

Evaluation Report for Category B, Subcategory 2.6, 3.4, 3.12 Application

Application Number: 2018-5428
Application: New End-Use Product – New Combination of Technical Active Ingredients; New End-Use Product Label – New Application Method, New site/host
Product: Prospect Herbicide
Registration Number: 33635
Active ingredients (a.i.): Halauxifen, present as methyl ester; Carfentrazone-ethyl
PMRA Document Number: 3057832

Purpose of Application

The purpose of this application was to register a new end-use product, Prospect Herbicide, for use as a postemergent control of annual broadleaved weeds prior to seeding canola, flax, mustard, soybeans, field peas, field corn, spring wheat, durum wheat and spring barley.

Chemistry Assessment

Prospect Herbicide is formulated as an emulsifiable concentrate containing halauxifen, present as methyl ester, at a concentration of 15 g/L and carfentrazone-ethyl at a concentration of 27.97 g/L. This end-use product has a density of 0.93 g/mL and pH of 4.69. The required chemistry data for Prospect Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Prospect Herbicide is of low acute toxicity to rats by the oral, dermal and inhalation routes. It is minimally irritating to the eye and skin of rabbits. It is not a potential skin sensitizer in mice.

Prospect Herbicide, for use as a preplant weed control herbicide on various crops, does not fit within the registered use pattern for halauxifen, present as methyl ester, with regards to handler exposure. The addition of aerial equipment for soybeans and field corn, as well as the addition of canola, flax, mustard and field peas, treated by both ground and aerial application equipment, required an updated mixer/loader/applicator risk assessment. The use of Prospect Herbicide also does not fit within the registered use pattern for carfentrazone-ethyl, since the addition of aerial application is considered an expansion of use. However, a quantitative mixer/loader/applicator risk assessment was not required due to the absence of toxicological triggers for short-term exposure. For both active ingredients, a quantitative postapplication risk assessment was not required as worker exposure to foliar residues will be negligible due to the preplant timing of application. No health risks of concern from exposure to halauxifen, present as methyl ester, and carfentrazone-ethyl are expected, provided workers wear the appropriate personal protective equipment and follow all label directions.

For carfentrazone-ethyl, there are adequate residue data on file to support the use of Prospect Herbicide. The established MRLs for residues of carfentrazone-ethyl on each of the crops are sufficient to cover the expected residue levels from the use of Prospect Herbicide as a preplant treatment on all crops.

For halauxifen, present as methyl ester, there are adequate residue data on file to support the use of Prospect Herbicide on wheat, barley, field corn and soybeans. The established MRLs for halauxifen, present as methyl ester, in/on wheat, barley, field corn and dry soybeans are sufficient to cover the expected residue levels from the use of Prospect Herbicide as a preplant treatment on these crops.

Residue data for halauxifen, present as methyl ester, from field trials conducted in Europe were submitted to support the Canadian use of Prospect Herbicide for preplant use on canola, flax and mustard, and previously reviewed residue data from field trials conducted in/on wheat, barley, field corn and soybeans were reassessed to support the registration of Prospect Herbicide on these crops. In addition, processing studies in wheat, field corn and soybeans were also reassessed to determine the potential for concentration of residues of halauxifen, present as methyl ester into processed commodities.

Based on this assessment, it was determined that exposure to residues of halauxifen, present as methyl ester, and carfentrazone-ethyl on canola, flax, mustard, soybeans, field pea, field corn, wheat and barley treated according to the approved use directions for Prospect Herbicide will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for halauxifen, present as methyl ester was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). An MRL to cover residues of halauxifen, present as methyl ester, is proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL 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 (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Oilseed rape	Foliar application/ 4.4-5.29	76-251	<0.01	<0.01	No quantifiable residues observed at exaggerated rates in the field corn processing study.	None	0.01 ppm in/on CSG20R-A

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

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of halauxifen, present as methyl ester. Residues in these crop 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 registration of Prospect Herbicide for preplant applications to canola, flax, mustard, soybeans, field pea, field corn, spring wheat, durum wheat, and spring barley to control emerged broadleaf weeds does not result in an increased risk to the environment. The risks associated with the use of the product are acceptable from the viewpoint of environmental protection when label instructions are followed.

