

Application category B, subcategory 5.0 (MRLs for registered active ingredients on domestic commodities)

Application No. 2005-3855

Product: MERTECT SC

Active Ingredient (a.i.): Thiabendazole (fungicide)

Registration Number: 13975 PMRA Document Number: 1421015

Background

Thiabendazole (Reg. No. 19605) is contained in the end use product, MERTECT SC Fungicide, for the control of fungal potato tuber diseases by treating potatoes post-harvest. Thiabendazole has been registered for use since 1963-07-01.

Purpose of Application

The purpose of this application is to increase the maximum residue limit (MRL) for thiabendazole in/on potatoes from 4 to a value of 10 ppm. There is no proposed change to the MERTECT SC label.

Chemistry Assessment

A chemistry assessment was not required for this application since thiabendazole is already registered in Canada.

Health Assessment

A toxicology assessment and occupational/by-standard exposure assessment was not required for this application since the proposal is to increase the MRL for an active ingredient that is currently registered in Canada.

To support the increase in MRL for thiabendazole in/on potatoes, residue data from post-harvest treatment of field grown potatoes were reviewed.

MRL Recommendations

Recommendations for the increase in MRL from 4 to 10 ppm in/on potatoes were based on guidance provided in PRO 2005-04 ("Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data").



Based on the residues observed in treated potatoes (TABLE 1), the maximum residue limit (MRL) to cover residues of thiabendazole in/on potatoes will be revised.

TABLE 1. Summary of Residue Data for Field grown Potatoes Treated Post-Harvest Used to Increase the Maximum Residue Limit (MRL) from 4 to 10 ppm for Thiabendazole (TZL).

Application Rate (g a.i./tonne)	Days after Treatment (days)	Residue Value (ppm)
43.91	6	3.3, 2.8
43.91	34	5.8, 5.5
43.91	61	0.016, 0.017
43.91	119	0.16, 0.020
37.6	0	3.32
37.6	20	2.55
37.6	57	3.65
37.6	122	3.95
37.6	178	5.63
37.1	0	4.59
37.1	20	5.47
37.1	57	8.01
37.1	122	6.88
37.1	178	6.72
36.0	0	2.44
36.0	20	1.66
36.0	57	2.26
36.0	122	1.91
36.0	178	1.92
33.4	0	4.22
33.4	20	2.76
33.4	57	5.12
33.4	122	4.18
33.4	178	5.45

Environmental and Values Assessments

Environmental and value assessments are not required since there are no changes to the MERTECT SC label.

Conclusions

Following the review of submitted data, the MRL for thiabendazole in/on potatoes treated post-harvest may be increased from 4 to 10 ppm. This new MRL is harmonized with the US. Residues in/on potatoes treated post-harvest with thiabendazole will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

List of Studies Submitted by Registrant

PMRA Document Number	Reference
1103058	Kissling, M., 1999, Residue Study with thiabendazole (MK 360) in or on Potatoes in Netherlands, Novartis Crop Protection AG, 2237/98, MRID: N/S, DACO: 7.4.1
1103059	Kissling, M., 1999, Residue Study with thiabendazole (MK 360) in or on Potatoes in Netherlands, Novartis Crop Protection AG, 2238/98, MRID: N/S, DACO: 7.4.1
1103072	Kissling, M., 1999, Residue Study with Thiabendazole (MK 360) in or on Potatoes in Netherlands, Novartis Crop Protection AG, 2235/98, MRID: N/S, DACO: 7.4.1
1103073	Kissling, M., 1999, Residue Study with Thiabendazole (MK 360) in or on Potatoes in Netherlands, Novartis Crop Protection AG, 2236/98, MRID: N/S, DACO: 7.4.1
1271696	2006, Thiabendazole - Residue Levels on Potatoes (Tubers) from Trials Conducted with Mertect SC Applied in a Commercial Setting in Canada During 2005, Syngenta Crop Protection Canada, Inc., CER 05403/05, DACO: 7.4.1
1288795	2006, SUPERVISED RESIDUE TRIAL ANALYTICAL METHODOLOGY, ALS Laboratory Group, Environmental Division, M 333, DACO: 7.2.1

List of Additional Information Considered

None

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