Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.2.1. B.2.3, B.2.4 Application

Application Number: 2007-8429
Application: B.2.1 (New EP Product chemistry - Guarantee)
B.2.3 (New EP Product chemistry - Identity of formulants)
B.2.4 (New EP Product chemistry - Proportion of formulants)
Product: Puma 90:45 Herbicide
Registration Number: 29488
Active ingredients (a.i.): Fenoxaprop-p-ethyl (FPF)
PMRA Document Number : 1821206

Purpose of Application

The purpose of this application was to register the new end-use product Puma 90:45 Herbicide. This new product has an increase of the guarantee of the safener, and new/changes to the identity and proportion of formulants compared to the currently registered product Puma^{120} Super EC Herbicide (Registration Number 25864).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Puma 90:45 Herbicide (SP 10200001722) exhibits a low acute oral (LD_{50} > 2000mg/kg bw), dermal (LD_{50} > 2000mg/kg bw) and inhalation (LC_{50} > 2.08 mg/L) toxicity in the rat. It is corrosive [(MAS (24-72 hours) = 37.5 /110 and irreversible for up to 21days] to the eyes and moderately irritating [MAS (24-72 hours) = 4.8/8] to the skin of the rabbit. It is not a skin sensitizer in the guinea pig.

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

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The increased application rate of the safener in the Puma 90:45 Herbicide formulation will not affect the residues of the active ingredient fenoxaprop-p-ethyl on treated crops. The application rate of the active ingredient, PHI and use pattern on the proposed product are similar to those on other registered products containing the same active ingredient and safener. Residues of fenoxaprop-p-ethyl on spring wheat, durum wheat and barley are expected to remain covered by the 0.1 ppm General Regulations. Therefore, no increase in dietary exposure is anticipated.

Environmental Assessment

A full evaluation was conducted on the increase in the rate of the safener from 25 to 46 g/ha following application of Puma 45:90 alone and the increase in its cumulative rate from 33 to 54 g/ha following application of a tank mix with Infinity Herbicide (Registration Number 28738). The risk assessments for application of Puma 90:45 alone or application of the tank mix indicate there are no concerns about the increase in rate of the safener affecting earthworms, bees, predatory and parasitic arthropods, birds and small wild mammals, terrestrial plants, fish, aquatic invertebrates, algae, aquatic vascular plants, or amphibians.

Value Assessment

Data from a total of 55 field trial studies conducted in Alberta, Saskatchewan and Manitoba over 2 years (2006 and 2007) were submitted for review. In thirty-six of these trials efficacy was assessed along with crop tolerance of spring wheat, durum wheat and spring barley after post-emergence applications of Puma 90:45 Herbicide alone and in tank mix. Efficacy data were provided for labelled grassy weed species. The remaining nineteen trials were dedicated crop tolerance trials which assessed crop safety of spring wheat, durum wheat and spring barley after post-emergence applications of Puma 90:45 Herbicide alone and in tank mix.

Overall, percent visual control values for Puma 90:45 Herbicide treatments applied alone and in tank mix were similar to those of Puma 120 Super Emulsifiable Concentrate Post-Emergent Herbicide treatments. Puma 90:45 Herbicide and Puma 120 Super Emulsifiable Concentrate Post-Emergent Herbicide were shown to be agronomically equivalent. Antagonism was not observed with the tank mixture treatments.

Crop injury was visually assessed throughout the growing season in spring wheat, durum wheat and spring barley from the 1- to 6-leaf plus 3 tillers growth stage. Data collected with Puma 90:45 Herbicide alone and in tank mix at the 1x and 2x rates were similar to Puma 120 Super Emulsifiable Concentrate Post-Emergent Herbicide treatments and thus supported crop tolerance claims. Crop yield from Puma 90:45 Herbicide treatments applied alone and in tank mix at the 1x and 2x rates were similar to Puma 120 Super Emulsifiable Concentrate Post-Emergent Herbicide treatments.

Conclusion

The PMRA has completed an assessment of the subject application and has found the provided data to be sufficient to register the new end use product Puma 90:45 Herbicide.

References

PMRA 1510297 Acute Oral Toxicity Up and Down Procedure in Rats.Laboratory report number 23054. Study report date: 02-November-2007. DACO 4.6.1.

PMRA 1510298 Acute Dermal Toxicity Study in Rats. Laboratory report number 23055. Study report date: 02-November-2007. DACO 4.6.2.

PMRA 1510299 Acute Inhalation Toxicity Study in Rats. Laboratory report number 23056. Study report date: 02-November-2007. DACO 4.6.3.

PMRA 1510300 Primary Eye Irritation Study in Rabbits. Laboratory report number 23057. Study report date: 02-November-2007. DACO 4.6.4.

PMRA 1510301 Primary Skin Irritation Study in Rabbits. Laboratory report number 23058. Study report date: 02-November-2007. DACO 4.6.5.

PMRA 1510302 Dermal Sensitization study in Guinea Pigs (Buehler Method). Laboratory report number 23059. Study report date: 02-November-2007. DACO 4.6.6.

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PMRA 1510277 Efficacy frequency distribution table, DACO: 10.2.3.1
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