



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2019-3227
Application: New EP Product Chemistry-New Combination of Technical Grade Active Ingredients
Product: INTEGO Pulse Fungicide
Registration Number: 34011
Active ingredients (a.i.): Ethaboxam, mandestrobin and metalaxyl
PMRA Document Number : 3186496

Purpose of Application

The purpose of this submission was to register a new fungicide seed treatment product, INTEGO Pulse Fungicide, containing ethaboxam, mandestrobin and metalaxyl, for use on Crop Group 6 (Legume Vegetables (Succulent and Dried)) for the control or suppression of early season root diseases.

Chemistry Assessment

INTEGO Pulse Fungicide is formulated as a suspension containing metalaxyl at a concentration of 13.3 g/L, ethaboxam at a concentration of 24.9 g/L, and mandestrobin at a concentration of 33.2 g/L. This end-use product has a density of 1.06 g/cm³ and pH of 7.79. The required chemistry data for INTEGO Pulse Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

INTEGO Pulse Fungicide is of low acute oral, dermal and inhalation toxicity in rats. It is mildly irritating to the eyes and minimally irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

The use of INTEGO 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 and mandestrobin. An assessment of exposure to metalaxyl was conducted for commercial and on-farm treaters, and planters. No 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, mandestrobin or metalaxyl on Crop Group 6 (Legume Vegetables) were submitted to support the registration of the INTEGO Pulse Fungicide label. Previously reviewed residue data from field trials were reassessed in the framework of this petition. The dietary exposure assessments on file are considered adequate to cover the residues of ethaboxam, mandestrobin and metalaxyl expected from the use of this new product. No health risks of concern have been identified for any segment of the population

including infants, children, adults and seniors.

Environmental Assessment

After a scientific review of the available information, the PMRA has concluded that the environmental risks associated with the use of INTEGO Pulse Fungicide, containing the active ingredients ethaboxam, mandestrobin, and metalaxyl are acceptable when used according to the label directions.

Value Assessment

The results of efficacy trials and rationales were submitted to support the registration of INTEGO Pulse Fungicide for use on legume vegetables. Based on the weight of evidence of the value information, INTEGO Pulse Fungicide is expected to control or suppress the listed diseases on legume vegetables when applied at 300 mL/100 kg seed. The registration of INTEGO Pulse Fungicide will provide a broad spectrum seed treatment fungicide which will also provide multiple modes of action to control seed rot/pre-emergence damping-off caused by *Pythium* spp. on legume vegetables.

Conclusion

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

References

PMRA No.	Reference
3010112	2019, INTEGO Pulses Fungicide: 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
3010113	2019, INTEGO Pulses Fungicide: 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
3010114	2019, Validation of Enforcement Analytical Method for Determination of Mandestrobin, Ethaboxam, and Metalaxyl in V-10465 0.598 FS Fungicide, DACO: 3.4.1
3010115	2019, Physical and Chemical Properties of V-10465 0.598 FS Fungicide, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7
3125034	2020, Shelf-Life Storage Stability and Corrosion Characteristics of V-10465 0.598 FS Fungicide, DACO: 3.5.10,3.5.14
3010117	2019, Waiver of Acute Toxicology for INTEGO Pulse Fungicide, DACO: 4.1,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6

3034107	2019, V-10465 0.598 FS Fungicide: Acute Oral Toxicity Up-And-Down Procedure in Rats, DACO: 4.6.1
3034108	2019, V-10465 0.598 FS Fungicide: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3034109	2019, V-10465 0.598 FS Fungicide: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3034110	2019, V-10465 0.598 FS Fungicide: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3034111	2019, V-10465 0.598 FS Fungicide: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3034112	2019, V-10465 0.598 FS Fungicide: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3010106	2019, Value Summary for INTEGO Pulse Fungicide, a Fungicide Containing Ethaboxam, 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
3010108	2019, APPENDIX 2: Trial Reports for Metalaxyl Rate for "Value Summary for INTEGO Pulse Fungicide, a Fungicide Containing Ethaboxam, 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
3010110	2019, APPENDIX 3- Seed Safety Data for "Value Summary for INTEGO Pulse Fungicide, a Fungicide Containing Ethaboxam, 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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