Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.10, 3.11, 3.12 Application

Application Number: 2018-4844
Application: New Product Labels-Tank Mixes, New Pests and New Site or Host
Product: Certitude A
Registration Number: 33908
Active ingredient (a.i.): Topramezone
PMRA Document Number: 3155431

Purpose of Application

The purpose of this application was to register Certitude A for use on canola for the control of volunteer canola (all types, including glyphosate-tolerant) and for the control of kochia, including glyphosate-resistant biotypes, when tank-mixed with registered tank-mix partners.

Chemistry and Value Assessments

Chemistry and value assessments were not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of Certitude A prior to seeding canola (all types) for control of volunteer canola (all types, including glyphosate-tolerant) and control of kochia, including glyphosate-resistant biotypes, represents an expansion of the use pattern for topramezone. This expansion is not expected to result in increased potential occupational or bystander exposure over the previously registered use of topramezone. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Residue data from flax metabolism study and from canola field trials conducted in Canada and the United States were submitted to support the use of Certitude A. In the field trials, topramezone was applied preplant or pre-emergence to canola at the proposed label rate, and harvested according to label directions. In addition, a processing study in treated canola was reviewed to determine the potential for concentration of residues of topramezone into processed commodities.

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Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for topramezone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. An MRL to cover residues of topramezone in/on canola and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Topramezone Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Canola seed	Preplant soil application/ 5.60-6.73	84-163	<0.01	<0.01	No quantifiable residues observed when treated at exaggerated rates.	None	0.01 in/on Crop Subgroup 20A – Rapeseeds (Revised)

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the dietary burden and residue data, the MRLs of 0.01 ppm in eggs and meat of poultry and of 0.05 ppm in fat and meat byproducts of poultry to cover residues of topramezone are also proposed.

Following the review of all available data, the MRLs as proposed above are recommended to cover residues of topramezone. Residues in these food commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of topramezone at a seasonal rate of 25 g a.i./ha was previously assessed and therefore an additional assessment was not required for Certitude A at a seasonal rate of 6 g a.i./ha. The label includes all required precautionary hazards statements, including buffer zones information, which adequately mitigates risks to the environment.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Certitude A for use on canola for control of volunteer canola (all types, including glyphosate-tolerant) and control of kochia, including glyphosate-resistant biotypes, when tank–mixed with registered tank-mix partners.

References

PMRA Document Number	References
2920459	2018, Derz, K. Metabolism of [14C]-Topramezone (BAS 670 H) in Flax – Part 2: Analysis. DACO 6.3
2920462	2013, Jones, J.E. Validation of BASF Analytical Method D1302: "Determination of Topramezone (BAS 670 H) and Its Metabolite (M670H05) in Plant Matrices by LC-MS/MS". DACO 7.2
2920463	2013, Rogers, P. and Fang, M. Independent Laboratory Validation of BASF Analytical Method D1302: “Determination of Topramezone (BAS 670 H) and Its Metabolite M670H05 (Reg. No. 388010) in Plant Matrices by LC-MS/MS”. DACO 7.2
3080608	2020, Denomme, M.A. Topramezone: Magnitude of the Residue on Flax. DACO 7.3
2920460	2018, Csinos, A. Magnitude of the Residue of BAS 670 H in/on Canola Raw Agricultural Commodity. DACO 7.4.1
2920461	2018, Csinos, A. Magnitude of the Residue of Topramezone (BAS 670 H) in Processed Commodities following a Pre-Plant Application of BAS 670 01 H in/on Canola. DACO 7.4.5