

Evaluation Report for Category B, Subcategory 3.12, 3.5 Application

Application Number:	2022-6457			
Application:	Changes to Product Labels-New Site or Host and Rotational			
	Crops\Plantback Interval			
Product:	Smoulder			
Registration Number:	33943			
Active ingredients (a.i.):	Metsulfuron-methyl and saflufenacil			
PMRA Document Number: 3550396				

Purpose of Application

The purpose of this application was to amend the label of the commercial-class end-use product Smoulder (Reg. No. 33943) to add oats, triticale and fall rye as new host crops, and to add imidazolinone-tolerant chickpeas as a rotational crop.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The addition of pre-seed application to oats, triticale and fall rye to the registered label of Smoulder represents an expansion of the use pattern for metsulfuron-methyl, while only the addition of pre-seed application to triticale and fall rye represents an expansion of the use pattern for saflufenacil. For metsulfuron-methyl, an updated mixer/loader/applicator quantitative risk assessment was conducted. For saflufenacil, the risk assessment on file was adequate to address the potential exposure for workers during mixing, loading and application. Based on the timing of application, postapplication exposure from contact with treated weeds and soil is minimal, and quantitative risk assessments were not required. Bystander exposure is expected to be minimal. No health risks of concern were identified provided that workers wear the appropriate personal protective equipment and follow all label directions.

No new residue data for saflufenacil or metsulfuron-methyl in oats, triticale, and rye were submitted or were required to support the addition of these three crops, removal of the 60-day preharvest interval for all cereal crops, and amendments to the rotational crop statements on the Smoulder label. Previously reviewed residue data from field trials conducted in/on wheat, barley, and oats were reassessed in the framework of this application. In addition, processing studies in treated wheat and barley were reassessed to determine the potential for concentration of residues into processed commodities.



For saflufenacil, residues in/on oats, triticale, rye and in edible livestock commodities are adequately covered by the established maximum residue limits (MRLs), and no updates to the dietary exposure assessment on file were required. Consequently, dietary exposure to residues of this active ingredient is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

For metsulfuron-methyl, residues in edible livestock commodities are adequately covered by the established MRLs, residues in/on oats were recommended under submission 2022-2090, and new MRLs are being recommended in/on triticale and rye, as detailed below. The dietary exposure assessment on file was updated to include triticale and rye. As a result, no health risks of concern from chronic dietary exposure (food and drinking water) have been identified for any segment of the population, including infants, children, adults, and seniors.

A toxicology assessment was not required for this application.

Maximum Residue Limits

The recommendation for proposed MRLs for metsulfuron-methyl was based upon previously reviewed field trial data on file, and the guidance provided in the <u>OECD MRL Calculator</u>. MRLs to cover residues of metsulfuron-methyl and its metabolite 4-hydroxy metsulfuron-methyl in/on crops 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 (g a.i./ha)	PHI (days)	Residues (ppm) ¹		Experimental	Currently	Recommended
			LAFT	HAFT	Processing Factor	Established MRL (ppm)	MRL (ppm)
Wheat	Foliar treatment / 6-70	37-231	<loq< td=""><td><loq< td=""><td>No quantifiable residues were observed at exaggerated rates.</td><td>None</td><td>0.1 ppm for triticale & rye</td></loq<></td></loq<>	<loq< td=""><td>No quantifiable residues were observed at exaggerated rates.</td><td>None</td><td>0.1 ppm for triticale & rye</td></loq<>	No quantifiable residues were observed at exaggerated rates.	None	0.1 ppm for triticale & rye

ppm = parts per million; PHI = preharvest interval; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial ¹ Residues = metsulfuron-methyl and 4-hydroxy metsulfuron-methyl, expressed as parent equivalents

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of metsulfuron-methyl and its metabolite 4-hydroxy metsulfuron-methyl (expressed as parent equivalents). Dietary risks from exposure to residues of metsulfuron-methyl in these crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues as listed in Table 1 are considered safe to eat.

Environmental Assessment

The expansion of the Smoulder use pattern to include pre-seed application to oats, triticale, and fall rye for the control of broadleaf weeds is acceptable from an environmental perspective when used in accordance with the label directions.

Value Assessment

Value information was submitted in the form of crop phytotoxicity and yield data from 14 smallscale field trials conducted on oat, triticale and fall rye that were maintained weed-free. The data collectively demonstrated that each of these crops are tolerant of Smoulder applied at the labelled rate a minimum of one day prior to seeding or as plant-back crops in the event of a crop failure in Smoulder-treated fields. Crop phytotoxicity and yield data from four small-scale rotational crop tolerance trials demonstrated that imidazolinone-tolerant chickpea cultivars can be safely planted 11 or more months after application of Smoulder at the labelled rate.

The availability of Smoulder for use prior to planting oat, triticale, and fall rye provides growers an alternative option for early weed management in these crops, while the addition of imidazolinone-tolerant chickpea as a follow crop offers growers increased flexibility in crop rotation planning.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support amendments to the label of Smoulder to add oats, triticale and fall rye as new host crops, and to add imidazolinone-tolerant chickpeas as a rotational crop.

References

PMRA	
Document	
Number	Reference
3416865	2022, Field Trial Reports - Smoulder, DACO: 10.3.2(A),10.3.3
3435441	2023, Revised Trial Reports - Chickpea Rotational Crop Trials, DACO: 10.3.3
3430518	2010, Variation in chickpea germplasm for tolerance to imazethapyr and imazamox herbicides, DACO: 7.8

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