Health Canada Santé Canada

Evaluation Report for Category B Subcategory 3.12 Application

Application Number: 2010-1887
Application: Changes to product label: new site or host
Product: Tattoo Fungicide
Registration Number: 29554
Active ingredient (a.i.): Propamocarb hydrochloride
PMRA Document Number: 2054988
PMRA Document Number English PDF: 2074016

Purpose of Application

The purpose of this application was to amend the label by adding the new crops, field tomatoes and field lettuce (leaf and head).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessment

Exposure to workers mixing, loading and applying Tattoo Fungicide or entering treated areas is not expected to result in unacceptable risk following chemical handler and post-application worker risk assessments.

New residue data for propamocarb hydrochloride in head lettuce, leaf lettuce and tomatoes were submitted. In addition, processing studies on treated tomatoes were assessed to determine the potential for concentration of residues of propamocarb hydrochloride into processed commodities. Recommendations for maximum residue limits (MRLs) were based on guidance provided by the OECD MRL Calculator Statistical White Paper (2011). Based on statistical methodology and residue data from field trials conducted according to label directions, MRLs to cover residues of propamocarb hydrochloride in/on head lettuce, leaf lettuce and tomatoes will be established as shown in Table 1. Residues of propamocarb hydrochloride in processed commodities not listed in Table 1 are covered under the MRLs for the raw agricultural commodities (RACs). Residues of propamocarb hydrochloride in these commodities at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

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Table 1 Summary of field trial and processing data used to establish maximum residue limits (MRLs)

Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Head lettuce	Foliar broadcast/ 6.58-6.95 kg a.i./ha	1-2	9.35	60.0	—	None	150 ppm
Leaf lettuce	Foliar broadcast/ 6.58-6.95 kg a.i./ha	2	10.56	103.7	—	None	200 ppm
Tomatoes	Foliar broadcast/ 6.10-6.74 kg a.i./ha	4-5	0.094	1.83	Tomato paste: 3.1× No concentration observed in puree	0.01 ppm	2 ppm (tomatoes)* 5 ppm (tomato paste)

*the recommended MRL in/on tomatoes will be proposed to replace the currently established MRL of 0.01 ppm

Environmental Assessment

The application method and rates of Tattoo Fungicide on field lettuce and field tomatoes fall within the use pattern of Banol (Registration Number 26288) containing propamocarb hydrochloride; therefore, no new data were required to support this application. No environmental risk assessment was required as the new use of Tattoo Fungicide will not result in higher risk relative to Banol. No buffer zones are required; however, drift mitigation measures are required.

Value Assessment

Tattoo Fungicide applied at a rates of 2.3 L/ha (no more than 9.2L/ha per season) to control downy mildew (*Bremia lactucae*) on field lettuce and 1.5 L/ha (no more than 9 L/ha per season) to control late blight (*Phytophthora infestans*) on field tomatoes were supported by the submitted data. Three trials conducted in Brazil and Columbia from 2000-2003 on tomato late blight were submitted. Five potato trials carried out in North Dakota, Germany and Columbia from 2001-2008 were also considered as supplemental data. Five trials conducted in non-border US states (California, Arizona) were provided in support of the use of Tattoo Fungicide for control of downy mildew on field lettuce. A rationale for the inclusion of such trials was provided by the applicant and correctly demonstrated their climatic similarities to the Canadian growing conditions.

Tattoo Fungicide applied three to five times at 2.3 L/ha effectively controlled downy mildew severity on field lettuce in three of the five trials (90% reduction), which were conducted under moderate disease pressure. Moreover, the efficacy of Tattoo Fungicide was comparable to the commercial standard Aliette (fosetyl-al). In the two trials on tomato late blight, Tattoo Fungicide reduced disease severity by 70% under severe disease pressure, i.e. 100% disease severity in the untreated control. Supplemental data on potatoes also indicated that Tattoo Fungicide applied at 1.4 L/ha showed comparable efficacy to the commercial standard Ridomil Gold MZ, although disease reduction was lower in the Tattoo Fungicide treatment. A second potato trial showed that Tattoo Fungicide at 1.4 L/ha controlled late blight incidence under low to moderate disease pressure. The submitted data were sufficient to conclude that Tattoo applied at the indicated rates will adequately control late blight on field tomatoes and downy mildew on field lettuce.

Tattoo Fungicide at 1.5 L/ha tank-mixed with chlorothalonil- or mancozeb-containing fungicides for control of tomato early and late blight will also offer growers more flexibility by managing two common tomato diseases at once.

Conclusion

The PMRA conducted an evaluation of the subject application and concluded that new uses of Tattoo Fungicide in accordance with the label have value and will not pose unacceptable health or environmental risk.

References

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