

Evaluation Report for Category B, Subcategories B.3.10 (tank mixes) and B.3.12 (new hosts) Application

Application Number:	2005-0606			
Application:	Category B, subcategories: B.3.10 (tank mixes) and B.3.12 (new			
	hosts)			
Product:	Assure II Herbicide			
Registration Number:	25462			
Active ingredients (a.i.):	contained in product: - quizalofop-p-ethyl at 96 g a.i./L			
PMRA Document Number:	1365282			

Background

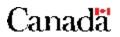
Assure II Herbicide has been registered since April 22, 1998. Assure II Herbicide is registered for postemergence use in canola, flax, soybeans, seed alfalfa, lentils, peas (field and processing), seedling legumes for seed production, seedling or established creeping red fescue for seed production, sugarbeets, snap beans, dry common beans (including pinto, otebo, navy beans, white and red kidney beans, white, cranberry, black), dry beans (including lima, adzuki, mung, brown eye and yellow eye beans) and rutabagas for the control of annual and perennial grasses. For specific details of uses, application rates and methods, precautions, restrictions and personal protective equipments, refer to the product label.

Purpose of Application

The purpose of this application is to amend the registration of Assure II Herbicide to include 1) both oilseed and condiment type oriental mustard, and 2) a tank mixture with Muster Herbicide Toss-N-Go (Reg. No. 23569), containing 75% ethametsulfuron-methyl. The tank mix is proposed for the control of certain broadleaved weeds as a postemergence use. The requested rates are 36.5-72 g a.i./ha plus a labelled non-ionic surfactant (Ag-Surf, Citowett Plus or Agral 90) in a minimum of 100 L/ha, which is the rate range listed on the label for currently labelled crops, one of which is canola. The preharvest interval (PHI) is 64 days.

Chemistry Assessment

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



Health Assessment

The use on condiment and oilseed type oriental mustard should not result in an increase in potential occupational or bystander (re-entry) exposure over registered uses of this active ingredient since the application rate, number of applications, frequency of application and method of application fell within that registered for other labelled oilseeds.

Residue data for quizalofop-p-ethyl in condiment and oilseed type oriental mustard were not submitted to support the use expansion of this active on the Assure II Herbicide label. Regulatory proposal (PRO2003-02), specifies that oilseed oriental mustard varieties are the same as those for a claim for any other oilseed, e.g., canola, if the label directions are the same. Previously reviewed residue data from field trials conducted in/on canola (rapeseed) 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 quizalofop-p-ethyl into processed commodities.

The present request is also to add Muster Herbicide Toss-N-Go as a tank mix partner to the Assure II Herbicide label for use on oilseed and condiment type oriental mustard. The proposed tank mix partner, ethametsufuron-methyl, is registered on oilseed and condiment type oriental mustard at rates equivalent to or lower than the rates on the Muster Herbicide Toss-N-Go label.

There is no evidence to suggest interactions and/or synergy between the two tank mix partners (ethametsulfuron-methyl and quizalofop-p-ethyl) within the oilseed crops since they have different modes of action. Accordingly, the disposition, translocation and magnitude of the residues of quizalofop-p-ethyl is not expected to be affected when tank mixed with Muster Herbicide Toss-N-Go. No additional dietary risk from quizalofop-p-ethyl is anticipated.

Maximum Residue Limit(s)

Based on the maximum residues observed in canola treated with quizalofop-p-ethyl, it was determined that residues of quizalofop-p-ethyl above the limit of quantitation are not expected in oilseed type oriental mustard as a result of the use of Assure II Herbicide. Canola data were extended to oriental mustard (condiment type) based on the fact that no residues above the limit of quantitation were observed in canola seeds.

