

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

Application Number: 2016-2508

Application: New End-use Product – Chemistry: Guarantee; Identity and

Proportion of Formulants; New combination of TGAIs

Product: CHA 5373 Herbicide

Registration Number: 32758

Active ingredients (a.i.): Florasulam and Tribenuron-methyl

PMRA Document Number: 2662565

Purpose of Application

The purpose of this application was to register a new end-use product, CHA 5373 Herbicide, for pre-plant and early postemergent application to spring wheat, durum wheat, and spring barley and in summer fallow for the control of emerged broadleaf weeds.

Chemistry Assessment

CHA 5373 Herbicide is formulated as wettable granules containing tribenuron-methyl at a nominal concentration of 30% and florasulam at a nominal concentration of 20%. This end-use product has a bulk density of 0.602-0.618 g/mL and pH of 6.12-6.14. The required chemistry data for CHA 5373 Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

In rats, CHA 5373 Herbicide is considered to be of low acute toxicity by the oral, dermal, and inhalation routes of exposure. The formulation is considered to be mildly irritating to the rabbit eye and skin. It is a not considered to be a skin sensitizer in mice.

The use of CHA 5373 Herbicide for pre-plant and early postemergent application to spring wheat, durum wheat and spring barley, and in summer fallow for the control of emerged broadleaf weeds is not expected to result in potential occupational or bystander exposure over the registered uses of tribenuron-methyl. Updated quantitative occupational exposure risk estimates were generated for florasulam. No health risks of concern are expected for mixer/loader/applicators and postapplication workers, provided workers follow the label directions and wear the personal protective equipment identified on the label.



No residue chemistry data were submitted for florasulam and tribenuron-methyl to support the registration of CHA 5373 Herbicide. Previously reviewed residue data were considered in the context of the current submission. The currently established MRLs for florasulam and tribenuron-methyl are sufficient to cover residues resulting from the registration of CHA 5373 Herbicide. Previous dietary exposure assessments are considered adequate to cover the residue levels of florasulam and tribenuron-methyl expected from the use of CHA 5373 Herbicide. No health risks of concern have been identified for any segment of the population including infants, children, adults and seniors.

Environmental Assessment

The use of the co-formulation CHA 5373 Herbicide will not result in increased environmental exposure or impact relative to existing registered products. Potential risks to the environment have been mitigated through adequate label statements.

Value Assessment

The co-formulation of the two active ingredients florasulam and tribenuron-methyl into a single product will be easily handled and convenient to apply for the control of a broader spectrum of broadleaf weeds. Both florasulam and tribenuron-methyl are Group 2 mode of action herbicides, but they belong to two chemical families, triazolpyramidines and sulfonylureas, respectively.

Value information submitted for review included data from small plot replicated field trials conducted in the Canadian Prairies in 2015. The product performance of CHA 5373 Herbicide, in terms of both efficacy and crop tolerance, was evaluated and compared to that of each component herbicide cited as precedent, applied alone or together in a tank mixture at comparable rates of active ingredient per hectare.

Given that trial data demonstrated that weed control provided by CHA 5373 Herbicide was comparable to that provided by the precedent products, all weed claims labelled for the precedent products are supported for inclusion on the CHA 5373 Herbicide label. Trial data also support the inclusion of control claims for lamb's-quarters and mustards, and a suppression claim for Russian pigweed as well as the tank mixtures with 2,4-D Ester/Amine, MCPA Ester/Amine, Pardner, or glyphosate herbicides.

Given that all host crops listed for CHA 5373 Herbicide, i.e., spring wheat, durum wheat, and spring barley, are registered on the precedent product labels, these crops can be expected to exhibit an adequate margin of crop tolerance to CHA 5373 Herbicide applied in accordance with the label instructions. This was corroborated with the crop tolerance information from the submitted field trials.

The rotational crop claims are supported based on the most restrictive label claim on a precedent product label.

Based on the weight of evidence, the registration of CHA 5373 Herbicide for pre-plant and early postemergent application to spring wheat, durum wheat and spring barley and in summer fallow for the control of emerged broadleaf weeds is considered to have acceptable value.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to register CHA 5373 Herbicide.

