

# **Evaluation Report for Category B, Subcategory 3.12 Application**

**Application Number:** 2018-1255

**Application:** Changes to End-Use Product Label – New Site or Host

**Product:** Paradigm Herbicide

**Registration Number:** 31304

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

PMRA Document Number: 2990473

# **Purpose of Application**

The purpose of this application was to add use of Paradigm Herbicide, in tank-mix with a registered glyphosate product, as pre-seed weed control on fields prior to planting oats.

## **Chemistry Assessment**

A chemistry assessment was not required for this application.

#### **Health Assessments**

A toxicological assessment was not required for this application.

The use of Paradigm Herbicide in a tank-mix with a registered glyphosate product used as a presed treatment on fields prior to seeding oats for the control of annual broadleaved weeds, is not expected to result in potential occupational or bystander exposure over the current registered uses of florasulam, halauxifen-methyl and glyphosate. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Acceptable residue data for halauxifen-methyl in/on oats were submitted to support the use of Paradigm Herbicide on oats. Previously reviewed residue data from field trials conducted in/on wheat, barley and field corn, as well as a confined crop rotational study were re-assessed in the framework of this petition. In addition, a processing study in treated wheat as a surrogate for oats was also re-assessed to determine the potential for concentration of residues of halauxifen-methyl into processed commodities.

#### **Maximum Residue Limit**

The established MRLs of 0.01 and 15 ppm for residues of florasulam and glyphosate, respectively, in/on oats are sufficient to cover the expected residue levels generated from the use of Paradigm Herbicide as a pre-seed treatment on fields prior to seeding oats.

The recommendation for a maximum residue limit (MRL) for halauxifen-methyl was based upon the submitted field trial data and the guidance provided in the OECD MRL Calculator. An MRL



to cover residues of halauxifen-methyl in/on oats and processed commodities 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 commodity (RAC).

TABLE 1. Summary of Field Trial Data Used to Support the Maximum Residue Limit (MRL)							
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residue LAFT	HAFT	Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
Oat grain	Postemergent foliar ground application/ 9.5-10.3	73- - 116	<0.01	<0.01	No quantifiable residues observed at exaggerated rates	None	0.01 in/on Oats
	Postemergent foliar ground application/19.0-20.3		<0.01	<0.01			

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

Based on the dietary burden and residue data, MRLs for residues of halauxifen-methyl and the metabolite X11449757 in livestock edible commodities are not required at this time. Residues of halauxifen-methyl and the metabolite X11449757 in milk, eggs, and in meat, meat by-products and fat of cattle, goats, hogs, horses, poultry and sheep will be covered under Part B, Division 15, subsection B.15.002(1) of the FDAR (i.e., <0.1 ppm).

#### **Environmental Assessment**

The use expansion to include pre-seed use on oats is within the currently registered use pattern of Paradigm Herbicide; therefore, no additional risk is expected from the use of Paradigm Herbicide. The label includes all the required environmental precautions, hazards and directions for use statements, including buffer zone information, which adequately mitigates risks to the environment.

#### **Value Assessment**

Expansion of the registration of Paradigm Herbicide to include oat as a host crop provides Canadian growers another option for pre-seed weed control in oat, including several hard-to-kill weeds at more advanced growth stages, e.g., wild buckwheat, chickweed, lamb's-quarters, redroot pigweed, and lady's-thumb at up to the 8-leaf stage and cleavers at up to the 9-whorls stage.

Value information submitted for review consisted of data from dedicated crop tolerance field trials. This information demonstrated that oat can be expected to have an adequate margin of crop tolerance to the pre-seed application of Paradigm Herbicide in tank mix with glyphosate as per the label instructions.

# **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the use expansion for pre-seed weed control in oats.

## References

#### **PMRA Document** Number Reference 2864398 2018, Rationale to Add Oats to the Paradigm Herbicide, PCP No. 31304 label as a Pre-Seed Crop, DACO 7.1 2894947 2012, Residues of XDE-729 in Oats Australia 2010, DACO: 7.4.1. 2894948 2012, Residues of XDE-729 in Oats Australia 2010, DACO: 7.4.1. 2894949 2012, Residues of XDE-729 in Oats Australia 2011, DACO: 7.4.1. 2894950 2012, Residues of XDE-729 in Oats Australia 2011, DACO: 7.4.1. 2437719 2014, Part 10 Value - GF-2687 Preplant efficacy and NSAE v7, DACO: 10.1, 10.2.3.1, and 10.3.2. 2437720 2014, Part 10 Value - Field trial reports (12 trials), DACO: 10.2.3.3.

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