

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2013-1463
Application: B.1.3 (Product Labels – New Site or Host)
Product: AXIAL BIA Herbicide
Registration Number: 30431
Active ingredients (a.i.): Pinoxaden (PRN)
PMRA Document Number: 3459321

Purpose of Application

The purpose of this application was to extend the registration of AXIAL BIA Herbicide (50 g pinoxaden/L with safener cloquintocet-mexyl at 1.26%, w/w) to Eastern Canada and to add a new crop, winter wheat, to the product label.

Chemistry Assessment

No chemistry assessment was required for this application.

Health Assessments

A toxicology assessment was not required since there was no change to the formulation.

The use on winter wheat should not result in an increase in potential occupational or bystander (reentry) exposure over registered uses of the active ingredient since the application rate, number of applications, frequency of application and method of application fell within that registered for spring wheat.

No new residue data for pinoxaden and cloquintocet-mexyl were submitted in support of the extension use of AXIAL BIA Herbicide in the regions including Eastern Canada and the addition of winter wheat on the label of AXIAL BIA Herbicide. Data on file support the national use of AXIAL BIA Herbicide on wheat (spring and winter) and barley. The use of AXIAL BIA Herbicide is not expected to increase the magnitude of pinoxaden and cloquintocet-mexyl residues in/on these crops. Therefore, the dietary exposure to pinoxaden and cloquintocet-mexyl 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 application timing and rates of AXIAL BIA Herbicide on winter wheat for Eastern Canada are identical to those of the currently registered product label on spring wheat and barley for Western Canada. Environmental concerns have been mitigated through statements on the product label.

Value Assessment

Value information submitted included rationales and data from five field trials conducted in Ontario at four locations in 2010. Crop safety of winter wheat was assessed for AXIAL BIA Herbicide at the labeled rate of 60 g a.i./ha. Crop injury was visually assessed on three occasions during the growing season and grain yield was reported as percent of an untreated control at harvest.

Mean crop injury was minor ($\leq 5\%$) or not detectable for AXIAL BIA Herbicide at 60 g a.i./ha in all five trials. Final grain yield further confirmed that winter wheat exhibited an adequate margin of crop safety to AXIAL BIA Herbicide applied in accordance with label directions.

Efficacy claims labeled for Western Canada can be extrapolated for Eastern Canada based on the herbicide mode of action and use history information of pinoxaden formulations registered in the US.

The registration of AXIAL BIA Herbicide for Eastern Canada would allow cereal growers across Canada to access an established graminicide in wheat and barley. In addition, AXIAL BIA Herbicide can also be applied with a number of tank mixture options that are currently approved in both Western and Eastern Canada cereal production systems. This may allow cereal growers the ability to manage both grasses and broadleaf weeds with a single pass herbicide application.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the expansion of use for AXIAL BIA Herbicide to Eastern Canada and to add the new crop winter wheat to the product label.

References

PMRA Document Number	References
2279238	2013, Efficacy Summary Axial BIA Add Eastern Canada, DACO: 10.2.3.1
2279240	2013, Efficacy: Small Scale Trials Axial BIA Add Eastern Canada, DACO: 10.2.3.3,10.3.2
2279241	2013, Efficacy: Small Scale Trials axial BIA Add Eastern Canada, DACO: 10.2.3.3
2279242	2013, Efficacy Small Scale Trials Axial BIA Add Eastern Canada, DACO: 10.2.3.3
2279244	2013, Efficacy: Small Scale Trials Axial BIA Add Eastern Canada, DACO: 10.2.3.3
2279245	2013, Non-Safety Adverse Effects Axial BIA Add Eastern Canada, DACO: 10.3.1

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