Health Canada Santé Canada

Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4, B.2.5, B.3.1, B.3.10, B.3.11 Application

Application Number: **2007-3344**

Application: B.2.1 (Changes Chemistry - Guarantee), B.2.3 (Changes Chemistry - Identity of formulants), B.2.4 (Changes Chemistry - Proportion of formulants), B.2.5 (Changes Chemistry - Formulation type), B.3.1 (Changes to Product label - application rate increase), B.3.10 (Changes to Product label - tank mixes), B.3.11 (Changes to Product label - new pests)

Product: Prowl H_2O Herbicide
Registration Number: 29542
Active ingredients (a.i.): Pendimethalin (PEN)
PMRA Document Number : 1872141

Purpose of Application

BASF Canada Inc. submitted an application to register a new water-based herbicide formulation, Prowl H_2O Herbicide containing pendimethalin. This formulation will replace the current solvent-based Prowl 400 EC Herbicide formulation (Registration Number 23439). Prowl H_2O Herbicide was proposed for use on the same crops with the same use patterns at the same active rates as the currently registered Prowl 400 EC Herbicide formulation.

Chemistry Assessment

Prowl H_2O Herbicide is formulated as a microcapsule suspension containing pendimethalin at a nominal concentration of 455 g/L. This end-use product has a density of 1.175 g/mL and pH of 7.8. The chemistry requirements for Prowl H_2O Herbicide are complete.

Health Assessments

Prowl H_20 Herbicide is of low toxicity to rats via the oral (LD_{50} > 5000 mg/kg), dermal (LD_{50} >5000 mg/kg), and inhalation routes (LC_{50} >5.23 mg/L). It is non- irritating to the eye and minimally irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The reformulation of pendimethalin into a microencapsulated formulation 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 fall within that registered for other products.

Canada

Prowl 400EC Herbicide is currently registered in Canada on the same crops as those on Prowl H_2O label. The main difference between the two products is the formulation (emulsifiable concentrate versus capsule suspension). To register Prowl H_2O Herbicide, the registrant submitted side-by-side residue trials comparing the two formulations and provided the analytical methodology used for the residue trials and storage stability data to support storage intervals.

The side-by-side field trials, using the capsule suspension (CS) and emulsifiable concentrate (EC) formulations, in/on field corn, soybeans, rice, cotton and wheat are adequate and can be extended to support the use of pendimethalin as a CS formulation in/on field corn, dry bulb onions, newly planted and established fruit trees (apple, peach, nectarine, cherry and apricot). The magnitude of residues were comparable between the EC and CS formulations. Therefore, the dietary exposure is not expected to increase, and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

MRL Recommendations

Based on the residue data, a maximum residue limit (MRL) to cover total residues of pendimethalin and the metabolite CL 202347, [2-methyl-3,5-dinitro-4-(pentan-3-ylamino)phenyl]methanol, in/on field corn, dry bulb onions, apples, apricots, peaches, nectarines, and cherries will be established as shown in Table 1.

Table 1. Summary of Field Trial Data Used to Establish Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Pendimethanlin		CL 202347		Recommended MRL (ppm)
			Min (ppm)	Max (ppm)	Min (ppm)	Max (ppm)	
Field corn	Pre-emergence/1.69	70 to 116	<0.05	<0.05	<0.05	<0.05	0.1
Dry bulb onions	Pre-plant, pre-emergence, or post-emergence/ 0.88 to 2.24	79 to 189	<0.05	<0.05	<0.05	<0.05	0.1
Apricots	Pre-emergence/2.0 and 4.0	24 to 56	<0.05	<0.068	<0.05	<0.05	0.1
Peaches, Nectarines	Pre-emergence/2.0	32	<0.05	<0.05	<0.05	<0.05	0.1
Cherries	Pre-emergence/2.0	34	<0.05	<0.05	<0.05	<0.05	0.1
Apples	Pre-emergence/2.0	30 to 35	<0.05	<0.05	<0.05	<0.05	0.1

Environmental Assessment

Prowl H_2O Herbicide which contains the active ingredient pendimethalin, will be less harmful to the environment than the original solvent-based herbicide. As a result of the reevaluation of the active ingredient pendimethalin, label statements have been updated and are required on the new label for Prowl H_2O Herbicide.

Value Assessment

A total of 36 field corn trial studies conducted in Ontario and Quebec over 3 years (2003-2005) were submitted for review. Sixteen trials assessed efficacy and crop tolerance after pre-emergence applications of Prowl H_2O Herbicide in field corn. Seventeen trials assessed efficacy and crop tolerance after post-emergence applications of Prowl H_2O Herbicide in field corn. In addition, reports from three trials were submitted for review conducted in 2000 and 2005 in Ontario that assessed efficacy and crop tolerance after post-emergence applications of Prowl H_2O Herbicide in dry bulb onions.

Efficacy data collected for Prowl H_2O Herbicide applied alone and in tank mix were similar to Prowl 400 EC Herbicide applied alone and in tank mix. Prowl 400 EC Herbicide and Prowl H_2O Herbicide were shown to be agronomically equivalent. Antagonism was not observed with the proposed tank mixtures.

Crop injury was visually assessed throughout the growing season in field corn and dry bulb onions. Data collected with Prowl H_2O Herbicide alone and in tank mix supported crop tolerance claims. Yield was assessed in 27 trials for field corn and 3 trials for dry bulb onions. Crop yield from Prowl H_2O Herbicide alone treatments and in tank mix was similar to Prowl 400 EC Herbicide alone treatments and in tank mix. Although there were no crop tolerance data reported for newly planted and established fruit trees (apple, peach, nectarine, cherry and apricot) in British Columbia, it is anticipated that the margin of crop safety would be similar to the data for field corn and dry bulb onions because the registered application rate of Prowl is 1680 g a.i./ha which is the same for field corn and tree crops are more tolerant to herbicide treatments than dry bulb onions.

Conclusion

The PMRA has completed the assessment of all available information and is able to support the registration of Prowl H_2O Herbicide.

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