



Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4 and B.3.1-S-N-EP Application

Application Number: 2006-0237
Application: B.2.1 (guarantee), B.2.3 (identity of formulants), B.2.4 (proportion of formulants), and B.3.1-S-N-EP (application rate increase)
Product: Bromoxynil + 2,4-D
Registration Number: 28779
Active ingredients (a.i.): bromoxynil (BRY) and 2,4-D (DXF)
PMRA Document Number: 1471377

Background

Bromoxynil and 2,4-D have been registered and are under re-evaluation. Bayer CropScience has a similar registered product, Thumper Emulsifiable Selective Weedkiller (Reg. No. 22659, guarantee: 280 g/L bromoxynil and 280 g/L 2,4-D). For specific details of uses, application rates, and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this submission is to register a new agricultural EP, Bromoxynil + 2,4-D (guarantee: bromoxynil 225 g/L and 2,4-D 225 g/L), which has similar application rate and use pattern as Thumper Emulsifiable Selective Weedkiller.

Chemistry Assessment

Bromoxynil + 2,4-D is formulated as an emulsifiable concentrate containing bromoxynil present as octanoate ester and 2,4-D present as 2-ethylhexyl ester, each at a nominal concentration of 225 g/L. This end-use product has a density of 1.121 g/mL and pH of 3.84 for a 1% solution. The chemistry requirements for Bromoxynil + 2,4-D are complete.

Health Assessments

Bromoxynil + 2,4-D is of moderate acute toxicity by the oral ($LD_{50} = 550$ mg/kg bw) and of low toxicity through the inhalation ($LD_{50} > 2000$ mg/kg bw) and dermal ($LD_{50} > 2.04$ mg/kg bw) routes in rats. It is moderately irritating for the eyes (MIS = 26/110 and MAS = 8.67/110) and the skin (MIS = 4/8 and MAS = 3.89) in rabbits. It also is a skin sensitizer in Guinea pigs.

Food Residue Exposure Assessment Section

To support the registration of the new end-use product Bromoxynil + 2,4-D (bromoxynil - present as ester at 225 g/L and 2,4-D isomer specific- present as ester at 225g/L), no new residue chemistry data were submitted. Following a comparison of the product labels, it is concluded that residues of bromoxynil and 2,4-D in/on wheat and barley are not expected to increase following treatment according to the proposed product label as the use directions are identical to the registered products Approve Herbicide (Registration No. 28123; 225 g/L bromoxynil and 250 g/L 2,4-D) and Thumper Emulsifiable Selective Weedkiller (Registration No. 22659; 280 g/L bromoxynil and 280 g/L 2,4-D). Therefore, no increase in dietary exposure is anticipated.

Occupational Exposure Assessment Section

A health assessment has been conducted for Bromoxynil + 2,4-D. It is not expected that exposure to handlers will increase over the currently registered products containing both Bromoxynil and 2,4-D active ingredients.

Environmental Assessment

An environmental assessment was not required as the application rate, number of applications, frequency of application, and tank-mix partners fell within that registered for spring wheat, durum wheat and barley. There are no environmental concerns with the use of the subject product that are not mitigated by the existing label statements. The label for this product will need to conform to the new label standard for 2,4-D and bromoxynil when the decision documents for these two active ingredients are published.

Value Assessment

To support the registration of Bromoxynil + 2,4-D, the registrant submitted bridging data from 10 efficacy trials conducted over one year and 3 crop tolerance trials conducted over one year.

The efficacy trials reported weed control ratings of 9 broadleaf and 2 annual grassy. The level of control was visually assessed (as % control) following each treatment up to 4 times throughout the growing season: early season (7 to 8 days after treatment [DAT]), mid season (14-30 DAT) and late season (55-65 DAT). Based on the efficacy data made available, Bromoxynil + 2,4-D and the tank-mix treatments with Bromoxynil + 2,4-D resulted in an acceptable level of weed control and were comparable to that of the commercial treatments containing the same active ingredients.

The crop tolerance data consisted of 3 trials conducted on spring wheat, 3 trials conducted on durum wheat and 4 trials conducted on spring barley. The level of crop injury was visually assessed (as % injury) following each treatment up to 4 times throughout the growing season: early season (7 to 8 DAT), mid season (14-30 DAT) and late season (55-65 DAT). Yield was reported in spring wheat (3 trials), durum wheat (2 trials) and barley (3 trials). Based on crop tolerance data made available, Bromoxynil + 2,4-D has demonstrated to be agronomically similar to the commercial standard treatments on spring wheat, durum wheat and barley.

Based on the bridging data provided, Makhteshim Agan of North America has demonstrated that Bromoxynil + 2,4-D is agronomically similar to the presently registered commercial products containing the same active ingredients when applied as an alone treatment, or tank-mixed.

Bromoxynil + 2,4-D is acceptable for registration from a Value perspective.

Conclusion

The PMRA has completed an evaluation of the subject applicaiton and has found the information sufficient to register the new EP.

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BROMOXYNIL + 2,4-D guarantee
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