Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.11 and 3.12 Application

Application Number: 2015-2328
Application: B.2.1 - New Guarantee
B.2.3 - New Identity of Formulants
B.2.4 - New Proportion of Formulants
B.2.6 - New Combination of TGAI's
B.3.11 - New Pests
B.3.12 - New Site or Host
Product: Talinor
Registration Number: 32681
Active ingredients (a.i.): Bromoxynil and Bicyclopyrone
PMRA Document Number: 2759269

Purpose of Application

The purpose of this application was to register the end use product, Talinor, which contains bicyclopyrone and bromoxynil, for use in spring wheat, durum wheat, and barley for broadleaf weed control.

Chemistry Assessment

Talinor is formulated as an emulsifiable concentrate containing bicyclopyrone at a nominal concentration of 37.5 g/L and bromoxynil at a nominal concentration of 175 g/L. This end-use product has a density of 1.09 g/mL and pH of 3.9. The required chemistry data for Talinor have been provided, reviewed and found to be acceptable.

Health Assessments

Talinor was of slight acute toxicity via the oral route and low acute toxicity by the dermal and inhalation routes in rats. It was minimally irritating to the eye and mildly irritating to the skin of rabbits. It was a dermal sensitizer in mice.

Occupational risks were assessed for exposures to Talinor when used on spring wheat, durum wheat, and barley to control broadleaf weeds. Use of Talinor fits within the registered use pattern of bromoxynil. Risks to mixers, loaders, applicators and re-entry workers exposed to bicyclopyrone are not of concern when following the precautions, including wearing the personal protective equipment, engineering controls, and the restrictions on the label.

Canada

Residue data from field trials conducted in Canada and the United States were submitted to support the registration of Talinor Herbicide on spring wheat, durum wheat and barley. Bicyclopyrone was applied to wheat and barley at the approved label application rate, and harvested according to label directions. In addition, processing data for treated wheat were reviewed to determine the potential for concentration of residues of bicyclopyrone into processed commodities.

Based on the application rates used in the submitted wheat and barley crop field trial studies, residues of bromoxynil are not expected to exceed the established MRLs of 0.05 ppm for both wheat and barley grain from the use of the proposed end-use product on these crops.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for bicyclopyrone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of bicyclopyrone (as the structurally similar moieties SYN503780 and CSCD686480, both moieties were expressed as bicyclopyrone equivalents) in/on wheat (spring and durum) and barley, 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 Limits (MRLs)

Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRLs (ppm)
			LAFT	HAFT			
Wheat grain	Ground foliar application / 47.4-52.5 g ai/ha	57-81	<0.01	0.031	2.1-2.3 for bran, 1.4 for germ, 0.2-0.3 for flour	None	0.04 for grain, 0.07 for bran
Barley grain	Ground foliar application / 49.2-54.7 g ai/ha	57-81	<0.01	0.051	2.1-2.3 for bran, 0.2-0.3 for flour	None	0.07 for grain, 0.15 for bran

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

Based on the increase in the dietary burden from the consumption of treated wheat and barley, the MRLs for ruminant byproducts will be revised to 2.0 ppm (from 1.5 ppm), while the MRL for swine meat byproducts will be revised to 0.5 ppm (from 0.2 ppm) to cover residues of bicyclopyrone (as the structurally similar moieties SYN503780 and CSCD686480, both moieties were expressed as bicyclopyrone equivalents).

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of bicyclopyrone from the use on spring and durum wheat and barley. Residues in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Registration of the end use product, Talinor, containing bicyclopyrone and bromoxynil for use on wheat (spring and durum) and barley is considered acceptable from an environmental perspective, when used according to label directions. Label statements are required for clarification regarding the directions for use and storage.

Environmental hazard statements for the protection of aquatic organisms and non-target terrestrial plants are required on the Talinor label. No-spray buffer zones to protect sensitive aquatic and terrestrial habitats were calculated for Talinor based on inputs from the bromoxynil re-evaluation, bicyclopyrone registration, and the end-use product-specific studies provided to support the registration of Talinor.

Value Assessment

Talinor has been shown to have activity against a number of broadleaf weeds, including some that are known to be difficult to control. The window of application for Talinor (relative to the crop) will provide flexibility to wheat and barley growers by allowing use either early in the season for weed control during the critical phase of early cereal growth or use late in the season for the control of a late flush of broadleaf weeds in the crop which could impact grain development and harvesting ease. When tank mixed, the Talinor treatment may provide a single pass treatment for both broadleaf and grassy weed control in wheat and barley grown across Canada. Furthermore, the inclusion of two active ingredients in Talinor may assist with improved weed resistance management.

Efficacy data from 72 trials demonstrated that Talinor applied at 1.0 L/ha (212.5 g ai/ha) would be expected to control cleavers, common chickweed, kochia, wild buckwheat, volunteer canola, wild mustard, lamb's-quarters, hempnettle, redroot pigweed, flixweed, shepherd's-purse, annual sow thistle, scentless chamomile, narrow-leaved hawk's-beard and stinkweed and suppress horsetail, Canada thistle, round-leaved mallow, Russian thistle, dandelion and white cockle in wheat (spring and durum) and spring barley. Furthermore, the data also demonstrated that acceptable weed and disease control would be expected when Talinor is tank mixed with Axial Bia (Reg. No. 30431), Traxos (Reg. No. 29855), Axial Xtreme (Reg. No. 30391), Broadband (Reg. No. 29138), Varro (Reg. No. 29070), Simplicity (Reg. No. 28887), Sierra 2.0 (Reg. No. 30430), Everest 2.0 (Reg. No. 30342) or Tilt 250E (Reg. No. 19346) and applied as directed.

