Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.1, 3.12 Application

Application Number: 2019-0421
Application: Changes to Product Label; New Site/Host and Rate Increase
Product: Xemium 325 Fungicide Seed Treatment
Registration Number: 30564
Active ingredient (a.i.): Fluxapyroxad
PMRA Document Number: 3085900

Purpose of Application

The purpose of this application was to amend the label of Xemium 325 Fungicide Seed Treatment to add claims for control of various seed and seedling diseases on rapeseeds (Crop Subgroup (CSG) 20A) at an increased application rate.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

An assessment was performed for commercial treaters and planters that may be exposed to Xemium 325 Fungicide Seed Treatment. 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 fluxapyroxad were submitted to support the amendment to the registration of Xemium 325 Fungicide Seed Treatment for use as a seed treatment on rapeseeds (CSG 20A). Previously reviewed residue data from field trials conducted with fluxapyroxad in/on canola were re-assessed in the framework of this application.

Residues in/on CSG 20A and animal commodities will be covered by the currently established MRLs for fluxapyroxad. Consequently, the dietary exposure to residues of fluxapyroxad is not expected to increase with the amendment to the registration of Xemium 325 Fungicide Seed Treatment and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

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Environmental Assessment

Despite an increase in the application rate on a per 100 kg seed basis, the application rate, on a g a.i./ha rate, for the use on CSG 20A seed is less than the currently registered rate for soybean seed. This difference is due to differences in seeding rates between soybean seed and seeds from CSG 20A, when expressed in grams of a.i. per hectare. The expansion of Xemium 325 Fungicide Seed Treatment to CSG 20A therefore falls within the current use pattern and does not represent an increase in application rates based on a grams of a.i. per hectare basis. The use expansion of Xemium 325 Fungicide Seed Treatment to CSG 20A therefore does not represent an increase in risk to earthworms, terrestrial invertebrates, pollinators, terrestrial plants, aquatic invertebrates or aquatic plants. The risks associated with this use to non-target organisms other than birds and mammals are acceptable.

A risk assessment was conducted for birds and mammals based on the use pattern for seed treatment of CSG 20A seed. The level of concern (LOC) for acute exposure was not exceeded for birds or mammals. The chronic LOC was not exceeded for mammals; however, it was slightly exceeded for small to medium sized birds identifying a potential risk from chronic exposure. Risk mitigation statements are required on the product label in order to mitigate the risk to non-target birds.

When the directions for use are followed, the risks to non-target organisms from the use of Xemium 325 Fungicide Seed Treatment to control various diseases on CSG 20A seed are acceptable from an environmental viewpoint.

Value Assessment

Results from six field and eight greenhouse efficacy trials showed that application of Xemium 325 Fungicide Seed Treatment to canola seed controlled seed rot / pre-emergent damping-off, seedling blight and root rot (*Fusarium avenaceum*, *Rhizoctonia solani*) and improved yields of canola. Value information derived from canola trials was deemed representative of Xemium 325 Fungicide Seed Treatment performance on rapeseed, CSG 20A (borage, crambe, cuphea, echium, flax seed, gold of pleasure, hare's ear mustard, lesquerella, lunaria, meadowfoam, milkweed, mustard seed, oil radish, poppy seed, rapeseed, sesame, sweet rocket, cultivars and/or hybrids of these). A higher application rate range on rapeseeds, CSG 20A, compared to the rate range registered for soybean will provide more effective disease control. A claim to control seed rot / pre-emergent damping-off, seedling blight and root rot on rapeseed, CSG 20A by Xemium 325 Fungicide Seed Treatment was supported by efficacy trial results and shown to have value.

Seed and seedling diseases reduce plant stand, increase weed pressure and reduce crop yields. Registration of Xemium 325 Fungicide Seed Treatment to control these diseases on rapeseeds, (CSG 20A), will provide growers with an effective and targeted tool for disease management.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of Xemium 325 Fungicide Seed Treatment for control of various seed and seedling diseases on rapeseeds (CSG 20A).

References

PMRA Document Number	Reference
2956868	2019, Xemium 325 a Fungicide Seed Treatment for Use in Crop Subgroup 20A, DACO: 10.1
2956873	2019, Raw Data Abstracts, DACO: 10.2.3.2(D),10.3.2(B)
2956874	2019, Summary Tables Efficacy and Crop Tolerance, DACO: 10.2.3.1,10.3.1
3045967	2019, Part 10 Clarification Response, DACO: 10.1
3045968	2019, GH CAN8 Canola Rhizoctonia Report Final 1, DACO: 10.2.3.2(D)

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