



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2021-5975
Application: New EP Product Chemistry-New combination of Technical Grade Active Ingredients
Product: OnDeck Herbicide
Registration Number: 34709
Active ingredients (a.i.): Tolpyralate, Bromoxynil
PMRA Document Number : 3421550

Purpose of Application

The purpose of this application was to register the new end-use product OnDeck Herbicide, for post-emergent control of grass and annual broadleaved weeds in wheat (spring, durum, winter) and barley. Its use pattern includes application either alone or in tank-mix with 2,4-D or MCPA ester and/or grass herbicides.

Chemistry Assessment

OnDeck Herbicide is formulated as an emulsifiable concentrate containing tolpyralate at a concentration of 18.7 g/L and bromoxynil at a concentration of 186.6 g/L, present as octanoate ester. This end-use product has a density of 1.06 and pH of 4.9. The required chemistry data for OnDeck Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

OnDeck Herbicide was moderately acutely toxic via the oral and dermal routes. It was of low acute toxicity via the inhalation route. It was mildly irritating to the eye and skin. OnDeck Herbicide is a skin sensitizer.

OnDeck Herbicide for use on wheat and barley via ground and aerial application for postemergent weed control represents an expansion of the use pattern for tolpyralate and bromoxynil. Mixer/loader/ applicator and postapplication quantitative risk assessments were conducted and no health risks of concern were identified, provided that workers wear the appropriate personal protective equipment and follow all label directions.

Residue data from field trials conducted in Canada and the United States were submitted to support the use of OnDeck Herbicide on barley and wheat. Tolpyralate was applied to barley and wheat at exaggerated rates, and harvested according to label directions. In addition, processing studies in treated barley and wheat were reviewed to determine the potential for concentration of residues of tolpyralate into processed commodities.

Previously reviewed residue data from field trials conducted with bromoxynil in/on barley and wheat were reassessed in the framework of this application. In addition, processing studies in treated barley and wheat were reassessed to determine the potential for concentration of residues of bromoxynil into processed commodities.

Maximum Residue Limits

The recommendation for proposed maximum residue limits (MRLs) for tolpyralate was based upon the submitted field trial data. MRLs to cover residues of tolpyralate 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).

| Commodity | Application Method/ Total Application Rate (g a.i./ha) | PHI (days) | Tolpyralate Residues (ppm) | | Experimental Processing Factor | Currently Established MRL (ppm) | Proposed MRL (ppm) |
|-----------|--|------------|----------------------------|-------|--------------------------------|---------------------------------|--------------------|
| | | | LAFT | HAFT | | | |
| Barley | Foliar Broadcast/ 37.3-42.4 | 47-56 | <0.01 | <0.01 | None | Not established | 0.01 |
| Wheat | Foliar Broadcast/ 38.4-41.6 | 47-58 | <0.01 | <0.01 | None | Not established | 0.01 |

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of tolpyralate. Dietary risks from exposure to residues of tolpyralate 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

Environmental risks associated with the use of OnDeck Herbicide for post-emergent control of grasses and broadleaved weeds in wheat (spring, durum, and winter) and barley are acceptable when used according to the label directions, which include spray buffer zones.

Value Assessment

The registration of OnDeck Herbicide provides users the first co-formulation of tolpyralate (Group 27) with bromoxynil (Group 6) for control of foxtail and certain broadleaf weeds in spring wheat, durum wheat, winter wheat, and barley. In addition, the application of OnDeck Herbicide in tank mix with a broad range of herbicides provides a valuable tool that helps to manage the development of herbicide-resistant weed biotypes in the host crops.

Value information submitted for review consisted of scientific rationales, a precedent registration, and data from replicated field trials. This information collectively demonstrated that the application of OnDeck Herbicide provided acceptable control of the labelled weeds and wheat (spring, durum, and winter) and barley as host crops exhibited adequate margins of tolerance to OnDeck Herbicide applied as per the label instructions.

Rotational crops are supported based on the precedent registration of a tolpyralate containing end-use product as well as data from replicated field trials. Certain tank mixtures are supported based on the claims and use patterns that are registered for tank mixture partners.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of OnDeck Herbicide.

References

PMRA

Document

Number Title

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- 3286829 2021, GF-5036 Group A Report, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI
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- 3290963 2021, 3.5.10 GF-5036 2week54C Storage in FHDPE and PE-EVOH, DACO: 3.5.10
- 3410837 2022, Formulating Process 23Nov2022, DACO: 3.2
- 3286831 2021 Acute Oral Toxicity Study of GF-5036 in Rats DACO 4.6.1
- 3286832 2021 Acute Dermal Toxicity Study Waiver DACO 4.6.2
- 3286833 2021 GF-5036: Inhalation Median Lethal Concentration (LC50) Study in Rats DACO 4.6.3
- 3286834 2021 Acute Eye Irritation Study of GF-5036 in Rabbits DACO 4.6.4
- 3286836 2021 Acute Dermal Irritation of GF-5036 in Rabbits DACO 4.6.5
- 3286837 2021 Skin Sensitisation Study of GF-5036 by Local Lymph Node Assay in Mice DACO 4.6.16
- 3286724 2021, Magnitude and Decline of the Residue of Tolpyralate in or on Wheat Raw Agricultural and Processed Commodities Following One Foliar Application of Tolpyralate 400 SC - 2019, DACO: 7.1,7.2.1,7.4.1,7.4.2
- 3286725 2021, Magnitude and Decline of the Residues of Tolpyralate and [CBI REMOVED] in or on Barley Raw Agricultural and Processed Commodities Following One Foliar Application of Tolpyralate 400 SC - 2020, DACO: 7.1,7.2.1,7.4.1,7.4.2
- 3286840 2021, DACO 10-Tolpyralate + Bromoxynil-Written summary, DACO: 10.
- 3286841 2018, DACO 10 Trial reports, DACO: 10.2.3.2 and 10.3.2

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