Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2022-6470
Application: New End-use Product – New combination of Technical Grade Active Ingredients
Product: Oxbow Prime
Registration Number: 35260
Active ingredients (a.i.): Bromoxynil, dichlorprop-p (present as 2-ethylhexyl ester), and florasulam
PMRA Document Number: 3595484

Purpose of Application

The purpose of this application was to register a new herbicide end-use product, Oxbow Prime, which contains a new combination of technical grade active ingredients, for the control of broadleaf weeds in wheat and barley.

Chemistry Assessment

Oxbow Prime is formulated as an emulsifiable concentrate containing bromoxynil (present as mixed heptanoate and octanoate esters) at a concentration of 170 g/L, dichlorprop-p (present as 2-ethylhexyl ester) at 425 g/L, and florasulam at 3 g/L. This end-use product has a density of 1.18 g/mL and pH of 3.78. The required chemistry data for Oxbow Prime have been provided, reviewed and found to be acceptable.

Health Assessments

Oxbow Prime is of high acute toxicity via the oral route and of low acute toxicity via the dermal and inhalation routes. It is mildly irritating to the eye and skin. It is a potential dermal sensitizer.

The occupational exposure and risks from the new co-formulation of the active ingredients bromoxynil, florasulam and dichlorprop-p were assessed. No health risks of concern to workers and bystanders are expected from the new uses, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for bromoxynil, dichlorprop-p, or florasulam in wheat and barley were submitted or were required to support the registration of Oxbow Prime. Previously reviewed residue data from field trials conducted in/on wheat and barley were reassessed in the framework of this application.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of bromoxynil, dichlorprop-p, and

florasulam is not expected to increase with the registration of the new end-use product Oxbow Prime and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The requested use of Oxbow Prime on wheat and barley is within the currently registered use pattern for florasulam, dichlorprop-p (present as 2-ethylhexyl ester) and bromoxynil. Therefore, the risk is acceptable when Oxbow Prime is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The registration of Oxbow Prime provides users with a co-formulation of bromoxynil, dichlorprop-p, and florasulam to control broadleaf weeds in wheat and barley. Oxbow Prime contains active ingredients from three 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 field trials. This information collectively demonstrated that efficacy and crop tolerance of Oxbow Prime for control of the labeled 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 Prime.

References

PMRA Document Number	Reference
3417254	2022, Reata Manufacturing Manual, DACO: 3.2,3.2.1,3.2.2 CBI
3417255	2022, Reata Selected Chemistry 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 CBI
3417256	2022, Method Validation of NFA-0210302, DACO: 3.4 CBI
3417257	2022, Accelerated Storage Stability and Corrosion Characteristics of NFA-0210302, DACO: 3.4.1,3.5.10,3.5.14 CBI
3417258	2022, Physical and Chemical Characteristics of NFA-0210302, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3472635	2023, Reata_Def. Response_230608, DACO: 3.4.1
3417260	2022, NFA-0210302: Acute Oral Toxicity- Up-And-Down Procedure in Rats, DACO: 4.6.1
3417261	2022, NFA-0210302: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3417262	2022, NFA-02 10302: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3417263	2022, NFA-0210302: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3417264	2022, NFA-0210302: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3417265	2022, NFA-0210302: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3417267	2022, Trial reports, DACO: 10.2.3.3(B).
3417268	2022, Trial reports, DACO: 10.2.3.3(B).
3417269	2022, Trial reports, DACO: 10.3.2(A).
3417270	2022, Trial reports, DACO: 10.3.2(A).
3458781	2023, A Rationale Based on Trial Data to Support the Weeds List on the Proposed Label for Reata, DACO: 10.2.3.1.

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