

Evaluation Report for Category B, Subcategories B.2.1, 2.3, 2.4, 2.6 Application

Application Number: 2023-6514
Application: New End-use Product (Product Chemistry) – Guarantee; Identity of Formulants; Proportion of Formulants; New combination of Technical Grade Active Ingredients
Applicant: Bayer CropScience Inc.
Product: ACCELERON PRIME
Registration Number: 35424
Active ingredients (a.i.): Fluoxastrobin, metalaxyl, prothioconazole
PMRA Document Number: 3669642

Purpose of Application

The purpose of this application was to register ACCELERON PRIME, a new end-use product for use on soybean seed to control several seed, seedling and soil borne diseases.

Chemistry Assessment

ACCELERON PRIME is formulated as a suspension containing fluoxastrobin at a concentration of 50.0 g/L, metalaxyl at a concentration of 100.0 g/L and prothioconazole at a concentration of 50.0 g/L. This end-use product has a density of 1.08-1.12 g/mL and pH of 6.5-7.5. The required chemistry data for ACCELERON PRIME have been provided, reviewed and found to be acceptable.

Health Assessments

ACCELERON PRIME is of low acute toxicity via the oral, dermal and inhalation routes. ACCELERON PRIME is non-irritating to the eye and non-irritating to the skin and is not a dermal sensitizer.

The registration of ACCELERON PRIME on soybean seed can be supported from an occupational exposure perspective, as it fits within the registered use patterns of the active ingredients in the end-use product. Therefore, exposure to these active ingredients is not expected to exceed that of the registered uses. No health risks of concern are expected, provided all label directions are followed.

No new residue data for fluoxastrobin, metalaxyl, or prothioconazole in soybeans were submitted to support the registration of these active ingredients on the ACCELERON PRIME label. Previously reviewed residue data from field trials conducted in/on soybeans were reassessed in the framework of this application. In addition, processing studies in treated soybeans were also reassessed to determine the potential for concentration of residues of fluoxastrobin, metalaxyl, or prothioconazole into processed commodities.

Based on this assessment, residues of fluoxastrobin, metalaxyl, and prothioconazole are not expected to increase and are expected to still be covered by the established relevant maximum residue limits (MRLs) on soybeans, dry beans, and livestock commodities. Consequently, dietary risks from exposure to residues of these active ingredients are considered to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for ACCELERON PRIME is within the registered use pattern of registered products containing these active ingredients. Risk from use of ACCELERON PRIME is acceptable from the environmental perspective when used according to label directions.

Value Assessment

Evidence to support the value of disease claims was extrapolated from precedent claims on registered products that contain the same active ingredients as those found in ACCELERON PRIME. A scientific rationale demonstrated that ACCELERON PRIME will deliver comparable rates of active ingredients as those registered against the same diseases on precedent product labels. ACCELERON PRIME can therefore be expected to manage seed and seedling diseases on soybean as listed on the label.

ACCELERON PRIME will provide soybean growers with a new combination of fungicides in a single product, thereby increasing the spectrum of disease management and, in certain cases, contribute to seed, seedling and soil borne disease resistance management.

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 ACCELERON PRIME.

References

PMRA Document Number	Reference
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3527040	2023, Product chemistry data to support the registration of Acceleron 26FO fungicide seed treatment product (product identity and composition), DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3527041	2023, Determination of fluoxastrobin, metalaxyl, and prothioconazole in formulations - HPLC, DACO: 3.4.1 CBI
3527042	2023, Validation of the analytical method AM250823LP3 for the determination of fluoxastrobin, metalaxyl, and prothioconazole in FXA+MTL+PTZ FS 200, specification 102000059553, DACO: 3.4.1 CBI
3527043	2023, Determination of physical chemical properties and accelerated storage stability study on FXA+MTL+PTZ FS 200, 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, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
3527044	2023, Fluoxastrobin + metalaxyl + prothioconazole FS 200 (50 + 100 + 50 g/L):Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO 4.6.1
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3527046	2023, Fluoxastrobin + metalaxyl + prothioconazole FS 200 (50 + 100 + 50 g/L): Acute Inhalation Toxicity in Rats, DACO 4.6.3
3527047	2023, Fluoxastrobin + metalaxyl + prothioconazole FS 200 (50 + 100 + 50 g/L): Primary Eye Irritation in Rabbits, DACO 4.6.4
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1733578	2009, JAU6476 100 FS seed treatment fungicide for cereal grains, corn, dried and field pea, chickpea, lentil and soybean, DACO: 10.2.3.1, 10.2.3.2(D)
1967126	2010, PENPROME 177FS, Sub. No. 2010-1280 - Bayer CropScience response to PMRA, VSAD questions from September 29, 2010 regarding efficacy claims for control of Pythium, DACO: 10.2.3.1, 10.2.3.2(D)
2630553	2016, Value assessment of fluoxastrobin ST seed treatment fungicide - Data supporting control of seed rot / pre-emergence damping-off of soybean caused by Rhizoctonia solani, DACO: 10.2.3.1,10.2.3.2(D)
2874336	2018, Value assessment of PTZ 480SC seed treatment fungicide - Data supporting a higher use-rate in soybean for improved control of root rot

PMRA Document Number	Reference
	caused by <i>Fusarium</i> spp., DACO: 10.2.3.1,10.2.3.2(D)
3527035	2023, Value assessment of Acceleron 26FO fungicide seed treatment for control of seed, seedling, and soil-borne diseases in soybean, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.3.1,10.3.2,10.4,10.5
3527037	2023, Compilation of trial reports - Value assessment of Acceleron 26FO fungicide seed treatment for control of seed, seedling, and soil-borne diseases in soybean, DACO: 10.3.2

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