



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2021-6665
Application: Changes to Product Labels-New Site or Host
Product: VAYANTIS Seed Treatment
Registration Number: 34138
Active ingredient (a.i.): Picarbutrazox
PMRA Document Number: 3469758

Purpose of Application

The purpose of this application was to amend the label of the registered product, VAYANTIS Seed Treatment, to add use on Crop Subgroup 6C (Dried Shelled Pea and Bean, including lentils, chickpeas, field peas and dry beans), Crop Group 15 (Cereals Grains, including wheat, barley and oats in addition to currently registered corn) and Crop Subgroup 20A (Canola/Rapeseed Subgroup, including canola) to control seed rot and pre-emergence damping-off caused by *Pythium* spp. and to expand the use pattern to include open transfer.

VAYANTIS Seed Treatment is currently registered for control of seed rot, pre-emergence damping-off and post-emergence damping-off caused by *Pythium* spp. on soybean and corn, and for control of seed rot, pre- and post-emergence damping-off caused by *Phytophthora sojae* on soybean.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The occupational exposure from the use of VAYANTIS Seed Treatment on on listed legume vegetables of crop subgroup 6C (Dried Shelled Peas and Beans), oilseeds of crop subgroup 20A (Rapeseeds/Canola) and small grain cereals of crop group 15 (Cereal Grains), as well as the expansion of use to include open transfer equipment and on-farm treatment was assessed. No risks of concern to workers in seed treatment facilities, workers handling and planting treated seed or bystanders are expected from use of the product, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No residue data on human food commodities were submitted to support the use of VAYANTIS Seed Treatment on Crop Subgroup 6C – Dried shelled pea and bean (except soybean), Crop Subgroup 20A – Rapeseeds, and Crop Group 15 – Cereal Grains. As the rates of VAYANTIS Seed Treatment on each of the requested crops are below 10 g a.i./100 kg seed, as per SPN2018-01, no residue data on human foods are required.

Residue data from field trials on relevant animal feed commodities conducted in Canada and the United States were submitted to support the use of VAYANTIS Seed Treatment on Crop Subgroup 6C – Dried shelled pea and bean (except soybean) and Crop Group 15 – Cereal Grains. Picarbutrazox was applied to dried beans, dried peas, wheat, and barley at exaggerated rates and harvested at normal commercial harvest.

Maximum Residue Limits

As no quantifiable residues of picarbutrazox are expected as result of the seed treatment uses on Crop Subgroup 6C – Dried shelled pea and bean (except soybean), Crop Subgroup 20A – Rapeseeds, and Crop Group 15 – Cereal Grains, the recommendation for proposed maximum residue limits (MRLs) for picarbutrazox was based upon the limit of quantitation for the enforcement method (i.e. 0.01 ppm).

Residues of picarbutrazox in/on animal commodities as a result of the seed treatment uses will be covered under the MRLs currently established (i.e. 0.01 ppm in/on eggs; fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep; milk).

Following the review of all available data, MRLs of 0.01 ppm in/on dried shelled pea and bean, except soybean (crop subgroup 6C); cereal grains (crop group 15); and rapeseeds (crop subgroup 20A) are recommended to cover residues of picarbutrazox. Dietary risks from exposure to residues of picarbutrazox in these commodities at the recommended and established 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 above are considered safe to eat.

A toxicology assessment was not required for this application.

Environmental Assessment

The risks to non-target organisms from the use expansion of VAYANTIS Seed Treatment are acceptable from the viewpoint of environmental protection when label directions are followed.

Value Assessment

Scientific rationales and results from controlled environment (CE) and field trials conducted on legumes (lentil, chickpea, field pea and dry bean), cereal grains (wheat, barley and oats) and canola in Canada and the USA between 2019 and 2021 were reviewed to support the proposed use claims on the VAYANTIS Seed Treatment. The efficacy results from CE studies and field trials demonstrated that VAYANTIS Seed Treatment at 1.25 or 2.5 g a.i./100 kg seed controls seed rot/pre-emergence damping-off caused by *Pythium* spp. The performance of VAYANTIS Seed Treatment was comparable to or superior to the commercial standard tested in the same studies and trials. In addition to the new uses on legumes, cereal grains and rapeseed/canola, VAYANTIS Seed Treatment may also be mixed with other fungicides or insecticides to provide broad spectrum control of seed- and soil-borne pathogens or insect pests.

VAYANTIS Seed Treatment has been confirmed to have value as data have demonstrated that it can be expected to protect against seed rot and pre-emergence damping-off caused by *Pythium* spp. of legumes, cereal grains or rapeseed/canola. Expanding the registration of VAYANTIS

Seed Treatment for these new uses will provide Canadian growers with a new mode of action to combat *Pythium* infection in Crop Subgroup 6C, Crop Subgroup 20A and listed cereal grains.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to make the requested amendments to the label of VAYANTIS Seed Treatment.

References

PMRA

Document

Number

Reference

3304192	2021, Picarbutrazox: Laboratory Dust-Off Measurements of Cereals, Canola and Pulses Treated with VAYANTIS and Bridging to Exposure Data Assessment, DACO: 5.15.
3401299	2021, Picarbutrazox (A20597B) - Magnitude of the Residues in or on Barley Hay and Straw only Following Seed Treatment, Canada, 2019, DACO: 7.4.1
3401300	2021, Picarbutrazox (A20597B) - Magnitude of the Residues in or on Dry Pea Vines (forage) and Hay only Following Seed Treatment, Canada 2019, DACO: 7.4.1
3401301	2021, Picarbutrazox (A20597B) - Magnitude of the Residues in or on Wheat following seed treatment, USA, 2019, DACO: 7.4.1
3401302	2020, Picarbutrazox (A20597B) - Magnitude of Residues in or on Dry Bean Vines and Hay Following Seed Treatment, USA, 2019, DACO: 7.4.1
3304151	2021, DACO 10 Value Summary: Efficacy and Crop Response for Control of Pythium spp. in Wheat, Barley, Oats, Canola, Lentils, Chickpeas, Field Peas, and Dry Beans with Vayantis, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3.1, 10.2.4, 10.3.1, 10.3.2, 10.3.3, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5, 10.6
3304153	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in chickpeas, DACO: 10.2.3.3
3304154	2020, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in canola, DACO: 10.2.3.3
3304155	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in chickpeas, DACO: 10.2.3.3
3304156	2020, Evaluate the lowest effective rate (LER) of Vayantis (Picarbutrazox, A20597B) for activity against Pythium in wheat, DACO: 10.2.3.3
3304157	2021, Evaluate the lowest effective rate (LER) of Vayantis (Picarbutrazox, A20597B) for activity against Pythium in barley, DACO: 10.2.3.3
3304158	2020, Evaluate the lowest effective rate (LER) of Vayantis (Picarbutrazox, A20597B) for activity against Pythium in barley, DACO: 10.2.3.3
3304159	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in field peas, DACO: 10.2.3.3
3304160	2021, Evaluate the lowest effective rate (LER) of Vayantis (Picarbutrazox, A20597B) for activity against Pythium in wheat, DACO: 10.2.3.3
3304161	2020, Evaluate the lowest effective rate (LER) of Vayantis (Picarbutrazox, A20597B) for activity against Pythium in wheat, DACO: 10.2.3.3
3304162	2021, Evaluate the lowest effective rate (LER) of Vayantis (Picarbutrazox, A20597B) for activity against Pythium in barley, DACO: 10.2.3.3
3304163	2020, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in canola, DACO: 10.2.3.3
3304164	2020, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in field peas, DACO: 10.2.3.3

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