Value Assessment

The registration of the two active ingredients halauxifen, present as methyl ester, and carfentrazone-ethyl, with two herbicide modes of action, in a single formulation provides farmers a novel option for control of a broader spectrum of broadleaf weeds and herbicide resistance management.

Value information submitted consisted of scientific rationales and data from replicated field trials conducted over multiple locations and years. The information demonstrated (1) the preplant application of Prospect Herbicide provided acceptable control of cleavers, eastern black nightshade, flixweed, hemp-nettle, lamb's-quarters, morning glory, redroot pigweed, shepherd's-purse, velvetleaf, volunteer canola, and tall waterhemp and suppression of wild buckwheat, dandelion, and stinkweed and (2) canola, flax, mustard, soybeans, field peas, field corn, spring wheat, durum wheat, and spring barley exhibited adequate margins of crop tolerance to Prospect Herbicide applied as per the label instructions.

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

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support registration of Prospect Herbicide.

References

PMRA Document Number	References
2928747	2018, Group B_Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, pH, Viscosity, and Density of GF-3758, an End Use Product Containing Halauxifen-methyl and Carfentrazone ethyl., DACO: 3.5.1,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2928748	2018, Analytical Method and Validation for the Determination of Halauxifen-methyl and Carfentrazone-ethyl in GF-3758 Formulation, DACO: 3.4.1 CBI
2928750	2018, Determination of Explosive Properties of GF-3758, DACO: 3.5.12 CBI
2928751	2018, Determination of Flash Point of GF-3758, DACO: 3.5.11 CBI
2929018	2018, Revised Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-3758, an End Use Product Containing Carfentrazone-ethyl and Halauxifen-methyl, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI
2929800	2018, GF-3758 Two-week Accelerated Storage Stability and Packaging Corrosion Characteristics in EVOH and Vented F-HDPE, DACO: 3.5.10,3.5.14 CBI
2997020	2019, 3.2.2 Prospect Herbicide - Formulation Process Description (2018-5428), DACO: 3.2.2 CBI
2928752	2018, Acute Oral Toxicity Study of GF-3758 in Rats, DACO 4.6.1
2928753	2018, Acute Dermal Toxicity Study of GF-3758 in Rats, DACO 4.6.2
2928754	2018, Acute Inhalation Toxicity Study of GF-3758 in Rats, DACO 4.6.3
2928755	2018, Acute Eye Irritation Study of GF-3758 in Rabbits, DACO 4.6.4
2928756	2018, Acute Dermal Irritation Study of GF-3758 in Rabbits, DACO 4.6.5
2928757	2018, Skin Sensitization Study of GF-3758 by Local Lymph Node Assay in Mice, DACO 4.6.6
2928759	2018, Residue Rationale for Adding Canola (including Juncea canola and Polish canola), Flax, Mustard (including Abyssinian, oriental, brown and yellow mustard), and Field Peas to the GF-3758 Herbicide Label, DACO 7.1
2928762	2016, Magnitude of the Residues of Halauxifen-Methyl and Clopyralid in Oilseed Rape (RAC Whole Plant, Seed and Straw), Following One Application of GF-3488, Northern and Southern Europe – 2015, DACO: 7.4.1.
2928763	2016, Magnitude of the Residues of Halauxifen-methyl and Picloram in Oilseed rape (RAC Whole Plant, Seed and Straw), following One Application of GF-3447, Northern and Southern Europe – 2015, DACO: 7.4.1.
2928766	2018, Rationale to support the use of weeds listed in GF-2685 label for GF-3384 Herbicide, DACO: 10.1, 10.2.1, 10.2.2, and 10.3.2.
2928768	2018, Small scale field trial reports / non safety adverse effects, DACO: 10.2.3.3 and 10.3.2.
2941340	2018, Value rationale revised label rate, GF-3758, DACO: 10.1.

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