

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2018-3290
Application: New End-Use Product, Product Chemistry – New Combination of Technical Grade Active Ingredients
Product: INTEGO SUITE Canola Seed Protectant
Registration Number: 33532
Active ingredients (a.i.): Ethaboxam, metconazole, mandestrobin and metalaxyl
PMRA Document Number: 3027526

Purpose of Application

The purpose of this application was to register INTEGO SUITE Canola Seed Protectant, an end-use product containing a new combination of active ingredients, for use as a fungicidal seed treatment on Crop Group 20A (rapeseed (canola varieties only)).

Chemistry Assessment

INTEGO SUITE Canola Seed Protectant is formulated as a suspension containing ethaboxam at a concentration of 10.21 g/L, mandestrobin at a concentration of 13.65 g/L, metalaxyl at a concentration of 5.44 g/L, and metconazole at a concentration of 2.04 g/L. This end-use product has a density of 1.23 g/cm³ and pH of 7.1. The required chemistry data for INTEGO SUITE Canola Seed Protectant have been provided, reviewed and found to be acceptable.

Health Assessments

INTEGO SUITE Canola Seed Protectant is of low acute oral, dermal and inhalation toxicity in rats. It is minimally irritating to the eye and skin of the rabbit. It is not a skin sensitizer in mice.

An assessment was performed for commercial treaters and planters that may be exposed to INTEGO SUITE Canola Seed Protectant. The product should not result in risks of concern to the active ingredients ethaboxam, mandestrobin, metconazole, and metalaxyl. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

No residue data for ethaboxam, mandestrobin, metalaxyl and metconazole on Crop Subgroup 20A (Rapeseed (canola varieties only)) were submitted to support the registration of INTEGO SUITE Canola Seed Protectant label. Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this application.

The dietary exposure assessments on file are considered adequate to cover the residues of ethaboxam, mandestrobin, metalaxyl and metconazole expected from the use of this product. No health risks of concern have been identified for any segment of the population including infants, children, adults and seniors.

Environmental Assessment

The registration of this product is supported from an environmental perspective provided that environmental risk reduction and hazard statements included on the INTEGO SUITE Canola Seed Protectant label are followed.

Value Assessment

The results of efficacy trials and a rationale were submitted to support the registration of INTEGO SUITE Canola Seed Protectant for use on canola/rapeseed (subgroup 20A). The sum of the value information provided demonstrated that management of seed and seedling diseases can be expected using a seed treatment application of INTEGO SUITE Canola Seed Protectant. INTEGO SUITE Canola Seed Protectant will provide growers with a single seed treatment product to manage seed and seedling diseases on canola/rapeseed (subgroup 20A). Therefore, the registration of INTEGO SUITE Canola Seed Protectant is supported from a value perspective.

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 SUITE Canola Seed Protectant.

References

PMRA Document Number	References
2905547	2018, Description of Starting Materials, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI
2905548	2018, Validation of Enforcement Analytical Method for Determination of Mandestrobin, Ethaboxam, Metalaxyl, and Metconazole in INTEGO SUITE Canola Seed Protectant, DACO: 3.4.1
2905550	2017, Physical and Chemical Properties of INTEGO SUITE Canola Seed Protectant, 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
2955785	2019, Shelf-Life Storage Stability and Corrosion Characteristics of INTEGO SUITE Canola Seed Protectant, DACO: 3.5.10,3.5.14
2905551	2018, V-10423: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
2905552	2018, V-10423: Acute Dermal Toxicity in Rats, DACO: 4.6.2
2905553	2018, V-10423: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2905554	2018, V-10423: Primary Eye Irritation in Rabbits, DACO: 4.6.4
2905555	2018, V-10423: Primary Skin Irritation in Rabbits, DACO: 4.6.5
2905556	2018, V-10423: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2914294	2018, Value Summary for INTEGO SUITE Canola Seed Protectant, a Fungicide Containing Ethaboxam, Mandestrobin, Metconazole and Metalaxyl for Control of Seed and Seedling Diseases of Crop Subgroup 20A, including Canola", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3
2914296	2018, Appendix 1 - Trial Reports for "Value Summary for INTEGO SUITE Canola Seed Protectant, a Fungicide Containing Ethaboxam, Mandestrobin, Metconazole and Metalaxyl for Control of Seed and Seedling Diseases of Crop Subgroup 20A, including Canola", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3
2905578	2018, Appendix 2 - Metalaxyl Efficacy Trial Reports for "Value Summary for INTEGO SUITE Canola Seed Protectant, a Fungicide Containing Ethaboxam, Mandestrobin, Metconazole and Metalaxyl for Control of Seed and Seedling Diseases of Crop Subgroup 20A, including Canola", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3

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