



Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2008-5886
Application: B.3.1 – Changes to Product Labels-Application Rate Increase
Product: Equinox EC Herbicide
Registration Number: 27603
Active ingredients (a.i.): Tepraloxydim [TPA]
PMRA Document Number : 1871530

Purpose of Application

The purpose of this application was to amend the registration of Equinox EC Herbicide to increase the maximum application rate used on canola when applied alone and to increase the maximum application rate on imazethapyr and imazamox tolerant canola when tank mixed with Odyssey WDG Herbicide.

Chemistry Assessment

Chemistry assessments were not required for this application.

Health Assessments

New residue data for tepraloxydim in canola and imazethapyr- and imazamox-tolerant canola (Clearfield trait) were not submitted to support the increase in application rate of this active on the Equinox EC Herbicide label. Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this petition. In addition, a processing study in treated canola was also reassessed to determine the potential for concentration of residues of tepraloxydim into processed commodities. Following review of the canola residue data, it was considered acceptable to support the 20% increase in the application rate and it was concluded that this increase does not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The proposed use of the end-use product, Equinox EC Herbicide, on canola and imazethapyr- and imazamox-tolerant canola falls within the registered use pattern for this active ingredient. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

The maximum application rate for tepraloxydim was less than the maximum application rate for other registered uses of products containing tepraloxydim. As a result, the rate increase from 33 g a.i./ha to 40 g a.i./ha for canola and imazethapyr and imazamox tolerant canola represents a maximum application rate less than the maximum rate registered for flax, dry peas and lentils of 50 g a.i./ha.

Re-analysis of the risk quotients for non-target terrestrial plants resulted in the addition of a 1 metre terrestrial buffer zone to the label, where there had been none previously. The addition of a 1 metre terrestrial buffer zone contributes to risk reduction by increasing protection for non-target terrestrial plants.

Value Assessment

Crop phytotoxicity and yield data were submitted from a total of 8 field trials conducted on canola throughout Alberta, Saskatchewan and Manitoba in 2007 and 2008. The crop phytotoxicity and yield data indicate that Equinox EC Herbicide does not cause unacceptable injury to canola when applied at the maximum rate of 0.2 L/ha (40 g a.i./ha). A rationale in lieu of trial data was provided to support the tank mix of Equinox EC Herbicide at a maximum rate of 40 g a.i./ha with Odyssey WDG Herbicide at 30 g a.e./ha. A rationale was also provided to support a change in the wording of the application timing to canola from “emergence to 6 leaf” to “emergence to rosette stage (prior to bud and flower formation)”. Based on the data provided, increasing the maximum application rate of Equinox EC Herbicide to 40 g a.i./ha when applied alone or in tank mix with Odyssey WDG Herbicide, as well as changing the wording of the application timing for Equinox EC Herbicide, can be supported from a value perspective.

Conclusion

Following the assessment of the submitted data, the PMRA is able to support the amendment of this application.

References

Published Data

PMRA#	Title
1847220	Other Studies, DACO: 10.6

Submitted Data

PMRA #	Title
1687246	2008, Application for EQUINOX EC (BAS 620 00H) Herbicide Label Rate Harmonization for use on Canola (All Types), DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.2,10.5.3,10.5.4.
1687248	2008, Application for EQUINOX EC (BAS 620 00H) Herbicide Label Rate Harmonization for use on Canola (All Types), DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.2,10.5.3,10.5.4
1744234	Non-Safety Adverse Effects - Applicant rationale.

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