manufacturing concentrate Multicide® Intermediate 2734 and the end-use product Multicide® Pressurized Roach Spray 27341, as a control of cockroaches, ants and other household pests, are eligible for full registration under the Pest Control Products Regulations.

Appendix I Comments and Responses

The majority of comments received by the PMRA concerning PRDD2005-02 were primarily regarding typographical errors, errors in nomenclature or transcription errors. None of the comments received affect the outcome of the risk assessment or the registration decision.

Page 1 (1.1 Identity of the Active Substance and Preparation Containing It)

The applicant wishes to correct the stated Chemical Abstracts Service (CAS) name from

[2,5-dioxo-3-(2-propynyl)-1- imidazolidinyl]methyl)2,2- dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate

to

[2,5-dioxo-3-(2-propynyl)-1- imidazolidinyl]methyl-2,2- dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate

The PMRA agrees with the proposed change.

Page 2 (1.2 Physical and Chemical Properties of the Active Substance)

The applicant wishes to correct the following:

1) The temperature for Henry's law constant should be 25°C and not 20°C as stated in PRDD2005-02.

2) The temperature for the solubility in water should be 25°C and not 20°C as stated in PRDD2005-02.

The PMRA agrees with the proposed changes.

Page 5 (Paragraph 2, sentence 2)

The applicant wishes to correct the above-noted sentence to read, "It is non-irritating to skin and minimally irritating to eyes." (PRDD2005-02 lists the reverse).

The PMRA agrees with the proposed change.

Page 9 (5.1.3 Transformation Products)

The applicant wishes to correct the Section 5.1.3 to read:

The major positively identified transformation product in the hydrolysis study was CPG (N-carbamoyl- N-propargylglycine) (26.2% of total recovery at pH 7 on day 30; 89.7% of total recovery at pH 9 at hour 122); PGH (1-propargylimidazolidine- 2,4-dione) (1.81% of total

recovery at pH 7 on day 30; 4.26% of total recovery at pH 9 at hour 122) was a minor transformation product. There was also an unidentified peak observed (2.0% of total recovery at pH 7 on day 30; 4.5% of total recovery at pH 9 at hour 122). Submitted literature also indicates that CRA (2,2-dimethyl-3-(2- methylprop-1-enyl) cyclopropanecarboxilic acid) will probably be the major transformation product from the cyclopropanecarboxylic moiety. The total CO_2 and volatile compounds were not determined.

The PMRA agrees with the proposed change.

Page 14 (Appendix I, Summary Table of Toxicity Studies with Imiprothrin Metabolism) (Paragraph 1, final sentence)

The applicant wishes to correct the above-noted sentence to read, “Approximately 87–93% of the trans isomer was excreted in the urine within 24 h, with 2–7% in the feces and 0.3–0.5% in expired air.” (PRDD2005-02 lists different numerical values).

The PMRA agrees with the proposed change.

Page 17 (Appendix I, Short-term Toxicity: 21-day dermal)

The applicant wishes to change the systemic NOAEL for this study. Due to the nature of the change, the PMRA re-examined the study review and reaffirmed the reviewer’s conclusions.

The PMRA disagrees with the proposed change and will not amend the systemic NOAEL.

Page 18 (Appendix I, Short-term Toxicity: 90-day dietary)

The applicant wishes to correct some of the target organ and significant effects for this study. The PMRA examined the proposed changes and consulted the original reviews to generate the following changes (please note that the suggested PMRA amendments are not identical to those proposed by the applicant):

3000 ppm and above: decreased food consumption (females), decreased Hb (males), Hct (both sexes) and triglycerides (males); increased reticulocytes (females), α_2-globulin (males), and total cholesterol (males).

6000 ppm and above: decreased body-weight gain with body-weight effects (both sexes) and food consumption (males), decreased Hb (females); increased phospholipids, albumin, total protein, leukocytes, lymphocytes, basophils, extended prothrombin time and activated thromboplastin time (males); increased hepatocellular hypertrophy (males).

10 000 ppm: decreased RBC and γ-globulin (both sexes); increased reticulocytes and neutrophils (males), increased total cholesterol (females); increased eosinophilic hepatocyte (males), and hepatocellular hypertrophy and eosinophilic hepatocyte (females).