Host crop tolerance data from 21 trials demonstrated that Talinor applied alone or in tank mix with any of the aforementioned tank mix partners would not be expected to negatively impact host crop tolerance of wheat (spring and durum) or spring barley.

Rotational crop tolerance data from eight trials demonstrated that acceptable rotational crop tolerance would be expected for alfalfa, canola, chickpea, flax, mustard, potato, soybean, barley, oats and wheat (spring and durum) when planted 10 months after the application of Talinor and for dry bean, field pea and lentil when planted 22 months after Talinor application.

Conclusion

The PMRA has reviewed the information provided in support of the end use product, Talinor. Based on the results of this review, Talinor for use in spring wheat, durum wheat and barley for weed control is acceptable for full registration.

References

2539640 2015, Trial Summary Data, DACO: 10.2.3.4,IIIA 6.1.3
2585145 2015, Individual trial report, DACO: 10.3.2
2585146 2015, Individual trial report, DACO: 10.3.2
2585147 2015, Individual trial report, DACO: 10.3.2
2585148 2015, Individual trial report, DACO: 10.3.2
2585149 2015, Individual trial report, DACO: 10.3.2
2585150 2015, Individual trial report, DACO: 10.3.2
2585151 2015, Individual trial report, DACO: 10.3.2
2585152 2015, Individual trial report, DACO: 10.3.2
2585153 2015, Individual trial report, DACO: 10.3.2

2539643	2014, Bicyclopyrone/Bromoxynil-octanoate EC & S:Cloquintocet-mexyl (A19278A) - Acute Oral Toxicity - Up-And-Down Procedure in Rats Final Report, DACO: 4.6.1,IIIA 7.1.1
2539644	2014, Bicyclopyrone/Bromoxynil-octanoate EC & S:Cloquintocet-mexyl (A19278A) - Acute Dermal Toxicity in Rats Final Report, DACO: 4.6.2,IIIA 7.1.2
2539646	2014, Bicyclopyrone/Bromoxynil-octanoate EC &S:Cloquintocet-mexyl (A19278A) - Acute Inhalation Toxicity in Rats Final Report, DACO: 4.6.3,IIIA 7.1.3
2539647	2014, Bicyclopyrone/Bromoxynil-octanoate EC & S:Cloquintocet-mexyl (A19278A) -Primary Skin Irritation in Rabbits Final Report, DACO: 4.6.5
2539648	2014, Bicyclopyrone/Bromoxynil-octanoate EC & S:Cloquintocet-mexyl (A19278A) - Primary Eye Irritation in Rabbits Final Report, DACO: 4.6.4,IIIA 7.1.5
2539649	2014, Bicyclopyrone/Bromoxynil-octanoate EC & S:Cloquintocet mexyl (A19278A) ¿¿¿ Local Lymph Node Assay (LLNA) in Mice Final Report, DACO: 4.6.6,IIIA 7.1.6
2539651	2015, Bicyclopyrone : Occupational Risk Assessment for Talinor, DACO: 4.6.8,4.7.7,4.8,5.14,5.2,5.3,5.6,IIIA 7.11
2539652	2015, An Assessment of the Potential Developmental Toxicity of Bicyclopyrone , DACO: 4.6.8,4.7.7,4.8,5.14,IIIA 7.11

2115788	2008. Agricultural Reentry Task Force. Data submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. CBI

2539623	2015, Product Identification, DACO: 3.1.1,IIIA 1.1 CBI
2539628	2015, A19278A. Physico-Chemical Studies of the Formulation Product Chemistry Volume, DACO: 3.5.1,3.5.2,3.5.3,IIIA 2.1 CBI
2539634	2015, NOA449280 - OVERVIEW OF FIELD SOIL BEHAVIOUR FOR THE PURPOSES OF DETERMINING WATER CONCENTRATIONS FOR RISK ASSESSMENT Rationale, DACO: 3.7,5.14,8.6,IIIA 4.9

2539635	2014, A19278A - SF-1654/2 - Analytical Method and Validation, DACO: 3.4.1,IIIA 5.2.2 CBI

2569624	Bicyclopyrone/Bromoxynil EC (Al9278A). Residue Levels on Wheat (Forage, Hay, Grain and Straw) in Canada During 2013 - Final Report - AMENDMENT 1
2569625	Bicyclopyrone/Bromoxynil EC (A19278A) - Residue Levels on Barley (Hay, Grain and Straw) in Canada During 2013 - Final Report - AMENDMENT 1
2569626	Bicyclopyrone EC (A19278A) - Magnitude of the Residues in or on Wheat USA 2012
2569627	Bicyclopyrone EC (A19278A) - Magnitude of the Residues in or on Barley USA 2012

ISSN: 1911-8082