

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 Application

Application Number: 2023-1295
Application: New End-use Product (Product Chemistry) - Guarantee, Identity of Formulants, Proportion of Formulants; New Product Label - Application Rate Increase or Decrease
Product: V-10522 FS
Registration Number: 35174
Active ingredients (a.i.): Ethaboxam, inpyrfluxam, metalaxyl
PMRA Document Number: 3603077

Purpose of Application

The purpose of this application is to register a new end-use product, V-10522 FS, for use as a seed treatment against certain seed and seedling diseases on corn (field, sweet and popcorn), and Crop Group 6 (Legume Vegetables, succulent and dried).

Chemistry Assessment

V-10522 FS is formulated as a suspension containing ethaboxam at a concentration of 115.0 g/L, inpyrfluxam at a concentration of 76.7 g/L and metalaxyl at a concentration of 61.6 g/L. This end-use product has a density of 1.09 g/mL and pH of 7.69 (1% w/v). The required chemistry data for V-10522 FS have been provided, reviewed and found to be acceptable.

Health Assessments

V-10522 FS is moderately toxic via the oral route, and of low acute toxicity via the dermal and inhalation routes of exposure. V-10522 FS is minimally irritating to the eye and slightly irritating to the skin, and is not a dermal sensitizer.

The use pattern of V-10522 FS is within the registered use patterns for ethaboxam, inpyrfluxam, and metalaxyl. No health risks of concern were identified for workers treating seed commercially or planting V-10522 FS treated seed if they wear the appropriate personal protective equipment and follow all label directions.

No new residue data for ethaboxam, inpyrfluxam, and metalaxyl in Crop Group 6 (Legume Vegetables (Succulent or Dried), including soybeans), or corn (field, sweet and pop) were submitted. Previously reviewed residue data from field trials were reassessed in the framework of this application.

The use directions on the V-10522 FS label, including the target crops, method (seed treatment) and rates are comparable to the registered precedent end-use product. Based on this assessment, residues of ethaboxam, inpyrfluxam, 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 (MRLs). Consequently, dietary exposures to residues of ethaboxam, inpyrfluxam, and metalaxyl are not expected to increase with the registration of V-10522 FS 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-10522 FS is within the registered use patterns for ethaboxam, inpyrfluxam, and metalaxyl. Risks from V-10522 FS are acceptable from the environmental perspective when used according to label directions.

Value Assessment

The applicant submitted a scientific rationale based on current registrations for precedent products to support the registration of V-10522 FS for use as a seed treatment on corn, and dried and succulent legume vegetables, including soybeans. The rationale provides sufficient scientific support for the claim that V-10522 FS can be expected to manage labeled seed or seedling diseases on corn, legume vegetables and soybeans when applied as a seed treatment. The registration of V-10522 FS will provide growers with an additional end-use product option to control a broad-spectrum of seed and seedling diseases. The multiple modes of action in this seed treatment may also mitigate the risk of resistance development in some of the labeled pathogens.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of V-10522 FS.

References

PMRA Document Number	Reference
2111203	2011, Value Summary for V-10208 3.2 FS Fungicide (Ethaboxam), a Seed Treatment Providing Systemic Fungicide Protection Against Seed and Seedling Diseases Caused by Pythium, Phytophthora, and Aphanomyces Across a Wide Range of Crops, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.5.1, 10.5.2, 10.5.3, 10.5.4
2819652	2017, Value Summary for S-2399 3.2 FS Fungicide, a Seed Protectant Containing Inpyrfluxam, for Control of Seed and Seedling Diseases of canola, cereals, legumes, corn, soybeans and sugar beets, DACO:10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.5.1, 10.5.2, 10.5.3, 10.5.4
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
3449993	2023, Value Summary for V-10522 FS, a Seed Protectant Containing Inpyrfluxam, Ethaboxam, and Metalaxyl for Control of Seed and Seedling Diseases of Corn and Crop Group 6 - Legume Vegetables, including Soybeans, 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
3449994	2023, APPENDIX 1: Seed Safety Data for "Value Summary for V-10522 FS Fungicide, a Seed Protectant Containing Inpyrfluxam, Ethaboxam, and Metalaxyl for Control of Seed and Seedling Diseases of Corn and Crop Group 6 - Legume Vegetables, including Soybeans ", 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
3450003	2023, V-10522: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3450004	2023, V-10522: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3450005	2023, V-10522: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3450006	2023, V-10522: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3450007	2023, V-10522: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3450008	2023, V-10522: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3449998	2023, V-10522 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
3449999	2023, Validation of Enforcement Analytical Method for Determination of Inpyrfluxam, Ethaboxam and Metalaxyl in V-10522 FS, DACO: 3.4.1
3450000	2023, Physical and Chemical Properties of V-10522 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

PMRA Document Number	Reference
3450001	2023, Accelerated Shelf-Life Storage Stability and Corrosion Characteristics of V-10522 FS, DACO: 3.5.10, 3.5.14, 3.5.5
3450010	2022, Dust-Off Study in Support of Planting and Treating of target Crops with V-10522 Fungicide, DACO: 5.15

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