

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number:	2010-4627
Application:	New End-use product – New combination of technical grade active ingredients
Product:	Apron Advance Seed Treatment
Registration Number:	30627
Active ingredients (a.i.):	Fludioxonil, Metalaxyl-M, and Thiabendazole
PMRA Document Number:	2030814

Background

The actives, fludioxonil and metalaxyl-M, are both currently registered for use on soybeans, beans, chickpeas, lentils, lupins, faba beans and peas in the products Apron Maxx RTA Seed Treatment Fungicide (registration number 27577) and Apron Maxx RFC Seed Treatment Fungicide (registration number 28817). The current registered rates for application of these products via seed treatment are: 2.5 g FLD/100 kg seed and 3.7 g MFN/100 kg seed. Crown Systemic and Contact Seed Protectant (registration number 23430) is also a seed treatment for chickpea and lentil that contains the active ingredient, thiabendazole (plus carbathiin), and is currently registered at a rate of 34.8 g TZL/100 kg seed.

Purpose of Application

The purpose of this application was to register an end-use product, Apron Advance Seed Treatment, for control of certain seed-borne and soil-borne diseases of dry beans (including lupins and dry faba beans), dry peas, chickpeas and lentils. Apron Advance Seed Treatment is a premix formulation that contains the active ingredients fludioxonil, metalaxyl-M and thiabendazole.

Chemistry Assessment

Apron Advance Seed Treatment is a suspension containing the active ingredients thiabendazole, fludioxonil and metalaxyl-M and S-isomer at nominal concentrations of 150 g/L, 25 g/L and 20 g/L, respectively. This product has a density of 1.09 g/mL and pH of 5 – 8. The chemistry requirements for Apron Advance Seed Treatment have been completed.

Health Assessments

Apron Advance Seed Treatment is of low toxicity to rats via the oral ($LD_{50} > 5000$ mg/kg), dermal ($LD_{50} > 5050$ mg/kg), and inhalation routes ($LC_{50} > 2.68$ mg/L). It is not irritating to the eyes or skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The proposed use of metalaxyl-M, fludioxonil, and thiabendazole in Apron Advance Seed Treatment on Crop Subgroup 6C (dried shelled pea and bean (except soybeans), dry peas, chickpeas and lentils) is not expected to result in risks of concern to commercial and on-farm chemical handlers and post-application workers provided the products are applied according to the label directions, and the recommended label amendments are adopted.

New residue data for thiabendazole in dry beans and dry peas were submitted to support the registration of the new end-use product Apron Advance Seed Treatment. No new residue data were submitted for the co-actives fludioxonil and metalaxyl-M. Both active ingredients are registered for use on dry legume vegetables under similar use patterns.

Maximum Residue Limits

Based on the maximum residues observed in crops treated according to label directions and at exaggerated rates, a maximum residue limit (MRL) of 0.01 ppm for Crop Subgroup 6C (Dried Shelled Pea and Bean, except soybean) to cover residues of thiabendazole in/on crops will be established as shown in Table 1. There are no processed commodities associated with the crops in Crop Subgroup 6C. The MRLs currently established for fludioxonil and metalaxyl on dry beans and dry peas are adequate to cover these uses.

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRLs)							
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Dry Bean Seed	Seed Treatment/ 27.3-30.2 g a.i./100kg seed	101-128	<0.01	<0.01	Not applicable	None	0.01 ppm (Crop Subgroup 6C; Dried Shelled Pea and Bean, except soybean)
Dry Pea Seed	Seed Treatment/ 28.0-28.8g a.i./100 kg seed	104-122	<0.01	<0.01	Not applicable	None	

Based on dietary burden and residue data, finite residues of thiabendazole are not expected in the meat, meat byproducts, fat, milk and eggs when livestock are fed crops treated according to the approved use directions for Apron Advance Seed Treatment.

Following the review of all available data, the MRL of 0.01 ppm for Crop Subgroup 6C (Dried Shelled Pea and Bean, except soybean) is recommended to cover residues of thiabendazole. Residues in these food commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No additional environmental data were required for registration of the new end-use product, Apron Advance Seed Treatment. Environmental concerns have been mitigated through adequate statements on the proposed product label and no amendments are required at this time.

Value Assessment

The purpose of registering Apron Advance Seed Treatment is to provide an alternative seed treatment to a tank mix of Apron MAXX products (either Apron MAXX RTA Seed Treatment Fungicide or Apron MAXX RFC Seed Treatment Fungicide) with Dynasty 100FS Fungicide (registration number 28394). The Apron MAXX products are currently registered for the proposed claims, but growers apply them in tank mix with Dynasty 100FS Fungicide to legume seed to improve efficacy against ascochyta blight and anthracnose. The active ingredient in Dynasty 100FS Fungicide (azoxystrobin) has a high risk of developing pest resistance, so thiabendazole has been added to the active ingredients in the Apron MAXX products to increase efficacy against these diseases and act as a rotational seed treatment in order to maintain the sustainability of the tank mix with Dynasty 100FS Fungicide.

The registrant proposed a rate range of 100 – 200 ml/100 kg seed, but withdrew the higher rate. A total of seven trials were submitted to support the proposed uses.

Three controlled environment trials demonstrated control of ascochyta blight on chickpea when Apron Advance Seed Treatment was applied at 100 ml/100 kg seed. The efficacy of Apron Advance Seed Treatment was comparable to a tank mix with each of the Apron MAXX products and Dynasty 100FS Fungicide. Thiabendazole also demonstrated efficacy against this disease.

Three field trials demonstrated efficacy of Apron Advance Seed Treatment against anthracnose on dry bean, but application at 100 ml/100 kg seed was less efficacious than the tank mix. Thiabendazole did not demonstrate efficacy against this disease. The data did not demonstrate the value of the registration. An additional trial was submitted to show efficacy at the 100 ml/100 kg rate. The trial was reviewed as supplementary data because a foliar application of a fungicide registered to control anthracnose on dry bean was applied prior to the final disease assessment on bean pods. The results were statistically comparable to the tank mix with Dynasty 100FS Fungicide, although the tank mix provided numerically higher control. The efficacy of thiabendazole against anthracnose was also demonstrated in the trial.

Although the data suggests that azoxystrobin provides higher levels of efficacy against ascochyta blight and anthracnose compared to thiabendazole, the registration of Apron Advance Seed Treatment offers growers a means to improve efficacy against these diseases without tank mixing, while retaining the sustainability of azoxystrobin. The claims were supported at the proposed rate of 100 ml/100 kg seed.

Additional claims proposed on the Apron Advance Seed Treatment label were supported because they are currently registered on the Apron Maxx product labels. Since the two products contain the same active ingredients and the proposed and registered rates are similar, extrapolation of the claims was acceptable. A claim that Apron Advance Seed Treatment is safe to use with Rhizobium inoculants was also supported because other seed treatments containing the same active ingredients have been proven safe to use with inoculants.

Conclusion

Following the review of all available data, Apron Advance Seed Treatment, for control of certain seed-borne and soil-borne diseases of dried dry beans (including lupins and dry faba beans), dry peas, chickpeas and lentils (Crop Subgroup 6C), has been approved. MRLs have been recommended to cover residues of thiabendazole in these food commodities that will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

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