

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2016-6055
Application: Changes to Product Labels – New Site or Host
Product: TRAXOS Herbicide
Registration Number: 29855
Active ingredients (a.i.): Clodinafop-propargyl, Pinoxaden
PMRA Document Number: 2839167

Purpose of Application

The purpose of this application was to amend the label of TRAXOS Herbicide, containing clodinafop-propargyl and pinoxaden as active ingredients and the safener cloquintocet-mexyl, by adding a use on winter wheat, to expand the use to Eastern Canada and to include more detailed mixing instructions.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of the TRAXOS Herbicide on winter wheat is not expected to result in potential occupational or bystander exposure over the registered use of pinoxaden, clodinafop-propargyl and the safener cloquintocet-mexyl. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Clodinafop-propargyl residue data from field trials conducted in the United States, including Canadian representative growing regions, were submitted to support the use of TRAXOS Herbicide on winter wheat and to extend its use on wheat in Eastern Canada. Clodinafop-propargyl was applied to spring and winter wheat at exaggerated rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on spring wheat were also re-assessed in the framework of this petition. In addition, a processing study in treated spring and winter wheat was reviewed to determine the potential for concentration of residues of clodinafop-propargyl into processed commodities.

No new residue data for pinoxaden and the safener cloquintocet-mexyl in wheat were submitted to support the use of TRAXOS Herbicide on winter wheat and to extend its use on wheat in Eastern Canada. Both active and safener are registered for use on all types of wheat (spring, durum and winter wheat) across Canada at similar or higher rate as that on the TRAXOS Herbicide label. As such, this petition does not constitute an expansion of use for these actives.

Maximum Residue Limit (MRL)

The current MRL of 0.02 ppm is adequate to cover residues of clodinafop-propargyl, including the acid metabolite CGA-193469, in/on wheat grain. The review of a processing study on wheat treated at exaggerated rate indicated that no quantifiable residues were detected above the method limit of quantitation (LOQ) in any wheat grain human food processed commodities. As such, residues of clodinafop-propargyl, including the acid metabolite CGA-193469, in/on wheat grain processed commodities are covered under the current MRL for wheat grain.

Based on the dietary burden and residue data, an MRL of 0.01 ppm is proposed for all animal matrices to cover residues of clodinafop-propargyl and the acid metabolite CGA-193469.

Following the review of all available data, the current MRL of 0.02 ppm in/on wheat grain and the proposed MRL of 0.01 ppm for all animal commodities will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Additional environmental data were not required to expand the use of TRAXOS Herbicide to Eastern Canada and to include winter wheat. The rates are within the currently registered use pattern for pinoxaden and clodinafop-propargyl. Therefore, no additional risk is expected from the use of TRAXOS Herbicide. The required label corrections include precautionary hazard statements and buffer zones information, which adequately mitigate risks to the environment.

Value Assessment

The availability of TRAXOS Herbicide for use on spring and winter wheat in eastern Canada and on winter wheat in the Prairie region and the interior of British Columbia will provide growers of these crops an additional option for control of annual grass weeds whether applied alone or in tank mixtures with other pest control products, including with herbicides for broader spectrum weed control.

Value information in the form of data generated in small-scale performance trials conducted in eastern Canada was submitted. Phytotoxicity to winter wheat treated with TRAXOS Herbicide at the labelled rate of 60 g a.i./ha (1.2 L/ha) or at the exaggerated rate of 120 g a.i./ha was not usually visually detectable and never exceeded 5%. Grain yield was unaffected when applied at either rate in the trials in which slight injury was detectable. The relatively high level of crop safety to winter wheat observed in these trials along with the known high level of crop safety for spring wheat (including durum), support use on winter and spring wheat in Eastern Canada and winter wheat in the Prairie region and interior of British Columbia. Additionally, the performance of TRAXOS Herbicide applied in eastern Canada is expected to be similar to that in western Canada for control of labelled weeds.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the amendment of the label for TRAXOS Herbicide to add a use on winter wheat, to expand the use to Eastern Canada and to include more detailed mixing instructions.

References

PMRA Document Number	References
2159853	1991, Absorption, Distribution and Excretion of U ¹⁴ C Phenyl CGA 184927 After Multiple Oral Administration to a Lactating Goat, DACO: 6.2
1451512	1991, Distribution and Excretion of (U- ¹⁴ C)-Phenyl CGA 184927 After Multiple Oral Administration to Laying Hens, DACO: 6.2
1451511	1997, The Nature of the Metabolites in Milk, Eggs, Tissues, and Excreta of a Goat and Hens after Multiple Oral Administration of (U- ¹⁴ C)-Phenyl CGA 184927, DACO: 6.2
2785917	2002, ¹⁴ C-Pyridine and ¹⁴ C-Phenyl CGA-184927 - Nature of the Residue in Lactating Goats, DACO: 6.2
1451510	2002, ¹⁴ C-Pyridine and ¹⁴ C-Phenyl CGA-184927: Nature of the Residue in Laying Hens, DACO: 6.2
2736533	2017, Clodinafop Propargyl - Validation of the QuEChERS Method for the Determination of Residues of Clodinafop Acid (CGA193469) in Animal Matrices by LC-MS/MS, DACO: 7.2.2
2736535	2015, Clodinafop Propargyl: Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of Clodinafop Acid (CGA193469) in Animal Matrices by LC-MS/MS - Final Report Amendment 1, DACO: 7.2.3
1451513	2002, 14C-CGA-184927: Metabolism in Spring Wheat after Late Application, DACO: 6.3
1451514	2001, 14C-CGA-184927: Nature of the Residue in Spring Wheat (Interim Report), DACO: 6.3
1451515	2002, 14C-CGA-184927: Nature of the Residue in Spring Wheat (Final Report), DACO: 6.3
2686050	2001, CGA-184927 and CGA-185072 - Magnitude of the Residues in or on Winter Wheat, DACO: 7.4.1
2686051	2001, CGA-184927 and CGA-185072 - Magnitude of the Residues in or on Winter Wheat, DACO: 7.4.1
2686052	2002, CGA-184927 and CGA-185072 - Magnitude of the Residues in or on Winter Wheat, DACO: 7.4.1
2686043	2016, CAON0H2012016 Cowan, Syngenta Canada Inc., Plattsville ON, DACO: 10.3.2
2686044	2016, CAON0H2022016 Cowan, Syngenta Canada Inc., Bright ON, DACO: 10.3.2
2686045	2016, CAON0H2032016 Cowan, Syngenta Canada Inc., Plattsville ON, DACO: 10.3.2
2686046	2016, CAON0H2042016 Cowan, Syngenta Canada Inc., Hickson ON, DACO: 10.3.2

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