

Evaluation Report for Category B, Subcategory 3.5, 3.10, 3.12 Application

Application Number: 2014-2317

Application: Changes to Product Labels; Tank Mixes, New Site/ Host and Plant

Back interval.

Product: Paradigm Herbicide

Registration Number: 31304

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

PMRA Document Number: 2535605

Purpose of Application

The purpose of this application was to amend the Paradigm Herbicide label (Reg. No. 31304) to include a tank-mix with glyphosate products, for use as pre-seed burn-down of emerged weeds prior to planting of spring wheat, durum wheat, winter wheat, and spring barley or as an initial treatment in summerfallow.

Chemistry Assessment

As there were no changes to the product formulation, a chemistry assessment was not required for this application

Health Assessments

As there were no changes to the product formulation, a toxicology assessment was not required for this application.

The potential exposure for mixers, loaders, applicators and postapplication re-entry workers is not expected to exceed exposure to registered products when label directions are followed.

Previously reviewed residue data from field trials conducted on wheat and barley for florasulam, halauxifen-methyl and glyphosate were reassessed in the framework of this petition.

Residues of florasulam, halauxifen-methyl and glyphosate are not expected to exceed the currently established MRLs following a pre-seed treatment of fields with Paradigm Herbicide (co-formulation of florasulam and halauxifen-methyl) and a tank-mix with glyphosate containing end-use products. Therefore, the dietary exposure to the crops when treated with Paradigm Herbicide and glyphosate will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.



Environmental Assessment

The amendments to the Paradigm Herbicide label are not expected to impact environmental exposure, and risk, as compared to the previously registered product. Environmental concerns have been mitigated through existing statements on the product label.

Value Assessment

Efficacy information included data from seven field trials conducted on small grain cereals in the Canadian Prairies in 2012 and 2013. Efficacy of Paradigm Herbicide in tank mix with Vantage Plus Max II Herbicide (registration number 28840) was compared to that of PrePass Herbicde (florasulam + glyphosate, registration numbers 27395 and 27394), GF-2685 Herbicide (halauxifen, registration number 31305), and Vantage Plus Max II Herbicide at their respective labelled rates for control of a number of weed species.

Mean weed control following the application of Paradigm Herbicide in tank mix with Vantage Plus Max II Herbicide was comparable to PrePass Herbicide applied either in the fall or spring prior to planting of cereal crops. The experimental findings also indicated that the level of weed control provided by halauxifen or florasulam or glyphosate herbicide was not compromised when they were applied in a tank mixture. Therefore, efficacy claims that are labelled for either Paradigm Herbicide or glyphosate herbicide are supported for this tank mixture at the corresponding application rates.

Efficacy information in small grain cereals can be extrapolated to summerfallow since (1) no changes are made to efficacy claims in the summerfallow (i.e., weed species and growth stage) and (2) there is no crop and weed competition in small grain cereals (pre-seeding application) and summerfallow

Crop safety information included data from three combined efficacy and crop tolerance trials and five dedicated crop tolerance trials (with a hand weeded weed-free control) conducted in the Canadian Prairies in 2012 and 2013. Multiple crops were included in the dedicated crop tolerance trials.

Injury to spring wheat (5 trials), durum wheat (5 trials), spring barley (3 trials), and tame oats (3 trials) following the spring application of Paradigm Herbicide in tank mix with Vantage Plus Max II at the labelled 1 x rate and 2 x rates was evaluated. Crop safety with additional glyphosate herbicide in the tank mixture is not of concern since glyphosate herbicide has no soil residual activity. Crop injury was not observed for any treatments in the submitted trials. Yield data from four trials confirmed that spring wheat, durum wheat, spring barley, and tame oats can be expected to exhibit an adequate margin of crop safety to the tank mixture of Paradigm Herbicide in tank mix with glyphosate herbicide applied in the spring prior to planting these crops.

Crop safety information for the spring application can be extrapolated to the fall application since (1) the similar use pattern is presently labelled for herbicides containing florasulam (e.g., Florasulam II Herbicide; Reg. No. 31038) and (2) halauxifen-methyl is classified as non-persistent to slightly persistent herbicide under a variety of terrestrial field conditions (PRD2014-12).

Crop safety information on spring wheat and durum wheat can be extrapolated to winter wheat. Furthermore, winter wheat is labelled for post-emergence application of Paradigm Herbicide and pre-plant application of glyphosate herbicide.

The tank-mix of Paradigm Herbicide + glyphosate will provide growers a tool for control of many hard-to-kill broadleaf weeds at advanced growth stages (up to eight-leaf stage), due to the efficacy of Paradigm Herbicide on large weeds. In addition, due to the spectrum overlap of halauxifen-methyl with florasulam and glyphosate, this tank mixture will be an effective tool for management of weeds that have developed herbicide resistance. In fields where no resistant weed biotypes are present, Paradigm Herbicide plus glyphosate will provide three distinct modes of action on weeds for multi-mode-of-action resistance management to prevent and delay the selection for herbicide resistance.

Based on the weight of evidence, the amendments to the use pattern of Paradigm Herbicide have value and can be supported by VRD.

Conclusion

The amendment to the Paradigm Herbicide to include a tank-mix with glyphosate products, for use as pre-seed burn-down of emerged weeds prior to planting of spring wheat, durum wheat, winter wheat, and spring barley or as an initial treatment in summerfallow was accepted for full registration.

References

PMRA Document Number	Reference
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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