Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2022-0989
Application: New End-use Product- New combination of Technical Grade Active Ingredients
Product: VAYANTIS IV RFC
Registration Number: 34915
Active ingredients (a.i.): Sedaxane, metalaxy-M and S-isomer, fludioxonil, and picarbutrazox
PMRA Document Number: 3476151

Purpose of Application

The purpose of this application was to register the fungicide seed treatment end-use product, VAYANTIS IV RFC, for use on soybeans to control various seed and soil-borne diseases.

Chemistry Assessment

VAYANTIS IV RFC is formulated as a solution containing picarbutrazox at 1.81%, fludioxonil at 1.81%, metalaxyl-M and S-isomer at 7.24% and sedaxane at 1.81%. It has a density of 1.064 g/mL and pH of 8.4 (1% solution). The required chemistry data for VAYANTIS IV RFC have been provided, reviewed and found to be acceptable.

Health Assessments

VAYANTIS IV RFC is of low acute toxicity by the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eyes and not a dermal irritant. It is not a potential skin sensitizer.

VAYANTIS IV RFC was assessed for seed treatment use on soybeans. Quantitative occupational exposure risk assessments on file for sedaxane, metalaxyl-M and S-isomer, picarbutazox, and fludioxonil in this product are adequate to demonstrate that the registered use pattern of these active ingredients fits within their currently registered seed treatment use pattern on soybeans. No health risks of concern are anticipated for workers involved in commercial seed treatment facilities, on-farm treatment as well as for individuals handling treated seed while planting, provided all label use directions, precautions and restrictions are followed.

No new residue data for sedaxane, metalaxyl-M and S-isomer, fludioxonil, and picarbutrazox in soybeans were submitted or were required to support the registration of VAYANTIS IV RFC. Previously reviewed residue data from field trials conducted in/on soybean treated seeds were reassessed in the framework of this application. In addition, previously reviewed residue data from crop rotation studies were also reassessed.
Based on this assessment, residues of sedaxane, metalaxyl-M and S-isomer,

fludioxonil, and picarbutrazox are not expected to be greater than those for the currently registered uses and will be covered by the established maximum residue limits (MRLs) for the each of the active ingredients present in VAYANTIS IV RFC. Consequently, dietary exposure to these active ingredients is not expected to increase with the registration of this product and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

The registered uses of VAYANTIS IV RFC are not expected to pose any additional risks to the environment. The required environmental precautions statements to mitigate risks to the environment are included in the label and are sufficient to address environmental concerns. When used according to label directions, the environmental risks are acceptable for VAYANTIS IV RFC.

Value Assessment

Evidence to support the value of the disease claims was extrapolated from claims on currently registered fungicide products that contain active ingredients found in VAYANTIS IV RFC. A scientific rationale demonstrated that VAYANTIS IV RFC will deliver the same or similar rates of active ingredients as these registered products. VAYANTIS IV RFC is expected to control seed and seedling diseases caused by *Fusarium* spp., *Pythium* spp., *Phomopsis* spp., *Phytophthora sojae* and *Rhizoctonia* spp. when applied according to label directions.

Seedling diseases rank in the top five disease threats to soybean production in North America and number two after soybean cyst nematode in Ontario. VAYANTIS IV RFC will provide soybean growers with a new combination of fungicides to aid with the management of seed and soil borne 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 VAYANTIS IV RFC.

References

PMRA Document Number	Reference
3327387	2022, Rationale to register the new products VAYANTIS IV RFC and A23545 ST in Canada, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3.1,10.3.1,10.5, 10.5.1,10.5.2,10.5.3,10.5.4,10.5.5
3327388	2022, A23545B Manufacturing Process Description and Supporting Data, DACO: 3.1,3.2,3.2.1,3.2.2,3.2.3,3.3,3.3.1, 3.3.2,3.4,3.4.1,3.4.2 CBI
3327390	2022, A23545B Physical and Chemical Properties, DACO: 3.5,3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2,3.5.3,3.5.6, 3.5.7,3.5.8,3.5.9 CBI
3470091	2023, A23545B Manufacturing Process Description and Supporting Data (Addendum to PC-22-001), DACO: 3.1,3.2,3.2.1,3.2.2,3.3,3.3.1,3.3.2 CBI
3470092	2023, Formulation Comparison - Note to the Reviewer, DACO: 3.7 CBI
3470111	2023, A23545C Manufacturing Process Description and Supporting Data (Addendum to PC-22-001), DACO: 3.1,3.2,3.2.1,3.2.2,3.3,3.3.1,3.3.2 CBI
3460310	2023, A23545B Physical and Chemical Properties (Addendum to EPA MRID Number: 51486302)(Addendum to Syngenta Document Number: PC-22-00), DACO: 3.5,3.5.10,3.5.14,3.5.5 CBI
3470102	2023, A23545B Manufacturing Process Description and Supporting Data (Addendum to PC-22-001) DACO: 3.1,3.2,3.2.1,3.2.2,3.3,3.3.1,3.3.2 CBI