



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2009-0910
Application: B.2.6. – New Combination of TGAI’s
Product: Maxim Quattro Seed Treatment
Registration Number: 29871
Active ingredients (a.i.): Azoxystrobin (AZY), Fludioxonil (FLD), Metalaxyl-M (MFN), Thiabendazole (TZL)
PMRA Document Number : 1958811

Purpose of Application

The purpose of this application was to register an end use product containing a new combination of active ingredients to control seedling diseases on corn. Maxim Quattro Seed Treatment contains fludioxonil, metalaxyl-m and s-isomer, azoxystrobin and thiabendazole. Tank-mixes with Cruiser 5FS or Cruiser 350FS Seed Treatment Insecticides are also on the label.

Chemistry Assessment

Maxim Quattro Seed Treatment is a suspension containing the active ingredients thiabendazole, fludioxonil, metalaxyl-M and S-isomer and azoxystrobin at nominal concentrations of 26.5%, 3.32%, 2.65% and 1.33%, respectively. This product has a density of 1.13 g/mL and pH of 5-8. With the exception of the one year storage stability study and the corrosion characteristics study, the chemistry requirements for Maxim Quattro Seed Treatment have been completed. The one year storage stability study and the corrosion characteristics study will be submitted as part of the conditional registration of Maxim Quattro Seed Treatment.

Health Assessments

Maxim Quattro Seed Treatment is of low toxicity to rats via the oral ($LD_{50} \geq 5000$ mg/kg), dermal ($LD_{50} > 5000$ mg/kg), and inhalation routes ($LC_{50} > 2.55$ mg/L). It is minimally irritating to the eye and skin of rabbits. It is a dermal sensitizer in guinea pigs

Thiabendazole was not registered for use on corn in Canada. Plant metabolism and residue data for thiabendazole in corn were submitted to support the use of thiabendazole on corn. In addition, a processing study in seed-treated corn was also assessed to determine the potential for concentration of residues of thiabendazole into processed commodities. Residue data for azoxystrobin, fludioxonil, metalaxyl-M were not submitted and are not required since these active ingredients are currently registered in Canada for use as seed treatment on corn at equivalent or higher rates.

Maximum Residue Limits

Based on the maximum residues observed in corn treated according to label directions, maximum residue limits (MRLs) to cover residues of thiabendazole will be established as shown in Table 1. Residues of thiabendazole in processed commodities are covered under established MRLs for the raw agricultural commodity (RAC).

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL (ppm)
			Min	Max			
Field corn	Seed treatment/ 16.1 - 39.2	NA	<0.01	<0.01	No concentration observed in processed corn commodities	None	0.01
Popcorn grain	Seed treatment/ 19.6 - 39.2		<0.01	<0.01		None	0.01
Sweet corn kernels plus cob with husks removed	Seed treatment/ 16.7 - 39.2		<0.01	<0.01		None	0.01

Following the review of all available data, MRLs of 0.01 ppm for field corn, popcorn grain, and sweet corn kernels plus cob with husks removed are recommended to cover residues of thiabendazole. Residues of thiabendazole in these crop commodities at the recommended MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

A risk assessment for fludioxonil, metalaxyl and azoxystrobin was previously conducted since these active ingredients were already registered for use on corn seed at the same rate.

A quantitative risk assessment was conducted for workers contacting thiabendazole resulting from the use of Maxim Quattro Seed Treatment on corn seed. The risk assessment for thiabendazole was conducted using surrogate exposure data for commercial seed treatment workers, and planters and chemical specific dermal absorption data for thiabendazole. Risk for workers treating corn seed in commercial facilities and risk for farmers planting commercially treated corn seed are above the target margin of exposure (MOE) for thiabendazole. The risk assessment supports the conditional registration of Maxim Quattro Seed Treatment on field, sweet and pop corn, pending confirmatory dust-off data. Dust off data is required to compare the dust off potential of canola treated with Helix XTra to that of corn treated with Maxim Quattro Seed Treatment and to compare the dust off potential of Apron FL on soybeans to corn treated with Maxim Quattro Seed Treatment.

Environmental Assessment

The EAD does not currently assess risk from a cumulative perspective for combination products. Although Maxim Quattro Seed Treatment is a combination of four fungicides, the risk to the environment was reviewed on the basis of the individual active ingredients, metalaxyl-m, azoxystrobin, fludioxonil, and thiabendazole. Each of the active ingredients are applied to corn seed at rates lower than already assessed in terms of environmental risk and, therefore, no additional environmental risk is expected from the use of Maxim Quattro Seed Treatment.

Value Assessment

Eight controlled environment and field trials were reviewed in support of the disease claims. Increased emergence and seedling dry weights were observed in the Maxim Quattro Seed Treatment applications indicating control of seed rot/pre-emergence damping-off and seedling blight. Control of post-emergence damping-off was also evident in the trials. The efficacy trials submitted clearly indicate superior control of *Fusarium verticillioides* with thiabendazole alone or in Maxim Quattro Seed Treatment over the other active ingredients (commercial standards), which broadens the disease spectrum of the tank-mix of Dynasty 100 FS and Maxim XL.

Tank mixing Cruiser 5FS Seed Treatment Insecticide with Maxim Quattro Seed Treatment had no negative effects on fungicide efficacy and no phytotoxicity was observed. Cruiser 350FS Insecticide contains the same active ingredient as Cruiser 5FS (thiamethoxam) at a lower concentration, and so is not expected to negatively affect fungicide efficacy or cause phytotoxicity on corn plants. Uses for corn are currently registered on both of the insecticide labels, so the tank mixes can be supported by both the fungicide and the insecticide perspective.

Conclusion

The PMRA has conducted an assessment of available information for Maxim Quattro Seed Treatment and has found the information sufficient to support conditional registration of the subject product.

The applicant must submit the following scientific information as a condition of registration by September 30, 2011:

- one year storage stability study
- corrosion characteristics study
- confirmatory dust off data

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