Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.2.3 & B.2.4 Application (Identity of formulants, Proportion of formulants)

Application Number: 2007-6008
Application: Category B, subcategory B.2.3 (Identity of formulants), B.2.4 (Proportion of formulants)
Product: Bengal 120 EC
Registration Number: 29268
Active ingredients (a.i.): fenoxaprop-P-ethyl
PMRA Document Number: 1723348

Purpose of Application

The purpose of this application was to register Bengal 120 EC, an end-use product containing the active ingredient, fenoxaprop-P-ethyl, for the control of annual grass weeds in spring wheat and durum wheat. The product is intended for post-emergence application at 46, 80, or 92 g ai/ha. Bengal 120 EC is intended for application alone or in tank mixtures with certain other herbicides for broad spectrum weed control.

Background

The requested use pattern of this product is similar to that of Puma^{120} Super EC Herbicide (Reg. No. 25864). For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Bengal 120 EC 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 1.045 g/mL and pH of 5.02. With the exception of an analytical method and the storage stability and corrosion characteristics study, which are conditions of registration, the chemistry requirements for Bengal 120 EC are complete.

Health Assessments

Bengal 120 EC is of low toxicity via the oral (LD_{50} = 3129 mg/kg bw), dermal (LD_{50} >5000 mg/kg bw) and inhalation routes (LC_{50} = 2.08-5.07 mg/L). It is severely irritating to the eye (MAS = 33.3/110 with irritation persisting past 7 days post-instillation) and mildly irritating to the skin (MAS = 2.56/8) of rabbits. It is not a dermal sensitizer in guinea pigs (Buehler method).

Canada

New residue data for fenoxaprop-P-ethyl in wheat were not submitted to support the registration of this active on the Bengal 120 EC label as this formulation is similar to the registered end-use product PUMA 120 Super. Previously reviewed residue data from field trials conducted in/on wheat were reassessed in the framework of this petition. In addition, a processing study in treated wheat was also reassessed to determine the potential for concentration of residues of fenoxaprop-P-ethyl into processed commodities. Following the comparison of the new formulation to the registered formulation, there is no indication that the new end-use product will have an impact on the magnitude of the residues of fenoxaprop-P-ethyl when Bengal120 EC will be used according to the label, since the use directions are identical. Therefore, no increase in dietary exposure is anticipated.

The proposed uses should not result in an increase in potential occupational or bystander (reentry) exposure over registered uses of the active ingredient since the crops, application rate, number of applications, frequency of application and method of application fell within that registered for other labeled crops.

Environmental Assessment

No new environmental fate or ecotoxicological data were submitted to support the new commercial insecticide Bengal 120 EC (guarantee 120 g/L fenoxaprop-P-ethyl). The subject product is based on the precedent product Puma 120 Super (PCP No. 25864). The uses and application rates of the subject product are subsets of the permitted uses for the registered precedent. The environmental risk profile of the new commercial herbicide is expected to be similar to that of other registered fenoxaprop-P-ethyl products; therefore, no increase in environmental risk of fenoxaprop-p-ethyl is anticipated. The EAD also evaluated the environmental risk from the exposure of two components in the product formulation: a safener and a petroleum distillate. No environmental risk from the exposure of the petroleum distillate was expected. The safener is not expected to pose any risk to earthworm, honey bees, soil microorganisms, fish, aquatic invertebrates, or algae. The agency does not have any data on terrestrial or aquatic vascular plants on this safener; therefore, the EAD has identified these data gaps as deficiencies.

Value Assessment

Value data were submitted to establish whether Bengal 120 EC was agronomically equivalent to Puma^{120} Super.

Efficacy data were submitted from 14 field trials conducted in 2005 or 2006 in Alberta, Saskatchewan or Manitoba. The level of weed control in treatments of Bengal 120 EC applied alone or in tank mixtures was similar to that in treatments of the same rate of Puma^{120} Super applied alone or in combination with the same tank mix partner products.

Crop phytotoxicity data were available from 14 field trials conducted in 2005 or 2006 in Alberta, Saskatchewan or Manitoba on spring wheat (8 trials) and durum wheat (6 trials). In all trials, the tolerance of spring wheat or durum wheat to an application of Bengal 120 EC was compared to that of spring wheat or durum wheat treated with the same rate of the registered precedent product, Puma^{120} Super. Injury to spring wheat or durum wheat treated with Bengal 120 EC

alone or in tank mix combination with other labeled herbicides was low and similar to the level of injury observed in treatments of Puma[120] Super applied alone or in tank mix combination with the same partner herbicide products. Crop tolerance was confirmed with grain yield data collected in 12 of the 14 trials.

Conclusion

The Agency has completed an assessment of available information for Bengal 120 EC and has found the information sufficient to allow for conditional registration, with registration being contingent upon fulfilling the following data requirements:

PART 2 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT

DACO 2.11.2 - Description of Starting Materials

DACO 2.11.3 - Detailed Production Process Description

DACO 2.11.4 - Discussion of Formation of Impurities

DACO 2.13.1 - Methodology/Validation

DACO 2.13.3 - Batch Data

DACO 2.14 - Chemical and Physical Properties

PART 3 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS

DACO 3.4.1 - Enforcement Analytical Method

DACOs 3.5.10, 3.5.14 - Chemical and Physical Properties: Storage Stability Data, Corrosion Characteristics

PART 9 ENVIRONMENTAL TOXICOLOGY

DACO 9.8.4 - Terrestrial vascular plants

DACO 9.8.5 - Aquatic vascular plants

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA # 1463872. Effect of Fenoxaprop-p-ethyl on Weed Control and Crop Tolerance in Durum Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463873. Effect of MANA FENOX 92 EC and MANA FENOX 120 EC on Weed Control and Crop Tolerance in Durum. DACO 10.2.3.3, 10.3.2.