Therefore, a MRL is proposed for condiment and oilseed type oriental mustard at the limit of quantitation of the enforcement method: 0.05 ppm. Residues of quizalofop-p-ethyl did not concentrate in any of the canola processed fractions including oil. Residues of quizalofop-p-ethyl in processed commodities 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)	Quizalofop-p- ethyl and Quizalofop-p- ethyl Acid Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Condiment and oilseed type oriental mustard*	Postemergent foliar broadcast spray/ 72-105	56-65	<0.05	0.05	No concentration of residues observed in oil fractions.	None	0.05 ppm

* The MRL is based on canola residue data.

Environmental Assessment

The proposed inclusion of new hosts and new tank mixes do not pose additional risk to the environment. Also, the proposed method and rate of application of the proposed use are identical to the currently registered canola uses for Assure II Herbicide and Muster Toss-N-Go, and that no additional environmental data are required.

Value Assessment

The data provided for review from a total of 6 trials conducted at different locations in Saskatchewan in 2004 support the addition of oilseed type oriental mustard to the Assure II label. The data also support the addition of a tank mix of Assure II + Muster Toss-N-Go to oilseed type oriental mustard.

Due to the known crop safety of Muster Toss-N-Go Herbicide to related crops, including canola, condiment and oilseed oriental mustard, and the known crop safety of Assure II Herbicide to broadleaved crops including canola, the extension of the registration of the tank mix of Muster Toss-N-Go + Assure II to condiment type oriental mustard is also acceptable from an ESAD point of view. Due to a minor use label expansion to expand the use of Muster Toss-N-Go to canola in the Okanagan and Creston Valley areas of British Columbia, the reference to westerm Canada on the proposed supplemental label is acceptable.

Conclusions

The PMRA has completed an evaluation of the subject application and has found the information sufficient to amend the registration of Assure II Herbicide for the addition of both oilseed and condiment type oriental mustard, and to include a tank mixture with Muster Herbicide Toss-N-Go.

<u>MRLs</u>

Following the review of all available data, an MRL of 0.05 ppm for condiment and oilseed type oriental mustard is recommended based on the canola residue data. Residues of quizalofop-p-ethyl at the recommended MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

List of Studies/Information Submitted by Registrant

Reference List

A.

Health Assessment 1171106 ANALYTICAL PHASE REPORT: RESIDUES OF QUIZALOFOP-P-ETHYL AND METABOLITES IN CANOLA, FLAX, LENTIL AND PEAS GROWN IN CANADA. MARCH 17,1997. [XEN96-26;96DUP01;38(XAM-38)], DACO: 7.2.1 1171105 MAGNITUDE OF RESIDUE OF QUIZALOFOP-P-ETHYL (ASSURE II) IN PEAS, FLAX, CANOLA AND LENTILS FOLLOWING POST-EMERGENCE BROADCAST APPLICATION. D.G.BECHTEL, MARCH 1997.(CAN-95-510;96-26)., DACO: 7.4.2 1166182 MAGNITUDE OF RESIDUES OF ASSURE II HERBICIDE IN CANOLA SEED AND ITS PROCESSED FRACTIONS (AMR 1435-89;1714-90-100-01-12B-11;91-P1441A), DACO: 7.4.6 1161255 MAGNITUDE OF RESIDUES OF ASSURE II HERBICIDE WHEN APPLIED TO CANOLA.(AMR1389-89;1714-90-100-01-12B-10;90-P1343).(QUIZALOFOP P-ETHYL), DACO: 7.4.2 Environmental Assessment None

Value Assessment

1031038	Submission to Register Assure II Herbicide and a tank mix of Muster Herbicide + Assure II Herbicide on Oil and Condiment Quality Brassica Juncea. March 3, 2005. E.I. du Pont Canada Company. DACO 10. pp. 144.
1031044	Test reports and raw data. E.I. du Pont Canada Company. DACO 10.

B. Additional Information Considered

i) <u>Published Information</u>

Health Assessment

- 1315208 PRO2003-02 English, DACO: 11.1
- 1315210 PRO2003-02 French, DACO: 11.1

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