

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

**Application Number:** 2020-4513  
**Application:** New EP Product Chemistry- Guarantee; Identity of Formulants; Proportion of Formulants; New Combination of Technical Grade Active Ingredients  
**Product:** Zeltera Fungicide Soybeans  
**Registration Number:** 34331  
**Active ingredients (a.i.):** inpyrfluxam, ethaboxam, mandestrobin, metalaxyl  
**PMRA Document Number :** 3282586

### 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 Fungicide Soybeans is formulated as a suspension containing metalaxyl at 24.6 g/L, ethaboxam at 46.0 g/L, mandestrobin at 61.4 g/L, and inpyrfluxam at 30.7 g/L. This end-use product has a density of 1.08 g/cm<sup>3</sup> and pH of 8.42. The required chemistry data for Zeltera Fungicide Soybeans have been provided, reviewed and found to be acceptable.

### Health Assessments

Zeltera Fungicide Soybeans is slightly acute toxic via the oral route and of low acute dermal and inhalation toxicity. It is minimally irritating to the eyes and skin and is not a dermal sensitizer.

To support the use of Zeltera Fungicide Soybeans on legume vegetables, a dust off study was submitted that compared the measured dust-off of Zeltera Fungicide Soybeans 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 Fungicide Soybeans 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.

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 Fungicide Soybeans label. Previously reviewed residue data from field trials were reassessed in the framework of this application. The use directions on the

Zeltera Fungicide Soybeans 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 those 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 Fungicide Soybeans 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 Fungicide Soybeans is within the registered use patterns for ethaboxam, inpyrfluxam, mandestrobin and metalaxyl. Risks from Zeltera Fungicide Soybeans 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 Fungicide Soybeans 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 Fungicide Soybeans 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 Fungicide Soybeans 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 Fungicide Soybeans.

**References**

<b>PMRA Document Number</b>	<b>Reference</b>
3156716	2020, V-10475 FS: Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Description of Formulation Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, Enforcement Analytical Method, Submittal of Samples, DACO:3.2.1,3.2.2,3.2.3,3.3.1 CBI
3156717	2020, Validation of Enforcement Analytical Method for Determination of Mandestrobin, Ethaboxam, Inpyrfluxam, and Metalaxyl in V-10475 FS, DACO: 3.4.1

3156718	2020, Physical and Chemical Properties of V-10475 FS, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3230235	2020, Physical and Chemical Properties of V-10475 FS, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3156720	2020, Summary of Acute Toxicology for Zeltera Fungicide Soybeans (V-10475 FS), DACO: 4.1
3156721	2020, V-10475 FS: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3156722	2020, V-10475 FS: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3156723	2020, V-10475 FS: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3156724	2020, V-10475 FS: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3156725	2020, V-10475 FS: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3156726	2020, V-10475 FS: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3156727	2020, Summary of Occupational Risk Assessment for Zeltera Fungicide Soybeans, DACO: 5.1, 5.2, 5.3, 5.4, 5.6
3156728	2020, Dust-Off Study in Support of Planting and Treating of Target Crops with Zeltera Fungicide Soybeans, DACO: 5.15
3155822	2020, APPENDIX 6: Trial Reports for "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
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
3156712	2020, Value Summary for Zeltera Fungicide Soybeans, 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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