

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

Application Number: 2020-4436
Application: New EP Product Chemistry- Guarantee; Identity of Formulants; Proportion of Formulants; New Combination of Technical Grade Active Ingredients
Product: V-10504 FS Fungicide
Registration Number: 34330
Active ingredients (a.i.): inpyrfluxam, ethaboxam, metalaxyl
PMRA Document Number: 3282582

Purpose of Application

The purpose of this application was to register a new fungicide seed treatment containing inpyrfluxam, ethaboxam and metalaxyl, for use against seed and seedling diseases on corn (field, sweet and popcorn) and crop group 6 (legume vegetables-succulent or dried).

Chemistry Assessment

V-10504 FS Fungicide is formulated as a suspension containing metalaxyl at 30.7 g/L, ethaboxam at 57.5 g/L, inpyrfluxam at 38.3 g/L. This end-use product has a density of 1.06 g/cm³ and pH of 7.77. The required chemistry data for V-10504 FS Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

V-10504 FS Fungicide was of slight acute toxicity in rats via the oral route. It was of low acute toxicity via the dermal and inhalation routes of exposure. It was minimally irritating to the eyes and non-irritating to the skin and was not a skin sensitizer.

To support the use of V-10504 FS Fungicide on corn and legume vegetables, a dust off study was submitted that compared the measured dust-off of V-10504 FS 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 V-10504 FS Fungicide as a corn and legume vegetable seed treatment is not expected to result in occupational or bystander exposures of concern relative to the registered uses of ethaboxam, 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, and metalaxyl in crop group 6 (legume vegetables-succulent or dried) or corn (field, sweet and pop) were submitted to support the use expansions of these active ingredients on the V-10504 FS Fungicide label.

Previously reviewed residue data from field trials were reassessed in the framework of this application. The use directions on the V-10504 FS 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, 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, and metalaxyl are not expected to increase with the registration of V-10504 FS 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 V-10504 FS Fungicide is within the registered use patterns for ethaboxam, inpyrfluxam and metalaxyl. Risks from V-10504 FS Fungicide are acceptable from the environmental perspective when used according to label directions.

Value Assessment

The applicant submitted a scientific rationale to support the registration of V-10504 FS Fungicide for use as a seed treatment on corn, crop group 6 (legume vegetables-succulent or dried). Based on the current registrations of the active ingredients, V-10504 FS Fungicide can be expected to control or suppress certain seed or seedling diseases on corn and legume vegetables-succulent or dried (crop group 6) when applied as a seed treatment. The registration of V-10504 FS 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 V-10504 FS Fungicide.

References

PMRA

Document

Number	Reference
3156054	2020, V-10504 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
3156056	2020, Validation of Enforcement Analytical Method for Determination of Ethaboxam, Inpyrfluxam, and Metalaxyl in V-10504 FS, DACO: 3.4.1
3156057	2020, Physical and Chemical Properties of V-10504 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
3230229	2021, Shelf-Life Storage Stability and Corrosion Characteristics of V-10504 FS, DACO: 3.5.10, 3.5.14
3156059	2020, Summary of Acute Toxicology for V-10504 FS Fungicide, DACO: 4.1
3156060	2020, V-10504 FS: Acute Oral Toxicity- Up-And-Down Procedure in Rats, DACO: 4.6.1
3156061	2020, V-10504 FS: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3156062	2020, V-10504 FS: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3156063	2020, V-10504 FS: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3156064	2020, V-10504 FS: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3156065	2020, V-10504 FS: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3156067	2020, Summary of Occupational Risk Assessment for V-10504 FS Fungicide, DACO: 5.1, 5.2, 5.3, 5.4, 5.6
3156068	2020, Dust-Off Study in Support of Planting and Treating of Target Crops with V-10504 FS Fungicide, DACO: 5.15
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
3156038	2020, Value Summary for V-10504 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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