Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2007-3407
Application: B.4.1, Conversion to full registration without consultation
Product: Entrust 80 W Naturalyte Insect Control Product
Registration Number: 27825
Active ingredients (a.i.): Spinosad
PMRA Document Number: 1825576

Purpose of Application

The purpose of this application was to convert Entrust 80 W Naturalyte Insect Control Product from conditional to full registration.

Chemistry Assessment

The chemistry data requirements for the conversion of this product to full registration have been fulfilled.

Health Assessments

No toxicological data were required for this conversion application, therefore, there is no change to the toxicity profile of this product.

The apple field trial data requirement identified in REG2001-10 were submitted and deemed to be adequate. From the food residue point of view, the full registration of Entrust 80W Naturalyte Insect Control Product can be supported. The full registration of this product is not expected to result in an increase in exposure for any segment of the population, including infants, children, adults and seniors.

A risk assessment for registered uses of Entrust 80 W Naturalyte Insect Control Product was conducted previously (Submission number 2004-1744) and all margins of exposure were above the target with the required personal protective equipment.

Environmental Assessment

A new environmental assessment was not conducted as no additional environmental data were required to support the conversion of the registration of Entrust 80W Naturalyte Insect Control Product from conditional to full registration.

Value Assessment

Canada

As a condition for conversion to full registration, the registrant was required to submit efficacy data to establish the lowest effective rates of application for control of obliquebanded leafroller on apple and for control of European corn borer on potato. Efficacy data were submitted from a total of 11 field trials, six for oblique-banded leafroller on apple and five for European corn borer on potato. The submitted efficacy data supports the currently registered application rate of 109 g/ha as the lowest effective rate for control of obliquebanded leafroller on apple and indicate that the lowest effective rate for European corn borer on potato is 75 g/ha.

Conclusion

The PMRA has conducted a review of the available information for this application and has determined that the conversion of Entrust 80 W Naturalyte Insect Control Product from conditional to full registration is acceptable.

References

List of Studies/Information Submitted by Registrant

1387336 2006, Storage Stability and Package Corrosion Characteristics of Entrust 80W; A One-Year Study, FOR-05-001, DACO: 3.5.10 CBI

1061290 2002, Magnitude of Residue of Spinosad in Apples Following Treatment with Success 480 SC, DAS01102, DACO: 7.4.1

1412792 2005, Early season control of oblique banded leafroller on apple with GF-1640 and Success 480 SC; 2005, Trial ID: AGM05001, DACO: 10.2.3.3

1412792 2006, XDE-175 / Spinosad / Oblique-banded and Three Lined Leafroller / Summer / Apple, Trial ID: IB6DAKK1, DACO: 10.2.3.3

1412792 2004, XDE-175/Spinosad/Intrepid/OBLR/Apple, Trial ID: DAS05I04, DACO: 10.2.3.3

1412793 2004, Efficacy of Success Against Overwintering Oblique-banded Leafroller on Apple, Trial ID: DAS04I04B, DACO: 10.2.3.3

1412793 2004, Efficacy of Spinosad and XDE-175 Against Summer Generation of Oblique-banded Leafroller on Apples, Trial ID: DAS04I06A, DACO: 10.2.3 .3

1412793 2004, Efficacy of Spinosad and XDE-175 Against Summer Generation of Oblique-Banded Leafroller on Apples, Trial ID: DAS04I06B, DACO: 10.2.3.3

1446571 2003, Evaluation of Success for control of European Corn Borer in Potatoes, Trial ID: POT0323, DACO: 10.2.3.3

1446572 2003, Evaluation of Success for control of European Corn Borer in Potatoes, Trial ID: POT0324, DACO: 10.2.3.3

1446573 2004, Evaluation of Success and Entrust for the control of European Corn Borer on potatoes, Trial ID: POT0426, DACO: 10.2.3.3

1446574 2005, To determine the lowest effective rate of Spinosad to control European corn borer on potatoes, Trial ID: POT0522, DACO: 10.2.3.3

1446575 2005, Determination of the lowest effective rate of Spinosad to control European corn borer on potatoes, Trial ID: POT0523, DACO: 10.2.3.3

1412778 2004, The ORTEF Algorithm for Defining the Relationship of Transferable Turf Residues to Post-Application Dermal Exposure- Vol 1., DACO: 5.14

1412779 2004, Table 1: Summary of TTR and Rate of Dermal Exposure for Regression (RDER) Data for Studies used in the Regression Analyses, DACO: 5.14

1412780 2004, Determination of Potential Dermal Exposure to Adults and Children Reentering a Pesticide-Treated Turf Area, DACO: 5.14

1412781 2004, Appendix 2 - Residue Levels: Adjustment of Raw Analytical Values on Matrices for Recovery from Field Spikes, DACO: 5.14

1412782 2004, Appendix 3 - Transferable Turf Residue Data, DACO: 5.14

1412783 2004, Attachment 1: Data for TTR Sheets, DACO: 5.14

1412784 2004, The ORTEF Algorithm for Defining the Relationship of Transferable Turf Residues to Post-Application Dermal Exposure - Vol. 2., DACO: 5.14

1412785 2004, Attachment 23: Representative Chromatograms, Standard Curves and Spreadsheets, DACO: 5.14

1412786 2004, Appendix 8: Report for the Study "Determination of the Percent Active Ingredient in Liquid and Granular Formulations of Dithiopyr", DACO: 5.14

1412787 2003, Appendix 9: Field Phase Report for Determination of Potential Dermal Exposure to Adults and Children Reentering a Pesticide-Treated Turf Area, DACO: 5.14
1412788 2003, Attachment 1: List of Samples Collected, DACO: 5.14
1412789 2003, Attachment 2: Protocol, DACO: 5.14

ISSN: 1911-8082