

Evaluation Report for Category B, Subcategory B.2.1, 2.6 Application

Application Number: 2016-1868

Application: New / Changes EP or MA Product Chemistry-Guarantee

New / Changes EP or MA Product Chemistry-New combination of

Technical Grade Active Ingredients

Product name: INTEGO SUITE Cereals OF

Registration Number: 34326

Active ingredients (a.i.): Ethaboxam, metconazole, metalaxyl, clothianidin

PMRA Document Number: 2662599

Purpose of Application

The purpose of this application was to register a new seed treatment product, INTEGO SUITE Cereals OF, for use on wheat to provide suppression of wireworm feeding and protection against certain seed- and soil-borne diseases.

Chemistry Assessment

INTEGO SUITE Cereals OF is formulated as a suspension containing clothianidin, ethaboxam, metalaxyl, and metconazole at nominal concentrations of 29.5 g/L, 14.7 g/L, 8.82 g/L and 4.41 g/L, respectively. This end-use product has a density of 1.05 g/mL and pH of 5.97. The required chemistry data for INTEGO SUITE Cereals OF have been provided, reviewed and found to be acceptable.

Health Assessments

The end-use product was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was mildly irritating to the skin, minimally irritating to the eyes, and was not a skin sensitizer when tested in the local lymph node assay.

The use of the new end-use product on wheat seeds is not expected to result in potential occupational or bystander exposure over the registered uses of clothianidin, ethaboxam, metalaxyl and metconazole. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for clothianidin, ethaboxam, metconazole and metalaxyl in wheat were submitted to support the registration of INTEGO SUITE Cereals OF for use as a seed treatment on wheat. No new data are required given that the use pattern, including crop, application timing, rate and restrictions are the same as those on currently registered end-use products containing the above active ingredients.



Based on this assessment, dietary exposure to clothianidin, ethaboxam, metconazole or metalaxyl is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of INTEGO SUITE Cereals OF for seed treatment use on wheat is supported from an environmental perspective as the application rates, use description and environmental label language is similar to the registered uses of the same active ingredients. Therefore, the use of these same active ingredients as a combined product does not present an unacceptable risk to the environment. The environmental label statements were updated to reflect the risk mitigation measures in the recent re-evaluation decisions RVD2019-05 (Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation) and SRD2021-03 (Special Review Decision: Clothianidin Risk to Aquatic Invertebrates).

Value Assessment

A scientific rationale was provided in support of the claims. Since the activity of all three fungicide active ingredients against certain pathogens are already well-established, the value assessment focuses mainly on the value of the addition of ethaboxam with metalaxyl in INTEGO SUITE Cereals OF, for use on wheat to provide protection against *Pythium* spp. Metalaxyl has been considered as one of the most effective chemicals to control *Pythium* diseases in many crops and plants since its introduction. However, after many years of extensive use, resistance in *Pythium* spp. to metalaxyl has been documented in various crops.

Because of their different mobility within seedlings, the mixture of metalaxyl and ethaboxam will provide a fuller protection of wheat seedlings from *Pythium* infection. In addition, ethaboxam will provide protection for wheat seedlings against species or strains of *Pythium* not being adequately controlled due to metalaxyl-insensitivity in the *Pythium* populations in fields. INTEGO SUITE Cereals OF will provide Canadian growers a novel ready-to-use product to manage multiple seed- and soil-borne fungal diseases in wheat.

The applicant submitted a rationale extrapolating from the registered use pattern of clothianidin on wheat to support suppression and control claims against wireworms. It is expected that INTEGO SUITE Cereals OF will provide suppression of wireworms on wheat at the labelled application rate. Based on the rationale and precedent claims, the registration of INTEGO SUITE Cereals OF is supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the registration of this new end-use product.

References

PMRA No.	References
2650076	2016, Justification of Value for INTEGOTM SUITE Cereals OF Seed Protectant,
	DACO: 10.1, 10.2.1, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5
2628323	2016, Value Summary for INTEGOTM SUITE Cereals OF Seed Protectant, a
	Ready-To-Use Systemic Insecticide Plus Fungicide Seed Treatment Product For
	Use on Wheat to Provide Suppression of Wireworm Feeding and Protection
	Against Seed- and Soil-borne Diseases, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1,
	10.3, 10.3.1, 10.3.2, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.7.1, 10.7.2
2628324	2016, APPENDIX 1: Trial Reports for "Value Summary for INTEGO TM SUITE
	Cereals OF Seed Protectant, a Ready-To-Use Systemic Insecticide Plus Fungicide
	Seed Treatment Product For Use on Wheat to Provide Suppression of Wireworm
	Feeding and Protection Against Seed- and Soil-borne Diseases", DACO: 10.1,
	10.2.1, 10.2.2, 10.2.3.1, 10.3, 10.3.1,10.3.2, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4,
	10.7.1, 10.7.2
2628334	2016, V-10403: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO:
	4.6.1
2628335	2016, V-10403: Acute Dermal Toxicity in Rats, DACO: 4.6.2
2628336	2016, V-10403: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2628337	2016, V-10403: Primary Eye Irritation in Rabbits, DACO: 4.6.4
2628338	2016, V-10403: Primary Skin Irritation in Rabbits, DACO: 4.6.5
2628339	2016, V-10403: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2628341	2016, INTEGO SUITE Cereals OF: Product Identity, Composition, and Analysis,
	DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4.2
2628342	2016, INTEGO SUITE Cereals OF: Product Identity, Composition, and Analysis,
	DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4.2 CBI
2628333	2015, Validation of Enforcement Analytical Method for Determination of
	Clothianidin, Ethaboxam, Metalaxyl, and Metconazole in V-10403, DACO: 3.4.1
2628340	2016, Physical and Chemical Properties of INTEGO SUITE Cereals OF, DACO:
	3.5,3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9
2737864	2017, Shelf-Life Storage Stability and Corrosion Characteristics of INTEGO
	SUITE Cereals OF

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