Health Canada Santé Canada

Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application

Application Number: 2009-2730
Application: **Category C, subcategory 6.3 (URMULE)**
Product: APRON XL LS Fungicide
Registration Number: 25585
Active ingredient (a.i.): Metalaxyl-M and S-isomer (33.3%)
PMRA Document Number: 2159029

Background

APRON XL LS Fungicide has been registered since June 18, 1998. APRON XL LS Fungicide is registered for the control of early season *Phytophthora* root rot, systemic downy mildew, and *Pythium* causing damping-off, and seed rot diseases of certain crops. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to product label.

Purpose of Application

The purpose of this application was to amend the registration of APRON XL LS Fungicide to include the claim of control of *Pythium* damping-off in/on Crop Group 8 (Fruiting Vegetable Group, except Cucurbits). The product is intended as a seed treatment application at a rate of 20 – 40 mL product/100 kg seed with a maximum of one application per year. Since this is a seed treatment, the minimum pre-harvest interval is not applicable.

Chemistry Assessment

A chemistry assessment was not required as there was no change to product chemistry.

Health Assessment

A toxicology assessment was not required since there was no change to the formulation.

APRON XL LS fungicide is registered for use on a variety of seed types at the proposed application rate. Since the treated seeds are to be imported only, there is potential exposure for workers planting treated seed in the field or in the greenhouse. Margins of exposure were estimated for workers handling the treated seed. All margins were well above the level of concern, provided seeds are planted by mechanical means only.

To support the use expansion of metalaxyl-M to Crop Group 8 (Fruiting Vegetable Group, except Cucurbits) residue data from supervised residue trials conducted in the US were assessed for metalaxyl applied at exaggerated rates to tomatoes and peppers (bell and

non-bell), with crops harvested at short PHIs.

In addition, a processing study in treated tomato was assessed to determine the potential for concentration of residues of metalaxyl-M into juice and puree.

Maximum Residue Limit

Based on the maximum residue observed in the representative crops (tomato and peppers [bell and non bell]) treated with metalaxyl, it was determined that residues of metalaxyl-M in tomatoes and peppers are expected to be covered under the MRL of 1.0 ppm currently established for these commodities.

Residues of metalayxl-M in tomato processed commodities will be covered under the MRL currently established for tomatoes.

A MRL of 1.0 ppm is recommended for the remaining crops within Crop Group 8 *(e.g.,* eggplants, groundcherries, pepinos, and tomatillos) as a result of this new use.

Environmental Assessment

The main environmental concern associated with the use of APRON XL LS Fungicide is related to the risk to birds from the consumption of seeds treated with this product. However, the amount of active ingredient on the seeds of fruiting vegetables was found to be within the range of that on seeds which are currently treated with APRON XL LS Fungicide. Therefore, to include fruiting vegetables to the list of registered uses does not represent an increase in environmental risk. Appropriate environmental statements are included on the label.

Value Assessment

No data was submitted in support of this registration request. Instead, a rationale was provided by the applicant, which states that the fungicidal effect of APRON XL LS on *Pythium* is well known and that the proposed use pattern is identical to those already registered in Canada for a number of other crops. Certain factors known to affect seed treatment efficacy were considered in this evaluation, including seed size and translocation of the active ingredient into and within the developing seedling. Based on the rationale provided, published standards, and the broad spectrum of plants in which metalaxyl is systemic, it is reasonable to assume that a seed treatment with APRON XL LS in fruiting vegetables will be effective in controlling *Pythium* damping-off in seedlings. The tank mix with MAXIM 480FS has already been evaluated in previous submissions and this product is already registered for use on seeds of fruiting vegetables. No further concerns regarding the tank mix arise from this proposed registration.

Conclusions

The PMRA has completed an evaluation of the subject application and has found the information sufficient to amend the registration of APRON XL LS Fungicide to include the claim of control of *Pythium* damping-off in/on Crop Group 8 (Fruiting Vegetable Group, except Cucurbits).

<u>MRLs</u>

Following the assessment of all available data, it was determined that the currently established MRL of 1.0 ppm for residues of metalaxyl in/on peppers and tomatoes, and the recommended MRL of 1.0 ppm for residues of metalaxyl in/on eggplants, groundcherries, pepinos, and tomatillos, are considered adequate to cover residues of metalaxyl-M in/on these crops as a result of this new use. Residues of metalaxyl-M in these crops at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

List of References

PMRA Document Number	Reference
1595120	1985, Metalaxyl – Fruiting Vegetables, DACO: 7.4.1
1595112	DACO: 0.8
1595113	DACO: 0.8.1

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