Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6, 3.1, 3.2 Application

Application Number: 2017-2938
Application: New EP Product Chemistry-New combination of TGIAs
New Product Labels-Application Rate Increase or Decrease
New Product Labels-Application Timing
Product: Tavium plus VaporGrip Technology Herbicide
Registration Number: 33268
Active ingredients (a.i.): S-metolachlor and R-enantiomer, Dicamba (present as Acid, Amine Salt, Ester, Potassium Salt, Or Sodium Salt)
PMRA Document Number : 2809291

Purpose of Application

The purpose of this application was to register a new combination of actives in a co-formulated end-use product, Tavium plus VaporGrip Technology Herbicide.

Chemistry Assessment

Tavium plus VaporGrip Technology Herbicide is formulated as a microcapsule suspension containing S-Metolachlor and R-enantiomer at 271 g/L and Dicamba as the diglycolamine salt at 134 g/L. This end-use product has a density of 1.132 g/cm^3 and pH of 6.6. The required chemistry data for Tavium plus VaporGrip Technology Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Tavium plus VaporGrip Technology Herbicide is of low toxicity to rats via the oral, dermal, and inhalation routes. It is minimally irritating to the eyes of rabbits and is slightly irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

The use pattern of Tavium plus VaporGrip Technology Herbicide on Roundup Ready 2 Xtend® soybeans is not expected to increase potential occupational or bystander exposure over the registered uses of dicamba and S-metolachlor and R-enantiomer. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue data for dicamba in soybeans were submitted to support the registration of Tavium plus VaporGrip Technology Herbicide. Based on a comparison of the use directions of Tavium plus VaporGrip Technology Herbicide to the precedent end-use product, residues of dicamba in/on treated soybean commodities as a result of this action should not increase given that the method and timing of application are identical, the application rate is lower and the pre-harvest interval (PHI) is longer. As such, residues of dicamba in/on treated soybean commodities will be covered under the maximum residue limit (MRL) of 10 ppm currently

established for dicamba in/on dry soybeans (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php). Likewise, residues of dicamba in livestock derived food commodities (i.e., meat, meat byproducts, eggs and milk) will not increase and will continue to be covered under Part B, Division 15, Subsection B.15.002(1) of the Food and Drugs Act and Regulations (i.e., ≤0.01 ppm).

Residue data from field trials conducted in the United States in representative Canadian growing regions were submitted to support the domestic use of Tavium plus VaporGrip Technology Herbicide on Roundup Ready 2 Xtend soybeans. *S*-metolachlor was applied to soybeans at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated soybean was reviewed to determine the potential for concentration of residues of *S*-metolachlor into processed commodities.

Maximum Residue Limits (*S*-Metolachlor)

Based on the residue data submitted for *S*-metolachlor in soybeans, residues in/on treated soybean commodities will be covered under the MRL of 0.2 ppm currently established for *S*-metolachlor in/on dry soybeans as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the established MRL for the raw agricultural commodities (RAC).

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues[1] (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Soybean seed	Pre-plant incorporated + broadcast foliar/ 2.8-2.9	85-103	<0.08	0.11	No quantifiable residues observed at exaggerated rate.	0.2 ppm	None

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

[1] Total *S*-metolachlor: sum of SYN506357 and SYN508500.

Based on the soybean residue data and the restriction on the label of Tavium plus VaporGrip Technology Herbicide preventing the grazing of the immature soybean crop or cutting for hay, the dietary burden for *S*-metolachlor will not increase as a result of this action. As such, residues of *S*-metolachlor in/on livestock-derived food commodities used for human consumption will continue to be covered under the MRLs currently established (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php).

Residues of dicamba and *S*-metolachlor in/on soybean commodities treated according to the use

directions for Tavium plus VaporGrip Technology Herbicide will not pose unacceptable health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Tavium plus VaporGrip Technology Herbicide on soybean is within the currently registered use patterns for other end-use products containing dicamba and S-metolachlor and R-enantiomer. Therefore, no additional risk is expected from the product. The label includes the required environmental hazard statements and aquatic buffer zones.

Value Assessment

Roundup Ready 2 Xtend soybean production is likely to increase in Canada as it provides users access to a new mode of action to control broadleaved weeds in soybeans to help control weeds that have developed resistance to glyphosate and are becoming more and more common. Tavium plus VaporGrip Technology Herbicide provides users control of emerged annual and perennial broadleaf weeds (including glyphosate resistant weeds) as well as residual control of annual grassy weeds.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Tavium plus VaporGrip Technology Herbicide, and has found the information sufficient to support the registration of the end-use product.

References

PMRA Document Number	Reference
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2772656	2017, Evaluate S-metolachlor/dicamba pre-mix (A21472C) efficacy and tolerance concepts in soybean, DACO: 10.3.2
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2772673	2016, Dicamba/S-Metolachlor CS (A21472C) - Acute Dermal Toxicity in Rats, DACO: 4.6.2

2772681	2016, Dicamba/S-Metolachlor CS (A21472C) -Acute inhalation toxicity in rats, DACO: 4.6.3
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2772688	2017, Description of Starting Materials, DACO: 3.2.1,3.3.1,3.3.2 CBI
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