Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2019-6082
Application: New EP Product Chemistry - Identity and Proportion of Formulants
Product: F2971aa Fungicide
Registration Number: 33982
Active ingredients (a.i.): Fluoxastrobin, Tetraconazole
PMRA Document Number: 3177222

Purpose of Application

The purpose of this application was to register F2971aa Fungicide, a new end-use product (EP) for use on wheat (spring, durum, winter), barley, corn (field and seed), Crop Subgroup 6C (Dried Shelled Pea and Bean, except soybean) and Crop Subgroup 20A (Rapeseeds, revised) to control various diseases.

Chemistry Assessment

F2971aa Fungicide is formulated as a suspoemulsion containing fluoxastrobin and tetraconazole each at a concentration of 100 g/L. This end-use product has a density of 1.06 g/mL and pH of 8.58 for a 1% dilution. The required chemistry data for F2971aa Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

F2971aa Fungicide is of low acute toxicity via the oral, dermal, and inhalation routes in rats. It is mildly irritating to the eyes and to the skin of rabbits. F2971aa Fungicide is a potential dermal sensitizer in mice.

The use of F2971aa Fungicide is not expected to result in potential occupational or bystander exposure over the registered use of fluoxastrobin and tetraconazole. 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 fluoxastrobin or tetraconazole were submitted to support the registration of these actives on the F2971aa Fungicide label. Previously reviewed residue data from field trials conducted in/on wheat, barley, corn, dry pea and bean, and canola were reassessed in the framework of this application. In addition, processing studies were also reassessed to determine the potential for concentration of residues of fluoxastrobin and tetraconazole into processed commodities.

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Following the reassessment of all available data, residues at the current MRLs of fluoxastrobin and tetraconazole for the crops and livestock commodities relevant to the current application will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern of F2971aa Fungicide is identical to the use pattern registered for the precedent product. The formulation does not contain any formulants and/or contaminants that require environmental risk mitigation measures or management. The label includes all the required environmental precautions, hazards and directions for use statements, including the spray buffer zones information, which adequately mitigates risks to the environment. Therefore, environmental risk is acceptable when F2971aa Fungicide is used according to the label directions.

Value Assessment

Value information was submitted in the form of data generated in five field trials in which the efficacy of F2971aa Fungicide was directly compared to that of a registered precedent product for particular crop-disease combinations. Based on these data, it was concluded that F2971aa Fungicide is biologically equivalent to the precedent product when applied at the same rate of active ingredient. Therefore, all disease claims included on the precedent product label are supported for extrapolation to the F2971aa Fungicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register F2971aa Fungicide.

References

PMRA Document Number	Reference
3048462	2019, Additional Product Chemistry for F2971aa Fungicide, DACO: 3.1.1, 3.1.2, 3.5.4, 3.5.5 CBI
3048463	2019, F2971aa: Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
3048464	2019, F2971aa: Physical Properties, DACO: 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
3048465	2018, Method Validation for F2969aa Fungicide, DACO: 3.4.1 CBI
3048466	2019, F2971aa Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits - Confidential Attachment, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3048467	2019, F2971aa Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0, 3.1, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4, 3.4.1 CBI
3048470	2019, F2971aa: Acute Oral Toxicity Up-And-Down Procedure in Rats, DACO: 4.6.1
3048472	2019, F2971aa: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3048473	2019, F2971aa: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3048474	2019, F2971aa: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3048475	2019, F2971aa: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3048476	2019, F2971aa: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3048491	2019, Efficacy of ARY-0473-044 Formulations in Corn, DACO: 10.2.3.3(D)
3048492	2019, Efficacy of ARY-0473-044 Formulations in Pulses, DACO: 10.2.3.3(D)
3048493	2019, Efficacy of ARY-0473-044 Formulations in Peas., DACO: 10.2.3.3(D)
3048494	2019, Efficacy of Zolera FX on Cereal Leaf Diseases, DACO: 10.2.3.3(D)
3048495	2019, Efficacy of Zolera FX on Cereal Leaf Diseases, DACO: 10.2.3.3(D)