Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2022-0398
Application: New End-use Product (Product Chemistry) – New Combination of Technical Grade Active Ingredients
Product: Oxbow Herbicide
Registration Number: 34883
Active ingredients (a.i.): Bromoxynil and Dichlorprop P-isomer (present as 2-ethylhexyl ester)
PMRA Document Number: 3462371

Purpose of Application

The purpose of this application was to register Oxbow Herbicide, a commercial class end-use product for post-emergent control of labelled broadleaf weeds in wheat (spring, durum, and winter) and barley, based on precedent products owned by the applicant.

Chemistry Assessment

Oxbow Herbicide is formulated as an emulsifiable concentrate containing bromoxynil at a concentration of 174 g/L and dichlorprop P-isomer (present as 2-ethylhexyl ester) at a concentration of 435 g/L. This end-use product has a density of 1.158 g/mL and pH of 3.73. The required chemistry data for Oxbow Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Oxbow Herbicide is of high acute toxicity via the oral route of exposure. It is of low acute toxicity via the dermal and inhalation routes of exposure. It is minimally irritating to the eyes and mildly irritating to the skin. It is considered a skin sensitizer.

The registration of Oxbow Herbicide can be supported from an occupational exposure perspective. The mixer/loader/applicator exposure and risk assessments were updated for bromoxynil and dichlorprop P-isomer using the registered use pattern. 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 bromoxynil and dichlorprop P-isomer in wheat and barley were submitted or were required to support the registration of Oxbow Herbicide. Previously reviewed residue data from field trials conducted in/on wheat and barley were reassessed in the framework of this application. The registration of Oxbow Herbicide does not represent an expansion of use for either active ingredient and as such, is not expected to impact dietary exposure. There are no health risks of concern identified for any segment of the population,

including infants, children, adults and seniors.

Environmental Assessment

The uses on the Oxbow Herbicide label are within the currently registered use pattern of bromoxynil. The maximum single application rate exceeds the registered use pattern of dichlorprop P-isomer, present as 2-ethylhexyl ether, but is within its maximum yearly application rate. Therefore, new spray buffer zones were calculated. In addition, the risk assessment to beneficial arthropods was updated and risk was determined to be negligible when label directions are followed (see Table 1). No additional risk is expected when Oxbow Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Table 1. Refined Risk Assessment for Beneficial Arthropods Exposed to Oxbow Herbicide

Organism	**Exposure**	**Test substance**	**EEC* (g a.i./ha)**	**Endpoint (g a.i./ha)**	**UF**	**Endpoint/UF**	**RQ**	**LOC**	**Comment**
Predatory arthropod	Glass-plate, in-field	Dichlorprop P-isomer, present as 2-ethylhexyl ester	69.9	LR_{50} = 261	1	261	0.268	1	LOC not exceeded

EEC = estimated environmental concentration; LOC = level of concern; LR_{50} = lethal rate 50%; RQ = risk quotient; UF = uncertainty factor

*The EEC was refined considering a minimum foliar interception factor of 0.1.

Value Assessment

The registration of Oxbow Herbicide provides users with the first co-formulation of bromoxynil with dichlorprop P-isomer to control broadleaf weeds in wheat and barley. Oxbow Herbicide contains active ingredients from two herbicide mode of action groups, providing users with a valuable tool that may help manage the development of herbicide-resistant weed biotypes.

Value information submitted for review consisted of scientific rationales, precedent registrations, and data from replicated field trials. This information collectively demonstrated that efficacy and crop tolerance of Oxbow Herbicide for control/suppression of the labelled weeds in wheat (spring, durum, and winter) and barley have acceptable value.

Conclusion

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

References

PMRA Document Number	Reference
3314885	2022, A Rationale Based on Trial Data to Support the Weeds List on the Proposed Label for Oxbow Herbicide, DACO: 10.2.3.1,10.2.3.3,10.3.1, 10.3.2,10.3.2(A)
3314887	2021, Oxbow, 2021_047A, Trial reports, DACO: 10.2.3.3,10.3.2(A)
3314888	2021, Oxbow, 2021_047East, Trial reports, DACO: 10.2.3.3,10.3.2(A)
3314889	2021, Oxbow, 2021_047T1, Trial reports, DACO: 10.3.2(A)
3314890	2022, Oxbow Herbicide Selected Phys/Chem Properties, DACO: 3.1.1,3.1.2, 3.1.3,3.1.4,3.3.1,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5
3314891	2022, NFA-0210208 Manufacturing Manual, DACO: 3.2,3.2.1,3.2.2 CBI
3314892	2021, NFA-0210208: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, Flammability, pH, Viscosity, and Density/Relative Density, DACO: 3.5,3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7, 3.5.8,3.5.9
3314893	2022, NFA-0210208: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
3314894	2022, NFA-0210208: Enforcement Analytical Method, DACO: 3.4.1
3441067	2022, 57198 Data, DACO: 3.4.1 CBI
3314895	2021, NFA-0210208: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3314896	2021, NFA-0210208: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3314897	2021, NFA-0210208: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3314898	2021, NFA-0210208: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3314899	2021, NFA-0210208: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3314900	2021, NFA-0210208: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6