Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2019-6081
Application: New EP Product Chemistry – Identity and Proportion of Formulants
Product: F2969aa Fungicide
Registration Number: 33981
Active ingredients (a.i.): Fluoxastrobin, Tetraconazole
PMRA Document Number: 3177212

Purpose of Application

The purpose of this application was to register F2969aa 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

F2969aa Fungicide is formulated as a suspension containing fluoxastrobin and tetraconazole each at 200 g/L. This end-use product has a density of 1.0664– 1.0665 g/mL and pH of 7.21 for a 1% suspension. The required chemistry data for F2969aa Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

F2969aa Fungicide is of low acute toxicity via the oral, dermal, and inhalation routes in rats. It is mildly irritating to the eyes and slightly irritating to the skin of rabbits. F2969aa Fungicide is a potential dermal sensitizer in mice.

The use of F2969aa 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 F2969aa 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 F2969aa 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 F2969aa 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 F2969aa Fungicide was directly compared to that of a registered precedent product for particular crop-disease combinations. Based on these data, it was concluded that F2969aa Fungicide is biologically equivalent to the precedent product. Therefore, all disease claims included on the precedent product label are supported for extrapolation to the F2969aa Fungicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register F2969aa Fungicide.

References

PMRA Document Number	Reference
3048417	2019, Additional Product Chemistry for F2969aa Fungicide, DACO: 3.1.1, 3.1.2, 3.5.4, 3.5.5 CBI
3048418	2019, F2969aa: Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
3048419	2019, F2969aa 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
3048420	2019, F2969aa 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
3048448	2019, F2969aa: 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
3048449	2018, Method Validation for F2969aa Fungicide, DACO: 3.4.1 CBI
3048423	2019, F2969aa: Acute Oral Toxicity Up-And-Down Procedure in Rats, DACO: 4.6.1
3048424	2019, F2969aa: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3048425	2019, F2969aa: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3048426	2019, F2969aa: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3048427	2019, F2969aa: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3048428	2019, F2969aa: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3048442	2019, Efficacy of ARY-0473-044 Formulations in Corn, DACO: 10.2.3.3(D)
3048443	2019, Efficacy of ARY-0473-044 Formulations in Pulses, DACO: 10.2.3.3(D)
3048444	2019, Efficacy of ARY-0473-044 Formulations in Peas., DACO: 10.2.3.3(D)
3048445	2019, Efficacy of Zolera FX on Cereal Leaf Diseases, DACO: 10.2.3.3(D)
3048446	2019, Efficacy of Zolera FX on Cereal Leaf Diseases, DACO: 10.2.3.3(D)