Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 2.6, 3.12 Application

Application Number: 2024-1948
Application: New End-use Product (Product Chemistry) - New combination of Technical Grade Active Ingredients;
New Product Label - New Site or Host
Applicant: Bayer CropScience Inc.
Product: EverGol Rise Seed Treatment Fungicide
Registration Number: 35641
Active ingredients (a.i.): Metalaxyl, Penflufen, Prothioconazole, Trifloxystrobin
PMRA Document Number: 3708684

Purpose of Application

The purpose of this application was to register a new end-use product, EverGol Rise Seed Treatment Fungicide, for the control or suppression of certain diseases on Crop Subgroup 6-21E (Pulses, dried shelled beans, except soybeans), Crop Subgroup 6-21F (Pulses, dried shelled peas), and soybeans.

Chemistry Assessment

EverGol Rise Seed Treatment Fungicide is formulated as a suspension (SU) containing metalaxyl at 50 g/L, penflufen at 50 g/L, prothioconazole at 50 g/L and trifloxystrobin at 50 g/L. This end-use product has a density of 1.14 - 1.18 g/cm^3 and pH of 5.5 - 7.0. The required chemistry data for EverGol Rise Seed Treatment Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

EverGol Rise Seed Treatment Fungicide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was non-irritating to the eye and non-irritating to the skin, and was not a skin sensitizer.

The use of EverGol Rise Seed Treatment Fungicide as a seed treatment on Crop Subgroups 6-21E, 6-21F and soybeans is not expected to result in an increase in the potential occupational or bystander exposure over the registered uses of trifloxystrobin, prothioconazole, metalaxyl or penflufen. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

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No new residue data for trifloxystrobin, prothioconazole, metalaxyl, or penflufen in dry soybeans, beans, or peas were submitted or were required to support the registration of EverGol Rise Seed Treatment Fungicide. Previously reviewed residue data from field trials conducted in/on dry soybeans, beans, and peas were reassessed in the framework of this application.

Maximum Residue Limits

The recommendation for proposed maximum residue limits (MRLs) for trifloxystrobin was based upon the previously reviewed residue data. MRLs to cover residues of trifloxystrobin and CGA-321113 in/on crops are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 1 Summary of Field Trial and Processing Data for Trifloxystrobin and CGA-321113 Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Proposed MRL (ppm)
			LAFT	HAFT			
Dry beans	Foliar / 258-272	28-32	<0.02	0.023	Not required	0.06 CSG 6C: Dried shelled pea and bean (except soybean)	0.06 CSG 6-21E: Pulses, dried shelled beans, except soybeans)
Dry peas	Foliar / 261-266	29-31	<0.02	0.032			0.06 CSG 6-21F: Pulses, dried shelled peas

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

The recommendation for proposed maximum residue limits (MRLs) for penflufen was based upon the previously reviewed residue data. MRLs to cover residues of penflufen in/on crops are proposed as shown in Table 2. Residues in processed commodities not listed in Table 2 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 2 Summary of Field Trial and Processing Data for Penflufen Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Proposed MRL (ppm)
			LAFT	HAFT			
Dry bean seed	5	69-118	<0.01	<0.01	Not required	0.01 Commodities within CG 6: Legume Vegetables (succulent or dried) that belong to CSG 6C: Dried shelled pea and bean (except soybean)	0.01 CSG 6-21E: Pulses, dried shelled beans, except soybeans)
Dry pea seed		89-113	<0.01	<0.01			0.01 CSG 6-21F: Pulses, dried shelled peas

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, the MRLs proposed in Tables 1 and 2 are recommended to cover residues of trifloxystrobin and penflufen, respectively. Dietary risks from exposure to residues of trifloxystrobin and penflufen in these crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues as listed in Tables 1 and 2 are considered safe to eat.

The existing MRLs for prothioconazole and metalaxyl are protective and the dietary risks from exposure are also acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

Environmental Assessment

The use on various pulse and soybean seeds is within the currently registered use pattern for metalaxyl, penflufen, prothioconazole, and trifloxystrobin. Therefore, the risk is acceptable when EverGol Rise Seed Treatment Fungicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The results of efficacy trials demonstrated the efficacy of EverGol Rise Seed Treatment Fungicide, applied according to the labelled use pattern, at managing certain seed or seedling diseases on pulses, dried shelled beans and dried shelled peas. Additionally, scientific rationales, which cited solo or co-formulated registered precedent products provided additional evidence that EverGol Rise Seed Treatment Fungicide can be expected to control or suppress the listed seed or seedling diseases on soybean, pulses, dried shelled beans and dried shelled peas when applied according to the labelled use pattern. The registration of EverGol Rise Seed Treatment Fungicide will provide growers with a single end-use product containing multiple modes of action for use against important seed and seedling diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of EverGol Rise Seed Treatment Fungicide.

References

PMRA Document Number	Reference
3586876	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3586877	2024, Waiver for an Acute Dermal Toxicity Study on the Mixture Formulation Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200, DACO: 4.6.2
3586878	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3586879	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Primary Eye Irritation in Rabbits, DACO: 4.6.4
3586880	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Primary Skin Irritation in Rabbits, DACO: 4.6.5
3586881	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3586884	2024, Laboratory Dust-off Study of crop group 6 (beans and peas) including soybean, excluding succulent beans and pea, and flax seed treated with EverGol Rise seed treatment formulation: Part 5 Exposure (Occupational/Bystander), DACO: 5.15
3586867	2024, Value assessment of EverGol Rise seed treatment fungicide for protection against various seed- and soil-borne diseases in Crop Group 6 (beans and pea) (including soybean, excluding succulent beans and pea), and flax., DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(D), 10.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5, 10.5.2, 10.5.3, 10.5.4
3586885	2024, Compilation of trial reports (small-scale field trials/laboratory trials), Value assessment of EverGol PRO seed treatment fungicide for protection against various seed- and soil-borne diseases in Crop Group 6 (beans and pea) (including soybean), and Flax., DACO: 10.2.3.2(D)
3586871	2024, Product Chemistry Data to Support the Registration of Trilex EverGol RTU Seed Treatment Product (Product Identity and Composition), DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3586872	2024, EverGol Rise: Quantities of raw materials (formulants) used in the formulating process, DACO: 3.2.2 CBI
3586873	2024, Validation of the analytical method [CBI Removed] for the determination of metalaxyl, penflufen, prothioconazole, and trifloxystrobin in MTL+PFL+PTZ+TFS FS 200, specification 102000060925, DACO: 3.4.1 CBI
3586874	2024, Validation of the analytical method [CBI Removed] for the determination of [CBI Removed] in MTL+PFL+PTZ+TFS FS 200, specification 102000060925, DACO: 3.4.1 CBI
3586875	2024, Determination of physical chemical properties and accelerated storage stability study on MTL+PFL+PTZ+TFS FS 200 (specification

PMRA Document Number	Reference
	number 102000060925), DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
3627704	2023, Determination of metalaxyl, penflufen, prothioconazole and trifloxystrobin in formulation - HPLC, DACO: 3.4.1 CBI
3627705	2023, Determination of [CBI Removed] in formulation - HPLC/MS/MS, DACO: 3.4.1 CBI