Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.10, 3.11, 3.12 Application

Application Number: 2010-5248
Application: New product chemistry: Identity and proportion of formulants
New product label: tank mixes, new pests, new site or host
Product: Vigil WB
Registration Number: 30844
Active ingredient (a.i.): Fenoxaprop-P-ethyl
PMRA Document Number: 2175098

Purpose of Application

The purpose of this application was to register a new post-emergent herbicide, Vigil WB, for use in spring wheat, durum wheat, spring barley and certain minor use crops in the Prairie Provinces and Peace River region of British Columbia, and in spring wheat in Eastern Canada. The application was based on the precedent product, Bengal WB, which was reviewed under application 2010-4149.

Background

The product Bengal WB was based on the precedent products Bengal 120 EC (Registration Number 29268) and Puma 120 Super EC (Registration Number 25864).

Chemistry Assessment

Vigil WB is formulated as an emulsifiable concentrate containing fenoxaprop-P-ethyl at a nominal concentration of 120 g/L. This end-use product has a density of 1.043 g/mL and a pH of 6.36. The chemistry requirements for Vigil WB are complete.

Health Assessment

Vigil WB is of low acute toxicity by the oral, dermal, and inhalation routes in rats. It is mildly irritating to the rabbit eye and only slightly irritating to the rabbit skin. The formulation is not a skin sensitizer in guinea pigs.

The use of Vigil WB should not result in increased occupational or bystander exposure over the registered uses of fenoxaprop-P-ethyl. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment as stated on the label.

Canada

As the use directions and restrictions for Vigil WB are similar to those of currently registered fenoxaprop-P-ethyl containing end-use products, no increase in the magnitude of residues of fenoxaprop-P-ethyl is expected. Established MRLs are adequate to cover residues of fenoxaprop-P-ethyl. Dietary exposure to fenoxaprop-P-ethyl is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Spray buffer zones specific to the Vigil WB are required for the protection of sensitive terrestrial habitats during application. No concerns were identified for aquatic plants.

Value Assessment

Efficacy and crop safety of Bengal WB, applied alone or in conjunction with one of 2,4-D Ester LV 700, Buctril M, Curtail, or Refine Extra, were directly compared to that of the cited precedent product Bengal 120 EC, applied alone or with the same herbicides, in a total of 11 field research trials conducted in Alberta, Manitoba, and Saskatchewan in 2008.

Efficacy of Bengal WB applied alone for control of wild oats, green foxtail, and yellow foxtail and Bengal WB applied with one of 2,4-D Ester LV 700, Buctril M, Curtail M, or Refine Extra for control of Canada thistle, common chickweed, dandelion, lamb's-quarters, kochia, redroot pigweed, volunteer canola, wild buckwheat, and/or wild mustard was visually assessed on three occasions during the growing season. Efficacy data demonstrated that control of grasses following the application of Bengal WB applied alone and that control of broadleaf weeds following the application of Bengal WB with one of the broadleaf herbicides was comparable to that of Bengal 120 EC applied alone and that of Bengal 120 EC with the same broadleaf herbicides, respectively.

Tolerance of four spring wheat varieties in four trials, and one durum wheat variety in three trials to Bengal WB applied alone or in conjunction with one of 2,4-D Ester LV 700, Buctril M, Curtail M, or Refine Extra was reported three times during the growing season. Visual percent injury to spring wheat and durum wheat following the application of Bengal WB applied alone or with one of the broadleaf herbicides was slight over locations and years and also comparable to the Bengal 120 EC applied alone or with the same broadleaf herbicides. Yield data collected confirmed that spring wheat and durum wheat exhibited adequate margins of crop safety to Bengal WB when applied in accordance with the label.

Crop tolerance data from four field research trials were submitted to support a host claim for spring barley. Crop injury and yield data with the Bengal WB treatments demonstrated that spring barley exhibited an adequate margin of crop safety to Bengal WB when applied in accordance with the label.

As (1) perennial ryegrass grown for seed was registered for Puma 120 Super EC based on data available to the public and (2) the agronomic equivalency between Puma 120 Super EC and Bengal 120 EC (under the submission number 2007-6008) and between Bengal WB and Bengal 120 EC have been established, a host claim for perennial ryegrass grown for seed production is, therefore, supported for labeling.

Conclusion

The PMRA conducted an evaluation of the subject application and determined that use of Vigil WB in accordance with the label has value and will not pose unacceptable health or environmental risk.

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