

Evaluation Report for Category B, Subcategory 3.10 & 3.12 Application

Application Number: 2006-3731
Application: B.3.10, Tank Mixes
B.3.12, New Host
Product: Equinox EC Herbicide
Registration Number: 27603
Active ingredients (a.i.): Tepraloxydim
PMRA Document Number: 1594003

Background

Equinox EC Herbicide has been registered since July 22, 2004. Equinox EC Herbicide is registered for post-emergence use in flax, dry pea and lentil, including lentil varieties that are imazethapyr and imazamox tolerant (i.e., varieties with the CLEARFIELD trait) in the Prairie provinces and Peace River region of British Columbia. Equinox EC Herbicide controls annual grass weeds at rates of 26.7-50 g a.i./ha, depending on species and environmental conditions. A control claim for quackgrass is included at the 50 g a.i./ha rate. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this application is to amend the registration of Equinox EC Herbicide to include:

1. use on canola, including imazethapyr and imazamox tolerant canola (i.e., varieties with the CLEARFIELD trait), as a post-emergence application at 33 g a.i./ha for control of annual grass weeds, and
2. a tank mixture of 33 g a.i./ha Equinox EC plus 30 g a.i./ha Odyssey WDG Herbicide (Reg. No. 25111) plus either 0.41% Dash HC (Reg. No. 27604) or 0.5% Merge adjuvant (e.g., Reg. No. 24702) for control of weed species listed on the Odyssey label and volunteer imazethapyr and imazamox tolerant wheat in imazethapyr and imazamox tolerant canola.

Chemistry Assessment

A chemistry assessment was not required since there was no change to product chemistry.

Health Assessments

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

The use on canola and imazethapyr and imazamox tolerant canola 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 fall within the registered uses for other cereal crops.

Residue data for tepraloxymid in canola were submitted to support the use expansion of this active on the Equinox EC Herbicide label. In addition, a processing study in treated rapeseed was reassessed to determine the potential for concentration of residues of tepraloxymid into processed commodities.

The current request is also to add Odyssey WDG Herbicide as a tank mix partner to the Equinox EC label for use on imazethapyr and imazamox tolerant canola (CLEARFIELD trait). The proposed tank mix partners, imazethapyr and imazamox, are registered on imazethapyr and imazamox tolerant canola (CLEARFIELD trait) at rates equivalent to or lower than the rates on the Equinox EC label.

There is no evidence to suggest interactions and/or synergy between the two tank mix partners (tepraloxymid and imazethapyr/imazamox) within the oilseed crops since they have different modes of action. Accordingly, the disposition, translocation and magnitude of the residues of tepraloxymid is not expected to be affected when tank mixed with Odyssey WDG Herbicide. No additional dietary risk from tepraloxymid is anticipated.

Maximum Residue Limit(s)

Based on the maximum residues observed in canola seeds treated according to label directions, a maximum residue limit (MRL) of 0.3 ppm to cover residues of tepraloxymid and the metabolites convertible to GP and OH-GP in/on rapeseed (canola) will be established as shown in Table 1. Residues of tepraloxymid and the metabolites convertible to GP and OH-GP in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodity (RAC).

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs)

| Commodity | Application Method/ Total Application Rate (g a.i./ha) | PHI (days) | Combined Residues of Tepraloxymid and the Metabolites convertible to GP and OH-GP (ppm) | | Experimental Processing Factor | Currently Established MRL | Recommended MRL |
|----------------------|---|---------------|---|------|--|---------------------------------|--------------------|
| | | | Min | Max | | | |
| Rapeseed (Canola) | One broadcast foliar application/ 30-34 | 58-61 | <0.10 | 0.26 | 0.17-0.18 (crude oil) 0.07-0.18 (refined oil) | None | 0.3 ppm |

Residues of tepraloxydim and the metabolites convertible to GP and OH-GP in canola at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

An environmental assessment was not required since the maximum annual application rate for canola, and imazethapyr and imazamox tolerant canola (CLEARFIELD trait) in the prairie provinces and Peace River region of British Columbia are within the rate registered for flax, dry peas, and lentils. Additionally, the crops are grown in the same ecoregions as those where flax, dry peas, and lentils are grown. As a result there is no increase in risk to the environment and additional data was not required to support this registration. Environmental concerns are mitigated on the existing label.

