

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2015-0524
Application: New end-use product chemistry: Guarantee, identity and proportion of formulants
Product: Sharda Deltamethrin 2.5 % EC Western Insecticide
Registration Number: 32447
Active ingredients (a.i.): Deltamethrin
PMRA Document Number: 2686266

Purpose of Application

The purpose of this application is to register the commercial class end-use product, Sharda Deltamethrin 2.5 % EC Western Insecticide (guarantee: 25 g/L deltamethrin), for use to control a variety of insect pests on terrestrial food and feed crops, shelterbelts, rangeland, pastures and roadsides in the prairie provinces and Peace River region of British Columbia only.

Chemistry Assessment

Sharda Deltamethrin 2.5 % EC Western Insecticide is formulated as an emulsifiable concentrate containing deltamethrin at a nominal concentration of 25 g/L. This end-use product has a density of 0.8891 g/mL and pH 6-7. The chemistry requirements for this product have been fulfilled.

Health Assessments

Sharda Deltamethrin 2.5% EC Western Insecticide is of moderate acute toxicity to rats via the oral route, and of low acute toxicity to rats via the dermal and inhalation routes. It is moderately irritating to the eye and mildly irritating to the skin of rabbits. It is a dermal sensitizer in guinea pigs.

The use of the end-use product Sharda Deltamethrin 2.5% EC Western Insecticide on labeled crops is not expected to result in potential occupational or bystander exposure over the currently registered use of deltamethrin. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data were submitted in support of the registration of the end-use product Sharda Deltamethrin 2.5% EC Western Insecticide. The use pattern of Sharda Deltamethrin 2.5% EC Western Insecticide was determined to be identical to that of two currently registered products. Therefore, the previously reviewed data was reassessed in the framework of the current application and confirmed that the use of Sharda Deltamethrin 2.5% EC Western Insecticide is not expected to result in an increase in the magnitude of deltamethrin residues in/on the treated crops. Therefore, the use of Sharda Deltamethrin 2.5% EC Western

Insecticide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No environmental concerns were identified as the proposed application rates for Sharda Deltamethrin 2.5% EC Western Insecticide are identical to two currently registered end-use products.

Value Assessment

The use pattern of Sharda Deltamethrin 2.5 % EC Western Insecticide is consistent with that of a currently registered product and the formulations of the two products are similar enough that efficacy is expected to be comparable.

Conclusion

The PMRA has completed a review of all available information in support of Sharda Deltamethrin 2.5% EC Western Insecticide, and found it sufficient to support registration.

References - List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2501060	2015, Scientific Rationale for Value for Sharda Deltamethrin 2.5 % EC Insecticide, DACO: 10.2.3.1, 10.3.2
2501037	2008, Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation Containing 2.5% Deltamethrin Stored at 54 C for 14 Days, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7 3.5.8, 3.5.9 CBI
2501038	2011, Partial Validation of the Method of Determination for Deltamethrin in Formulated Materials, DACO: 3.4.1 CBI
2501039	2011, Partial Validation of the Method of Determination for Deltamethrin in Formulated Materials, DACO: 3.4.1 CBI
2501040	2011, Partial Validation of the Method of Determination for Deltamethrin in Formulated Materials, DACO: 3.4.1 CBI
2501041	2014, Description of Formulation Process for Deltamethrin 2.5% EC, DACO: 3.2.1, 3.2.2, 3.3.1 CBI
2501048	2015, Additional Product Chemistry for Sharda Deltamethrin 2.5 % EC, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.4.2, 3.5.13, 3.5.15, 3.5.4, 3.5.5
2501049	2015, Additional Product Chemistry for Sharda Deltamethrin 2.5 % EC, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.4.2, 3.5.13, 3.5.15, 3.5.4, 3.5.5 CBI
2544296	2010, Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation Containing Deltamethrin 2.5% Stored at Ambient Temperature for 2 Years, in Compliance with Good Laboratory Practice, DACO: 3.5.10, 3.5.14, 3.5.7 CBI
2544297	2010, Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation Containing Deltamethrin 2.5% Stored at Ambient Temperature for 2 Years, in Compliance with Good Laboratory Practice, DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.7 CBI
2544298	2008, Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation Containing Deltamethrin 2.5% Stored at 54C +/-2C for 14 Days, in Compliance with Good Laboratory Practice, DACO: 3.5.10, 3.5.11, 3.5.12, 3.5.14, 3.5.7, 3.5.9 CBI
2544299	2010, Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation Containing Deltamethrin 2.5% Stored at 54C +/-2C for 14 Days, in Compliance with Good Laboratory Practice, DACO: 3.5.10, 3.5.11, 3.5.12, 3.5.14, 3.5.7, 3.5.9 CBI
2545004	2011, Deltamethrin 2.5% EC: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
2501042	2008, Acute Oral Toxicity Study in Rats with Deltamethrin EC, DACO: 4.6.1
2501043	2008, Acute Dermal Toxicity Study in Rats with Deltamethrin EC, DACO: 4.6.2
2501044	2008, Acute Inhalation Toxicity Study in Rats with Deltamethrin EC, DACO: 4.6.3

2501045	2008, Acute Eye Irritation/Corrosion Study in Rats with Deltamethrin EC, DACO: 4.6.4
2501046	2008, Acute Dermal Irritation/Corrosion Study in Rats with Deltamethrin EC, DACO: 4.6.5
2501047	2008, Contact Hypersensitivity in Albino Guinea Pigs Maximization Test with Deltamethrin EC, DACO: 4.6.6

References - Additional Information Considered

PMRA Document Number	Reference
2115788	Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. Submission #2006-0257.

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