Health Canada Santé Canada

IPCO Fenoxaprop-P-Ethyl 120 EC
Evaluation Report for Category B, Subcategory B.2.1 Application
(New / Changes EP or MA Product Chemistry-Guarantee)

Application Number: 2007-6017
Application: Category B, subcategory B.2.1 (New / Changes or MA Product Chemistry-Guarantee)
Product: IPCO Fenoxaprop-P-Ethyl 120 EC
Registration Number: 29273
Active ingredients (a.i.): fenoxaprop-p-ethyl
PMRA Document Number: 1726854

Purpose of Application

The purpose of this application was to register IPCO Fenoxaprop-P-Ethyl 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. IPCO Fenoxaprop-P-Ethyl 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

IPCO Fenoxaprop-P-ethyl 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, the chemistry requirements for IPCO Fenoxaprop-P-ethyl 120 EC are complete.

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Health Assessments

IPCO Fenoxaprop-p-ethyl 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).

New residue data for fenoxaprop-P-ethyl in wheat were not submitted to support the registration of this active on the IPCO Fenoxaprop-P-ethyl 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 IPCO Fenoxaprop-P-ethyl 120 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 IPCO Fenoxaprop-p-ethyl 120 EC(guarantee 120 g/L fenoxaprop-p-ethyl). The subject product is a 100% re-pack of a proposed new herbicide, Bengal 120 EC from Makhteshim Agan of North America Lt and has identical use patterns, application rates, tank mixes to the parent product. 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

The data package submitted in support of the registration of Bengal 120 EC under application number 2007-6008 is applicable to IPCO Fenoxaprop-p-ethyl 120 EC. 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 IPCO Fenoxaprop-p-ethyl 120 EC and has found the information sufficient to allow for conditional registration, with registration being contingent upon fulfilling requirements listed in Section 12.

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 # 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.

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