References

PMRA Document	Reference
Number	
2640564	2016, Part 3, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.3, 3.3.1,
	3.4.2, 3.5.11, 3.5.13, 3.5.15, 3.5.4, 3.5.5, 3.5.9, 3.6 CBI
2640578	2016, Florasulam 200+Tribenuron-methyl 300 g/kg WG (CHA 5373)
	Description of Formulation Process, DACO: 3.2,3.2.2 CBI
2640579	2015, Analytical Method VAM 239-01: Determination of Tribenuron-Methyl
	(CAS No. 101200-48-0) and Florasulam (CAS No. 145701-23-1) in
	Tribenuron-Methyl + Florasulam WG formulations., DACO: 3.4,3.4.1 CBI
2640580	2013, Validation of analytical method VAM 239-01 for determination of
	Tribenuron-Methyl (CAS No. 101200-48-0) and Florasulam (CAS No.
	145701-23-1) in Tribenuron-Methyl 600 g/kg + Florasulam 200 g/kg WG
	formulation., DACO: 3.4,3.4.1 CBI
2640581	2015, Amendment to Validation of analytical method VAM 239-01 for
	determination of Tribenuron-Methyl (CAS No. 101200-48-0) and Florasulam
	(CAS No. 145701-23-1) in Tribenuron-Methyl 600 g/kg + Florasulam 200
	g/kg WG formulation. , DACO: 3.4,3.4.1 CBI
2640582	2015, Determination of the accelerated storage stability for 12 weeks at 35°C
	of Tribenuron-Methyl 300 g/kg + Florasulam 200 g/kg WG formulation in
	commercial packaging, DACO: 3.5,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7 CBI
2640583	2015, Expert Statement on the Explosive Properties of Tribenuron-Methyl
	300 g/kg + Florasulam 200 g/kg WG (CHA 5373)., DACO: 3.5.12 CBI
2640584	2015, Determination of the Pour and Tap Bulk density of Tribenuron-Methyl
	300 g/kg + Florasulam 200 g/kg WG formulation., DACO: 3.5.6 CBI
2640585	2015, Expert Statement on the Oxidizing Properties of Tribenuron-Methyl
	300 g/kg + Florasulam 200 g/kg WG (CHA 5373)., DACO: 3.5.8 CBI
2733892	2016, Determination of the storage stability for 1 year at 20C of tribenuron-
	methyl 300 g/kg + florasulam 200 g/kg WG formulation in commercial
	packaging, DACO: 3.5.10,3.5.14
2657346	2013, Florasulam 200 g/kg + Tribenuron-methyl 600 g/kg WG: Acute Oral
	Toxicity Up And Down Procedure In Rats. Study No: 35234; DACO 4.6.1.
2657347	2013, Florasulam 200 g/kg + Tribenuron-methyl 600 g/kg WG: Acute
	Dermal Toxicity Study in Rats. Study No: 35235; DACO 4.6.2.
2657348	2013, Florasulam 200 g/kg + Tribenuron-methyl 600 g/kg WG: Acute
	Inhalation Toxicity Study in Rats. Study No: 35236; DACO 4.6.3.
2657349	2013, Florasulam 200 g/kg + Tribenuron-methyl 600 g/kg WG: Primary Eye
	Irritation Study in Rabbits. Study No: 35237; DACO 4.6.4.
2657350	2013, Florasulam 200 g/kg + Tribenuron-methyl 600 g/kg WG: Primary Skin
	Irritation Study in Rabbits. Study No: 35238; DACO 4.6.5