Value Assessment

The efficacy data submitted from 42 single season field trials conducted over six years (1996, 1997, 1998, 1999, 2004 and 2005) throughout the Prairie region collectively demonstrate that Equinox EC Herbicide plus either 0.41% v/v Dash HC or 0.5% v/v Merge adjuvant controls wild oat, green foxtail, volunteer barley, volunteer oat, and volunteer wheat. While data were submitted for only the 33 g a.i./ha rate (labelled for green foxtail control), use of 26.7 g a.i./ha (labelled for use in flax, lentil and dry pea) in canola for control of wild oat, volunteer barley and volunteer wheat, including imazethapyr and imazamox tolerant wheat, was supported. The tank mixture of Equinox EC Herbicide plus Odyssey WDG Herbicide plus either Dash HC or Merge adjuvant, assessed in 14 of these trials, was demonstrated to control the weed species listed on the Odyssey WDG label which includes the annual grass weed species listed on the Equinox EC label (up to the 33 g a.i./ha rate), as well as for the control of volunteer imazethapyr and imazamox tolerant wheat. The rate of Equinox EC supported for use in the tank mix is 26.7 g a.i./ha and not 33 g a.i./ha because there was no evidence of antagonism for control of either grass or broadleaved weeds when Equinox was included in the tank mix at 33 g a.i./ha; and because Odyssey WDG controls the annual grass weeds listed on the Equinox EC label. As the primary benefit of this tank mixture is for the control of volunteer imazethapyr and imazamox tolerant wheat in a crop of imazethapyr and imazamox tolerant canola, a statement to indicate that use of this tank mixture is for the control of volunteer imazethapyr and imazamox tolerant wheat in addition to other labelled weed species has been included on the Equinox EC label.

Crop safety data from 56 single season field trials conducted over seven years (1996, 1998, 1999, 2000, 2004 and 2005) throughout the Prairie region, were reviewed. The crop injury and yield data collectively indicate that canola, including imazethapyr and imazamox tolerant cultivars, is tolerant of an application of up to 33 g a.i./ha Equinox EC herbicide plus either 0.41% v/v Dash HC or 0.5% v/v Merge adjuvant, when applied up to and including the crop 6-leaf stage. The data also indicate that imazethapyr and imazamox tolerant canola is tolerant of an application of a tank mixture of up to 33 g a.i./ha Equinox EC Herbicide plus 30 g a.e./ha Odyssey WDG Herbicide plus either 0.41% v/v Dash HC or 0.5% v/v Merge adjuvant.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to amend the registration of Equinox EC Herbicide to include:

1. use on canola, including imazethapyr and imazamox tolerant cultivars, at 26.7 or 33 g a.i./ha rate for control of annual grass weeds, and
2. a tank mixture of 26.7 g a.i./ha Equinox EC plus 30 g a.e./ha Odyssey WDG Herbicide plus either 0.41% Dash HC or 0.5% Merge adjuvant for control of weed species listed on the Odyssey label and volunteer imazethapyr and imazamox tolerant wheat in imazethapyr and imazamox tolerant canola.

The PMRA is also recommending a 0.3 ppm MRL for rapeseed (canola) to cover residues of tepraloxydim and the metabolites convertible to GP and OH-GP.

References

Value Assessment

| <u>PMRA ID#</u> | <u>Reference</u> |
|-----------------|---|
| 1262593 | 2006, Application for ARAMO EC Herbicide for use on Canola and Mustard; Application for ODYSSEY Herbicide + ARAMO Herbicide Tank Mix in CLEARFIELD Canola, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3, 10.3, 10.3.1, 10.3.2, 10.3.3, 10 |
| 1400838 | 2007, Efficacy: Small Scale Trials, DACO: 10.2.3.3 |

Health Assessments

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| 1262545 | 2006, The Magnitude of BAS 620 H Residues in Clearfield Canola, Lab Report 138149, MRID: N/A, DACO: 7.4.1 |
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