PMRA # 1463874. Effect of MANA FENOX 92 EC and MANA FENOX 120 EC on Weed Control and Crop Tolerance in Durum Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463875. Effect of MANA FENOX 92 EC and MANA FENOX 120 EC on Weed Control and Crop Tolerance in Spring Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463876. Evaluation of MANA Fenoxaprop vs. Commercial Standard on Spring Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463877. Evaluation of MANA Fenoxaprop for Control of Weeds in Spring Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463878. Evaluation of MANA Fenoxaprop vs. Commercial Standard on Spring Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463879. Evaluation of MANA Fenoxaprop vs. Commercial Standard on Spring Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463880. Evaluation of the Efficacy and Phytotoxicity of MANA Fenoxaprop 92 EC versus Puma Super 120 EC on Weeds in Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463881. Evaluation of the Efficacy and Phytotoxicity of MANA Fenoxaprop 92 EC versus Puma Super 120 EC on Weeds in Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463882. Evaluation of the Efficacy and Phytotoxicity of MANA Fenoxaprop 92 EC and 120 EC versus Puma Super 120 EC on Weeds in Wheat (Durum). DACO 10.2.3.3, 10.3.2.

PMRA # 1463883. Evaluation of the Efficacy and Phytotoxicity of MANA Fenoxaprop 92 EC and 120 EC versus Puma Super 120 EC on Weeds in Wheat (Durum). DACO 10.2.3.3, 10.3.2.

PMRA # 1463884. Evaluation of the Efficacy and Phytotoxicity of MANA Fenoxaprop 92 EC and 120 EC versus Puma Super 120 EC on Weeds in Wheat (Spring Wheat). DACO 10.2.3.3, 10.3.2.

PMRA # 1463885. Evaluation of the Efficacy and Phytotoxicity of MANA Fenoxaprop 92 EC versus Puma Super 120 EC on Weeds in Wheat. DACO 10.2.3.3, 10.3.2.

PMRA # 1463887 2007, Product Identification - Fenoxaprop-P-ethyl 120 EC, N/A, MRID: N/A, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4 CBI

PMRA # 1463889 2007, Storage Stability and Corrosion Characteristics of Fenoxaprop-P-ehtyl 120 g/L + [CBI REMOVED] EC Stored at 54 degrees C for 14 Days., F07-03/2, MRID: N/A, DACO: 3.5.10,3.5.14 CBI

PMRA # 1463890 2006, FENOXAPROP-P-ETHYL 120 EC EXPLOSIVE PROPERTIES, PSF0009/063769, MRID: N/A, DACO: 3.5.12 CBI

PMRA # 1463891 2007, Waiver in Lieu of Miscibiliy Study, N/A, MRID: N/A, DACO: 3.5.13 CBI

PMRA # 1463892 2007, Waiver for Not Submitting Dielectric Breakdown Voltage Data for Fenoxaprop-p-ethyl 120 EC, N/A, MRID: N/A, DACO: 3.5.15 CBI

PMRA # 1463893	2007, Physical and Chemical Characteristics: Physical State, Oxidation/Reduction, Flammability, pH, Viscosity, and Density/Relative Density, 21025, MRID: N/A, DACO: 3.5.1,3.5.11,3.5.2,3.5.6,3.5.7,3.5.8,3.5.9 CBI
PMRA # 1463894	2007, Odour for Fenoxaprop-P-ethyl 120 EC, N/A, MRID: N/A, DACO: 3.5.3 CBI
PMRA # 1463895	2007, Formulation Type for Fenoxaprop-P-ethyl 120 EC, N/A, MRID: N/A, DACO: 3.5.4 CBI
PMRA # 1463896	2007, Container Material and Description for Fenoxaprop-P-ethyl 120 EC, N/A, MRID: N/A, DACO: 3.5.5 CBI
PMRA # 1718945	2007, [CBI REMOVED] Technical - Five Lots Analysis and Method Validation, 07-01/8, MRID: N/A, DACO: 2.13.3 CBI
PMRA # 1720746	2009, Description of the Production Process, Certified Limits and Enforcement Analytical Method for [CBI REMOVED] Technical, NS, MRID: NS, DACO: 2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
PMRA # 1720747	The Pesticide Manuel (14th edition), 2009, Chemistry-2.14-physical and chemical properties, NS, MRID: NS, DACO: 2.14
PMRA # 1463898.	Acute Dermal Toxicity Study in Rats-Limit Test. Eurofins Product Laboratories. Laboratory report number 21026. Study report date: 9-May-2007. DACO 4.6.1.
PMRA # 1463899.	Acute Dermal Toxicity Study in Rats – Limit Test. Eurofins Product Laboratories. Laboratory report number 21027. Study report date: 14-May-2007. DACO 4.6.2.
PMRA # 1463900.	Acute Inhalation Toxicity Study in Rats. Eurofins Product Safety Laboratories. Laboratory report number. Study report date: 11-May-2007. DACO 4.6.3.
PMRA # 1463901.	Primary Eye Irritation Study in Rabbits. Eurofins Product Safety Laboratories. Laboratory report number 21029. Study report date: 14-May-2007. DACO 4.6.4.
PMRA # 1463902.	Primary Eye Irritation Study in Rabbits. Eurofins Product Safety Laboratories. Laboratory report number 21030. Study report date: 14-May-2007. DACO 4.6.5.
PMRA # 1463903.	Dermal Sensitization Study in Guinea Pigs (Buehler Method). Eurofins Product Safety Laboratories. Laboratory report number 21030. Study report date: 14-May-2007. DACO 4.6.6.

ISSN : 1911-8015