PMRA Document	Reference
Number	2012 Floresylem 200 c/leg Tribonyron methyl 600 c/leg W.C. I coal Lymph
2657351	2013, Florasulam 200 g/kg + Tribenuron-methyl 600 g/kg WG: Local Lymph Node Assay (LLNA) in Mice. Study No: 35239; DACO 4.6.6
2640531	2015, Barley burndown_1_to determine the efficacy and selectivity of CHA-
2040331	5373 when applied as a burndown prior to planting spring barley in 2015,
	DACO: 10.2.3.3(B) and 10.3.2(A)
2640532	2015, Barley burndown_2_to determined the efficacy and selectivity of CHA-
2040332	5373 when applied as a burndown prior to planting spring barley in 2015,
	DACO: 10.2.3.3(B) and 10.3.2(A)
2640533	2015, Barley burndown_5_to determine the efficacy and selectivity of CHA-
2040333	5373 when applied as a burndown prior to planting spring barley in 2015,
	DACO: 10.2.3.3(B) and 10.3.2(A)
2640534	2015, Barley_1_to determine the efficacy and selectivity of CHA-5373 when
2010331	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640535	2015, Barley_2_to determine the efficacy and selectivity of CHA-5373 when
2010333	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640536	2015, Barley_3_to determine the efficacy and selectivity of CHA-5373 when
20.0000	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640537	2015, Barley_4_to determine the efficacy and selectivity of CHA-5373 when
	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640538	2015, Barley_5_to determine the efficacy and selectivity of CHA-5373 when
	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640539	2015, Barley_6_to determine the efficacy and selectivity of CHA-5373 when
	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640540	2015, Barley_7_to determine the efficacy and selectivity of CHA-5373 when
	applied post to spring barley in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640541	2015, Durum wheat burndown_1_CHA-5373 applied as pre-plant burndown
	in durum wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640542	2015, Durum wheat burndown_2_CHA-5373 applied as pre-plant burndown
	in durum wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640543	2015, Durum wheat burndown_3_CHA-5373 applied as pre-plant burndown
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2640544	2015, Durum wheat burndown_4_CHA-5373 applied as pre-plant burndown
	in durum wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640545	2015, Durum wheat burndown_5_CHA-5373 applied as pre-plant burndown
2510515	in durum wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640546	2015, Durum wheat_1_to determine the efficacy and selectivity of CHA-
0<10515	5373 when applied post to durum wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640547	2015, Durum wheat_2_to determine the efficacy and selectivity of CHA-
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2640549	2015, Durum wheat_4_to determine the efficacy and selectivity of CHA-
2640550	5373 when applied post to durum wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640550	2015, Durum wheat_5_to determine the efficacy and selectivity of CHA-5373 when applied post to durum wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
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PMRA Document Number	Reference
2640551	2015, Durum wheat_6_to determine the efficacy and selectivity of CHA-5373 when applied post to durum wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640552	2015, Durum wheat_7_to determine the efficacy and selectivity of CHA-5373 when applied post to durum wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640553	2015, Wheat burndown_1_efficacy and selectivity of CHA-5373 when applied as a burndown prior to planting spring wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640554	2015, Wheat burndown_2_efficacy and selectivity of CHA-5373 when applied as a burndown prior to planting spring wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640555	2015, Wheat burndown_3_efficacy and selectivity of CHA-5373 when applied as a burndown prior to planting spring wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
2640556	2015, Wheat burndown_4_efficacy and selectivity of CHA-5373 when applied as a burndown prior to planting spring wheat in 2015, DACO: 10.2.3.3(B) and 10.3.2(A)
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2640558	2015, Wheat_1_to determine the efficacy and selectivity of CHA-5373 when applied post to spring wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640559	2015, Wheat_2_to determine the efficacy and selectivity of CHA-5373 when applied post to spring wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640560	2015, Wheat_3_to determine the efficacy and selectivity of CHA-5373 when applied post to spring wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640561	2015, Wheat_4_to determine the efficacy and selectivity of CHA-5373 when applied post to spring wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640562	2015, Wheat_5_to determine the efficacy and selectivity of CHA-5373 when applied post to spring wheat, DACO: 10.2.3.3(B) and 10.3.2(A)
2640563	2015, Wheat_6_to determine the efficacy and selectivity of CHA-5373 when applied post to spring wheat, DACO: 10.2.3.3(B) and 10.3.2(A)

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