

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2007-8558
Application: Conversion to full registration without consultation
Product: Axial 100EC Herbicide
Registration Number: 28642
Active ingredients (a.i.): Pinoxaden (PRN)
PMRA Document Number : 1894138

Purpose of Application

The purpose of this application was to convert Axial 100EC (Registration Number 28642) from conditional to full registration. The initial registration decision is presented in Regulatory Note REG2006-14, Pinoxaden.

Chemistry Assessment

Axial 100EC Herbicide is a liquid product containing the active ingredient, pinoxaden, at a nominal concentration of 100 g/L. This product has a density of 1.03 g/cm³ and pH of 5.3 for a 1% solution in water. The chemistry requirements for Axial 100EC Herbicide have been completed.

Health Assessments

Refer to the Regulatory Note REG 2006-14 Pinoxaden for a detailed assessment of the toxicological database, occupational exposure assessment and food residue assessment for Pinoxaden Technical (Registration Number 28149), A1230C 100 EC (Crestivo Herbicide, Registration Number 28150) and Adigor Adjuvant (Registration Number 28151).

To support the full registration of pinoxaden end-use products, additional data regarding the enforcement method for analysis of pinoxaden and the metabolites in animal matrices, and the freezer storage stability for wheat processed fractions were submitted. The completion of the pinoxaden database confirmed the acceptability of the recommended MRLs. The full registration of Axial 100 EC Herbicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Axial 100EC Herbicide enters the environment when used as a herbicide for the control of specific grass weeds in spring wheat (*Triticum aestivum*), durum wheat (*Triticum turgidum*) and barley (*Hordeum* spp.) in the Prairie provinces and the Peace River, Okanagan and Creston Flats regions of British Columbia. Additional studies on the acute toxicity of pinoxaden to bees, fish and daphnia were submitted to the PMRA to support the conversion to full registration. No additional risk was identified upon review of these studies. The active ingredient, pinoxaden is only toxic to terrestrial plants from on-field application, therefore, a 1 metre buffer zone is required during application. There are no risks to other terrestrial organisms and aquatic organisms. There are two major transformation products formed in the environment, M2 and M3, which are not toxic to terrestrial and aquatic organisms.

Value Assessment

Efficacy data from sixty-nine (69) trials conducted in 2006 in Alberta, Saskatchewan and Manitoba were submitted by the applicant to establish the LER for wild oats, green foxtail, yellow foxtail, volunteer oats, volunteer canary seed and volunteer proso millet. All trials were conducted as randomized complete block design experiments with 4 replicates. Treatments included Axial 100EC at 30, 45 and 60 g ai/ha along with the adjuvant Adigor at 0.7 L/ha.

Based on the data made available for review and on the data made available for the original submission for pinoxaden (REG2006-14), the rate of 60 g ai/ha of pinoxaden + 0.7 L/ha of Adigor Adjuvant was confirmed as the rate of application for the control of wild oats, green foxtail, yellow foxtail, volunteer oats, volunteer canary seed and proso millet.

The data provided indicated that the rate of 60 g ai/ha of pinoxaden + 0.7 L/ha of Adigor Adjuvant was required to provide an acceptable level of control for wild oats, green foxtail, yellow foxtail, volunteer oats, volunteer canary seed and proso millet.

Conclusion

The PMRA has conducted a review of the available information can support the conversion of Axial 100EC (Registration Number 28642) from conditional to full registration.

References

Studies/Information Provided by Applicant/Registrant

<u>PMRA #</u>	<u>Reference</u>
1521756	2007, Validation of Analytical Method GRM017.03A for the Determination of Pinoxaden and its Metabolites NOA407854 (M2), SYN505164 (M4), SYN 502836 (M6) in Animal Tissues, Milk, Eggs by LC/MS/MS Method., DACO: 7.2
1521759	2006, Final Report: Pinoxaden: Stability of NOA407855 Residues in Wheat Processed Fractions Under Freezer Storage Conditions, DACO: 7.3
1521761	2007, Efficacy Summary: Conditions of Registration, DACO: 10.2.3.1
1521762	2007, Pivot Table, DACO: 10.2.3.1
1521764	2007, Field Trial Reports, DACO: 10.2.3.3

- 1521786 2007, Final Report: An Acute Oral Toxicity Study with the Honey Bee, DACO: 9.2.4.2 CBI
- 1521788 2007, Final Report: A 96-Hour Flow Through Acute Toxicity Test with the Saltwater Mysid, DACO: 9.4.2 CBI
- 1521790 2007, Final Report: A 96-Hour Flow Through Acute Toxicity Test with the Rainbow Trout, DACO: 9.5.2.1 CBI
- 1521792 2007, Final Report: A 7-Day Static-Renewal Toxicity Test with the Duckweed (*Lemna gibba* G3), DACO: 9.8.5 CBI
- 1521793 2007, Template: A 7-Day Static-Renewal Toxicity Test with the Duckweed (*Lemna gibba* G3), DACO: 9.8.5 CBI
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- 1521795 2007, Template: A 7-Day Static-Renewal Toxicity Test with the Duckweed (*Lemna gibba* G3), DACO: 9.8.5 CBI
- 1521796 2007, Final Report: A 7-Day Static-Renewal Toxicity Test with the Duckweed (*Lemna gibba* G3), DACO: 9.8.5 CBI

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Urban DJ; Cook NJ. 1986. Hazard Evaluation Division, Standard Evaluation Procedure, Ecological Risk Assessment. EPA 540/9-85-001. US EPA, Washington, DC.

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