



Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2021-6643
Application: New End-Use Product Chemistry-New Combination of Technical Grade Active Ingredients
Product: VIBRANCE TOTAL
Registration Number: 34890
Active ingredients (a.i.): Thiabendazole, Sedaxane, Metalaxyl-M and S-isomer, Fludioxonil and Picarbutrazox
PMRA Document Number: 3469523

Purpose of Application

The purpose of this application was to register a new fungicide seed treatment, VIBRANCE TOTAL, for use on Crop Subgroup 6C, including dried shelled pea and bean crops, chickpeas, lentils, lupin and faba beans, by commercial and on-farm treaters, to control listed seed and soil-borne fungal diseases.

Chemistry Assessment

VIBRANCE TOTAL is formulated as suspension containing picarbutrazox at a concentration of 0.72%, thiabendazole at 4.30%, sedaxane at 1.43%, metalaxyl-M and S-isomer at 1.07% and fludioxonil at 0.72%. This end-use product has a density of 1.08 g/mL and pH of 7.9. The required chemistry data for VIBRANCE TOTAL have been provided, reviewed and found to be acceptable.

Health Assessments

VIBRANCE TOTAL was of low acute toxicity via the oral, dermal, and inhalation routes. It was minimally irritating to the eye and slightly irritating to the skin and was not a skin sensitizer.

The occupational exposure from the use of VIBRANCE TOTAL on listed legume vegetables of crop subgroup 6C (Dried Shelled Peas and Beans) (i.e., dried shelled peas, dried shelled beans, chickpeas, lentils, lupins and faba beans), was assessed. There are no risks of concern to workers in seed treatment facilities, workers treating seed on-farm, workers handling and planting treated seed, or bystanders when label directions are followed, and when workers wear the personal protective equipment identified.

No new residue data for thiabendazole, sedaxane, metalaxyl-M and S-isomer, fludioxonil, or picarbutrazox in dried shelled beans, dried shelled peas, chickpeas, lentils, lupins, or faba beans were submitted to support the use of these active ingredients on the VIBRANCE TOTAL label.

No residue data on human food commodities were submitted to support the use of VIBRANCE TOTAL on dried shelled beans, dried shelled peas, chickpeas, lentils, lupins, and faba beans. As the seed treatment rate of VIBRANCE TOTAL on each of the listed 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 were conducted in Canada and the United States were submitted to support the use of VIBRANCE TOTAL on dried shelled beans, dried shelled peas, chickpeas, lentils, lupins, and faba beans. Picarbutrazox was applied to dried beans and dried peas 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 dried shelled beans, dried shelled peas, chickpeas, lentils, lupins, and faba beans, 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 proposed 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).

Residues of thiabendazole, sedaxane, metalaxyl-M and S-isomer, and fludioxonil in/on dried shelled beans, dried shelled peas, chickpeas, lentils, lupins, faba bean, and livestock commodities will be covered by the MRLs currently established for these actives in/on these commodities ([Health Canada's Maximum Residue Limits for Pesticides Database](#)).

Following the review of all available data, an MRL of 0.01 ppm in/on dried shelled pea and bean, except soybean (crop subgroup 6C) is recommended to cover residues of picarbutrazox.

Dietary risks from exposure to residues of thiabendazole, sedaxane, metalaxyl-M and S-isomer, fludioxonil, and picarbutrazox in these commodities at the proposed 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.

Environmental Assessment

The risks to non-target organisms from use of VIBRANCE TOTAL are acceptable from the viewpoint of environmental protection when label directions are followed.

Value Assessment

Nine efficacy trials conducted in Canada in 2021, and scientific rationales, were submitted to support the value of including picarbutrazox in a co-formulated seed treatment fungicide and to extrapolate registered claims from a precedent product label. The submitted data show that picarbutrazox contributes to the control of seed rot/pre-emergence damping off and post-emergence damping-off caused by *Pythium* spp., which establishes its value in the mixture with other active ingredients. The individual application rates for the remaining active ingredients in VIBRANCE TOTAL are identical to those from the equivalent registered uses of the precedent

product cited in the rationale. Since the efficacy of this combination of active ingredients has been supported previously against the remaining use claims, the extrapolation of all claims from the precedent label to the VIBRANCE TOTAL label is supported. Tank mixes with Cruiser 5FS Seed Treatment or Intego Solo were also supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to register VIBRANCE TOTAL.

References

PMRA

Document

Number	Reference
3303655	2021, A23332A - Manufacturing Process Description and Supporting Data, DACO: 3.1, 3.1.2, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2 CBI
3303657	2021, A23332A - Physical and Chemical Properties, DACO: 3.5, 3.5.1, 3.5.11, 3.5.12, 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
3430005	2023, A23332A Physical and Chemical Properties [CBI Removed]
3303661	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3303663	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3303664	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - Primary Eye Irritation in Rabbits, DACO: 4.6.4
3303665	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - In Vitro Eye Irritation Test in Isolated Chicken Eyes, DACO: 4.6.4
3303666	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - In Vitro Skin Irritation Test in the EPISKINTM Model, DACO: 4.6.5
3303667	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - Primary Skin Irritation in Rabbits, DACO: 4.6.5
3303668	2021, Thiabendazole/Picarbutrazox/Fludioxonil/Metalaxyl-M/Sedaxane FS (A23332A) - Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3303670	2021, Picarbutrazox: Laboratory Dust-Off Measurements of Pulses Treated with A23332A or A23435C and Bridging to Exposure Data, DACO: 5.15
3303640	2021, DACO 10 Value Summary: Efficacy and Crop Response for Control of Pythium spp. in Lentils, Chickpeas, and Field Peas with Vibrance Total, 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
3303642	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in chickpea, DACO: 10.2.3.3
3303643	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in chickpeas, DACO: 10.2.3.3
3303644	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in field peas, DACO: 10.2.3.3
3303645	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in chickpeas, DACO: 10.2.3.3
3303646	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in field peas, DACO: 10.2.3.3
3303647	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in lentils, DACO: 10.2.3.3
3303650	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in lentils, DACO: 10.2.3.3
3303651	2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for Pythium control in lentils, DACO: 10.2.3.3

3303652 2021, Evaluate the lowest effective rate (LER) of Vayantis (A20597B) for
Pythium control in field peas, DACO: 10.2.3.3

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