



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2017-7850
Application: New EP Chemistry-New combination of Technical Grade Active Ingredients
Product: Batalium
Registration Number: 33372
Active ingredients (a.i.): flucarbazone, fluroxypyr, bromoxynil and MCPA, present as esters
PMRA Document Number: 2947278

Purpose of Application

The purpose of this application was to register the end-use product Batalium for post-emergence application on wheat (spring, durum, & winter) for control of grass and broadleaf weeds in the Prairie Provinces and interior of British Columbia. This product represents a new mixture of active ingredients.

Chemistry Assessment

Batalium is formulated as a suspension containing flucarbazone (present as flucarbazone-sodium) at a concentration of 20.4 g/L, fluroxypyr (present as 1-methylheptyl ester) at a concentration of 90.5 g/L, bromoxynil (present as octanoate ester) at a concentration of 241 g/L, and MCPA (present as 2-ethylhexyl ester) at a concentration of 241 g/L. This end-use product has a density of 1.18 g/mL and pH of 4.98. The required chemistry data for Batalium have been provided, reviewed and found to be acceptable.

Health Assessments

Batalium is of moderate acute toxicity via the oral route and of low acute toxicity via the dermal and inhalation routes based on studies in rats, and slightly irritating to the skin and mildly irritating to the eye based on studies in rabbits. Batalium is a potential dermal sensitizer based on results of a local lymph node assay in mice.

The use of Batalium on wheat (spring, durum and winter) is not expected to result in potential occupational or bystander exposure over the registered use of bromoxynil, fluroxypyr, flucarbazone and MCPA. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue data were submitted for bromoxynil, flucarbazone, fluroxypyr or MCPA to support the registration of Batalium. Given that the use directions for Batalium on wheat (spring, winter and durum), including the timing, method and rate of application, pre-harvest interval, grazing restrictions and crop rotation restrictions are similar to currently registered

end-use products, residues in/on treated wheat commodities will not increase and will be covered under the maximum residues limits currently established in wheat at 0.5 ppm for fluroxypyr, 0.05 ppm for bromoxynil, 0.01 ppm for flucarbazone and 0.03 ppm for MCPA, and in wheat bran at 0.04 ppm for MCPA. As such, exposure in the diet as a result of this action will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The maximum label rates for Batalium are within the currently registered rates for all four active ingredients and safener. The use of Batalium following label instructions is not expected to increase environmental exposure to the four actives and safener over what is currently registered. A label review was conducted and updated label statements are required on the Batalium label.

Value Assessment

The co-formulation of flucarbazone, fluroxypyr, bromoxynil and MCPA will provide multiple modes of action to control both broadleaf and grassy weeds in wheat, helping with resistance management and residual weed control.

Value information submitted for review consisted of data from replicated field trials and scientific rationales including extrapolations from registered uses. Based on the weight of evidence, the registration of Batalium is supported from a value standpoint.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support the registration of the end-use product Batalium.

References

Studies/Information Provided by Applicant/Registrant

PMRA Document Number	References
2833730	2017, X1973 AB Herbicide: Storage Stability and Corrosion Characteristics, DACO: 3.5,3.5.10,3.5.14
2833731	2017, X1973 AB Herbicide: Physical Properties, 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
2833732	2017, Method Validation for X1973 AB Herbicide, DACO: 3.4.1
2833733	2017, X1973 AB Herbicide 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: 3.0,3.1,3.2,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2
2833734	2017, X1973 AB Herbicide 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: 3.0,3.1,3.2,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2 CBI
2833742	2017, BATALIUM Value Data Summary 2017, DACO: 10.2.3,10.2.3.1,10.3.1
2833743	2017, Active Ingredients: Flucarbazone sodium, Fluroxypyr, MCPA and Bromoxynil VALUE SUMMARY TO SUPPORT BATALIUM FOR CONTROL OF BROADLEAF AND GRASS WEEDS IN SPRING AND WINTER WHEAT, DACO: 10.1,10.2,10.5
2833744	2017, General Efficacy of Everest 3.0 1A and 2A, DACO: 10.2.3.3,10.3.2
2833745	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833746	2017, General Efficacy of Everest 3.0 on Broadleaf Weeds in Wheat, DACO: 10.2.3.3,10.3.2
2833748	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833751	2017, General Tolerance of Everest 3.0 Formulations on Wheat, DACO: 10.2.3.3,10.3.2
2833752	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833754	2017, General Efficacy of Everest 3.0 on Broadleaf Weeds in Wheat, DACO: 10.2.3.3,10.3.2
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2833758	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833759	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833760	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833761	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833762	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833763	2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
2833764	2017, General Efficacy of Everest 3.0 on Broadleaf Weeds in Wheat, DACO: 10.2.3.3,10.3.2

- 2833765 2017, General Efficacy of Everest 3.0 on Broadleaf Weeds in Wheat, DACO:
10.2.3.3,10.3.2
- 2833766 2017, General Efficacy of Everest 3.0, DACO: 10.2.3.3,10.3.2
- 2833735 2017, Batalium: Acute Oral Toxicity – Up-And-Down Procedure in Rats, DACO
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- 2833736 2017, Batalium: Acute Dermal Toxicity in Rats, DACO 4.6.2
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- 2833739 2017, Batalium: Primary Skin Irritation in Rabbits, DACO 4.6.5
- 2833740 2017, Batalium: Local Lymph Node Assay (LLNA) in Mice, DACO 4.6.6

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