Health Canada Santé Canada

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

Application Number: 2007-3528
Application: New end-use product with new identity and proportion of formulants, tank mixes and pests.
Product: Glyfos BIO Herbicide
Registration Number: 29363
Active ingredients (a.i.): Glyphosate (present as isopropylamine salt)
PMRA Document Number: 1773127

Purpose of Application

This application is for a new end-use product, Glyfos BIO Herbicide, which is a formulation that is comparable to Cheminova's existing end-use glyphosate registrations in Canada with respect to application rates and uses (Glyfos Soluble Concentrate Herbicide; Reg No. 24359). The new product is proposed for agricultural and industrial use.

Chemistry Assessment

Glyfos BIO Herbicide is formulated as a liquid product containing Glyphosate (present as isopropylamine salt) at 360 g/L. This end-use product has a density of 1.169 g/mL and pH of 5.1. The chemistry requirements for Glyfos BIO Herbicide are complete.

Health Assessments

Glyfos BIO Herbicide was found to be of low acute toxicity by the oral, dermal and inhalation routes in rats. It was minimally irritating to rabbit's eye, non irritating to rabbit skin and not a skin sensitizer in guinea pigs.

The use pattern for Glyfos BIO Herbicide is the same as the registered use pattern for Glyfos Soluble Concentrate Herbicide, except for a new tank mix with Express Toss-N-Go Herbicide (75%) or Express SG. Use precautions, and personal protective equipment required are the same on both products. The proposed use pattern for Glyfos BIO Herbicide fits within the existing use pattern for glyphosate.

Canada

The use rates and label directions for the proposed end-use product is identical to the registered ones. No impact in the magnitude of residue in the treated crops is expected. No increase in the dietary exposure is anticipated.

Environmental Assessment

Toxicity studies with terrestrial and aquatic vascular plants were required to adequately assess the risk to plants from exposure to Glyfos BIO Herbicide. These studies were not submitted. The environmental exposure resulting from the use of Glyfos BIO Herbicide is expected to be the same as for other registered glyphosate products, such as Glyfos Soluble Concentrate Herbicide. Consequently, in the absence of the required toxicity studies on vascular plants, buffer zones were set at the same size as those for Glyfos Soluble Concentrate Herbicide (15 metres for field sprayer application and 100 metres for aerial application).

Value Assessment

Efficacy data from 24 field trials conducted in Ontario, British Columbia, Manitoba, Alberta, and Saskatchewan in 2006 were considered to be acceptable for review. Glyfos BIO Herbicide alone or in combination with Marksman, Pursuit, Lontrel, or Express were applied as post-emergence, pre-harvest, pre-plant burndown, or pre-seed treatments in these trials. Weed control was visually assessed for a total of 28 species on 2 to 3 occasions through the field season. The registered product Glyfos Soluble Concentrate Herbicide was arranged side-by-side for direct comparison. It was concluded from these field trials that the product efficacy of Glyfos BIO Herbicide was agronomically equivalent to that of Glyfos Soluble Concentrate Herbicide.

Crop safety data from 12 combined efficacy and crop tolerance trials were considered to be acceptable for review. Crop tolerance of glyphosate tolerant soybeans, glyphosate tolerant corn, and glyphosate tolerant canola to post-emergence application of Glyfos BIO Herbicide alone or in combination with Marksman, Pursuit, and Lontrel was evaluated in these trials. The registered product Glyfos Soluble Concentrate Herbicide was arranged side-by-side for direct comparison. It was concluded that the crop tolerance to the treatments of Glyfos BIO Herbicide was similar to that of Glyfos Soluble Concentrate Herbicide. Overall, the registration of Glyfos BIO Herbicide can be supported.

Conclusion

The PMRA has completed an assessment of available information for Glyfos BIO Herbicide and has found the information sufficient to support the registration.

References

PMRA Document Number	Reference
1467163	2007, Acute Toxicology Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered Technical Grade of Active Ingredients or Intergrated System Products: Acute Studies, Laboratory No. 26237, DACO: 4.6.1 to 4.6.6 CBI
1414966	Part 10 - Efficacy requirements for the registration of manufacturing concentrates and end-use products formulated from registered technical grade of active ingredients or integrated system products: Efficacy studies. Cheminova Canada Inc. DACO 10.2.3.3. April 30, 2007. pp. 18.
1414973	Trial report - 1 (CHN06H04A). pp. 14.
1414974	Trial report - 2 (CHN06H04B). pp. 12.
1414975	Trial report - 3 (CHN06H04C). pp. 11.
1414976	Trial report - 4 (HB6CVWA1). pp. 11.
1414977	Trial report - 5 (HB6CVWA2). pp. 11.
1414978	Trial report - 6 (HM6CHWP2). pp. 7.
1414991	Trial report - 7 (HA6CVWJ4). pp. 13.
1414992	Trial report - 8 (HS6CHWS3). pp. 11.
1414993	Trial report - 9 (ICMS06EXPRESSMIX07). pp. 8.
1414994	Trial report - 10 (HA6CVBJ4). pp. 13.
1414995	Trial report - 11 (HS6CHBS3). pp. 9.
1414996	Trial report - 12 (ICMS06EXPRESSMIX08). pp. 8.
1414979	Trial report - 13 (CHN06H03A). pp. 19.
1414980	Trial report - 14 (CHN06H03B). pp. 16.
1414981	Trial report - 15 (CHN06H03C). pp. 15.
1414982	Trial report - 16 (CHN06H03D). pp. 16.
1414983	Trial report - 17 (CHN06H01D). pp. 25.
1414984	Trial report - 18 (CHN06H01C). pp. 24.
1414985	Trial report - 19 (CHN06H01B). pp. 16.

1414986 Trial report - 20 (CHN06H01A). pp. 19.

1414987 Trial report - 21 (CHN06H02A). pp. 19.

1414988 Trial report - 22 (CHN06H02D). pp. 12.

1414989 Trial report - 23 (CHN06H02C). pp. 22.

1414990 Trial report - 24 (CHN06H02B). pp. 21.

1414960 2007, Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered Technical Grade of Active Ingredients or Intergrated System Products: PRODUCT IDENTIFICATION, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1

1414961 2007, Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered Technical Grade of Active Ingredients or Intergrated System Products: CHEMICAL AND PHYSICAL PROPERTIES, DACO: 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.6, 5.2

1520097 Description of Formulation Process for Alternate Formulation, DACO: 3.2.2 CBI

1520098 MSDS for Additional Alternate Formulation Starting Material, DACO: 3.2.1 CBI

1520095 Cheminova Response to PMRAs Clarification Email, DACO: 0.8

ISSN: 1911-8082