Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 2.1, 2.3, 2.4, 2.6 Application

Application Number: 2020-4415
Application: New EP Product Chemistry- Guarantee; Identity of Formulants; Proportion of Formulants; New Combination of Technical Grade Active Ingredients
Product: Zeltera Pulse Fungicide
Registration Number: 34329
Active ingredients (a.i.): inpyrfluxam, ethaboxam, mandestrobin, metalaxyl
PMRA Document Number: 32825742

Purpose of Application

The purpose of this application was to register a new fungicide seed treatment containing inpyrfluxam, ethaboxam, mandestrobin and metalaxyl for use against seed and seedling diseases on Crop Group 6 (legume vegetables-succulent or dried).

Chemistry Assessment

Zeltera Pulse Fungicide is formulated as a suspension containing metalaxyl at 12.7 g/L, ethaboxam at 23.9 g/L, mandestrobin at 31.7 g/L, and inpyrfluxam at 15.9 g/L. This end-use product has a density of 1.06 g/cm^3 and pH of 8.39. The required chemistry data for Zeltera Pulse Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Zeltera Pulse Fungicide is of slight acute toxicity by the oral and of low acute toxicity by the dermal and inhalation routes of administration in rats. It is minimally irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

To support the use of Zeltera Pulse Fungicide on legume vegetables, a dust off study was submitted that compared the measured dust-off of Zeltera Pulse Fungicide with different seed types and formulations to allow the use of surrogate exposure studies for the risk assessment. The results of the dust-off study and the risk assessment indicated that the use of Zeltera Pulse Fungicide as a legume vegetable seed treatment is not expected to result in occupational or bystander exposures of concern relative to the registered uses of ethaboxam, mandestrobin, inpyrfluxam, and metalaxyl. Therefore, no health risks of concern to workers are anticipated, provided they follow the label directions and wear the personal protective equipment identified on the label.

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No new residue data for ethaboxam, inpyrfluxam, mandestrobin, and metalaxyl in crop group 6 (legume vegetables-succulent or dried) were submitted to support the use expansions of these active ingredients on the Zeltera Pulse Fungicide label. Previously reviewed residue data from field trials were reassessed in the framework of this application. The use directions on the Zeltera Pulse Fungicide label, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, and crop rotation restrictions are identical to the precedent end-use products.

Based on this assessment, residues of ethaboxam, inpyrfluxam, mandestrobin, and metalaxyl are not expected to be greater than that for the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposures to residues of ethaboxam, inpyrfluxam, mandestrobin, and metalaxyl are not expected to increase with the registration of Zeltera Pulse Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern of Zeltera Pulse Fungicide is within the registered use patterns for ethaboxam, inpyrfluxam, mandestrobin and metalaxyl. Risks from Zeltera Pulse Fungicide are acceptable from the environmental perspective when used according to label directions.

Value Assessment

The applicant submitted the results of efficacy trials and scientific rationales to support the registration of Zeltera Pulse Fungicide for use as a seed treatment on crop group 6 (legume vegetables-succulent or dried). Based on the results of these trials, and on the current registrations of the active ingredients, Zeltera Pulse Fungicide can be expected to control or suppress certain seed or seedling diseases on legume vegetables-succulent or dried (crop group 6) when applied as a seed treatment. The registration of Zeltera Pulse Fungicide will provide growers with a single end-use product to control a broad-spectrum of seed and seedling diseases while also providing multiple modes of action for the management of certain pathogens, which may reduce the risk of resistance development.

Conclusion

The Pest Management Regulatory Agency has conducted an assessment of the information provided and has found it sufficient to support the registration of Zeltera Pulse Fungicide.

References

PMRA No.	Reference
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3230226	2021, Shelf-Life Storage Stability and Corrosion Characteristics of V-10491 FS, DACO: 3.5.10,3.5.14
3155829	2020, V-10491 FS: Product Identity and Composition, Description of Materials Enforcement Analytical Method, Submittal of Samples, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3155830	2020, Validation of Enforcement Analytical Method for Determination of Mandestrobin, Ethaboxam, Inpyrfluxam (a.k.a. S-2399) and Metalaxyl in V-10491 FS, DACO: 3.4.1
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3155835	2020, V-10491 FS: Acute Dermal Toxicity in Rats, DACO: 4.6.2
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3155824	2019, APPENDIX 2: Trial Reports for Metalaxyl Rate for "Value Summary for Zeltera Pulse Fungicide, a Fungicide Containing Ethaboxam, Mandestrobin, Inpyrfluxam, and Metalaxyl for Control of Seed and Seedling Diseases of Crop Group 6: Legume Vegetables", DACO: 10.1,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3,10.5.1,10.5.2,10.5.3
3155820	2020, Value Summary for Zeltera Pulse Fungicide, a Fungicide Containing Ethaboxam, Inpyrfluxam, Mandestrobin, and Metalaxyl for Control of Seed and Seedling Diseases of Crop Group 6: Legume Vegetables, DACO: 10.1,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3,10.5.1,10.5.2,10.5.3
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3207859	2021, Appendix 1: Trial Reports for "Value Clarification Response for Zeltera Pulse Fungicide, a Fungicide Containing Ethaboxam, Inpyrfluxam, Mandestrobin, and Metalaxyl for Control of Seed and Seedling Diseases of Crop Group 6: Legume Vegetables", DACO: 10.1,10.2.3.1,10.2.3.3