

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2022-0962
Application: New End-use Product (Product Chemistry) – New Combination of Technical Grade Active Ingredients
Product: VELUM RISE
Registration Number: 34871
Active ingredients (a.i.): Fluopyram and Penflufen
PMRA Document Number: 3453862

Purpose of Application

The purpose of this application was to register VELUM RISE, a commercial class end-use product for use in potatoes as a soil treatment for control or suppression of labelled fungal diseases and suppression of labelled plant pathogenic nematodes.

Chemistry Assessment

VELUM RISE is formulated as a suspension containing fluopyram at a concentration of 250 g/L and penflufen at a concentration of 106 g/L. This end-use product has a density of 1.11 – 1.15 g/mL and pH of 6.708 (1% solution). The required chemistry data for VELUM RISE have been provided, reviewed and found to be acceptable.

Health Assessments

VELUM RISE is of slight acute toxicity via the oral and dermal routes. It is of low acute toxicity via the inhalation route. It is non-irritating to the eye and minimally irritating to the skin. It is not a dermal sensitizer.

The use of VELUM RISE, in-furrow when planting potatoes, is not expected to result in potential occupational or bystander exposure over the registered uses of either fluopyram or penflufen. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for fluopyram or penflufen in potatoes were submitted or were required to support the registration of VELUM RISE. Previously reviewed residue data from field trials conducted in/on potatoes were reassessed in the framework of this application. In addition, a processing study for each active ingredient in treated potatoes was reassessed to determine the potential for concentration of residues of fluopyram and penflufen into processed commodities.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs) for fluopyram and penflufen in potatoes and livestock commodities.

Consequently, dietary exposure to residues of fluopyram and penflufen is not expected to increase with the registration of VELUM RISE and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern of VELUM RISE is within the registered use pattern of fluopyram and penflufen, therefore, no additional risk is expected from the use of this product.

The label includes all the required environmental precautions and directions for use information, which adequately mitigate risks to the environment.

Risk from use of VELUM RISE is acceptable from an environmental perspective when used according to label directions.

Value Assessment

Five efficacy trials and a scientific rationale were accepted to support the value of VELUM RISE. Results from the efficacy trials demonstrated commercially acceptable levels of efficacy against economically important fungal diseases of potato. A scientific rationale based on comparable application rates and absence of phytotoxicity or antagonism between the co-formulated active ingredients was accepted to support the extrapolation of registered label claims from the precedent products that contain either fluopyram or penflufen alone, to the VELUM RISE label. As this co-formulation involves concurrent management of labelled nematodes and fungal diseases, its value is to broaden the spectrum of pests managed using a single product.

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 VELUM RISE.

References

PMRA Document Number	Reference
3326807	2022, Value Assessment of In-furrow Application of Velum Rise Fungicide/Nematicide for Control/Suppression of Certain Diseases and Nematodes in Potatoes, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3.1,10.2.3.3(D), 10.3.1,10.3.2(B),10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3,10.5.4,10.5.5
3326809	2022, Compilation of Trial Reports: Value Assessment of In-furrow Application of Velum Rise Fungicide/Nematicide for Control/Suppression of Certain Diseases and Nematodes in Potatoes., DACO: 10.2.3.3(D),10.3.2(B)
3326810	2022, Velum Rise - Part 3 Chemistry Requirements, DACO: 3.1,3.1.1,3.1.2, 3.1.3,3.1.4,3.2.1,3.3.1,3.5.4,3.5.5 CBI
3326811	2022, Product Chemistry Data to Support the Registration of FLU + PFL SC 356 (356 g/L, Velum Rise), a Fungicide Product (Product Identity and Composition), DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
3326812	2022, Validation of the Analytical Method for the Determination of Fluopyram and Penflufen in Fluopyram + Penflufen SC 356, DACO: 3.4.1 CBI
3326813	2022, Product Chemistry Study on Fluopyram + Penflufen SC 356, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2, 3.5.3,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3326815	2022, Waiver Summary Report for FLU + PFL SC 356 (356 g/L, Velum Rise), End Use Product, DACO: 3.5.13,3.5.15 CBI
3326816	2022, Accelerated Aging and Package Stability of Fluopyram + Penflufen SC 356, DACO: 3.5.10,3.5.14,3.5.4,3.5.5 CBI
3326817	2022, FLU+PEN 356 SC: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3326818	2022, Waiver for an Acute Dermal Toxicity Study on FLU + PEN 356 SC, DACO: 4.6.2
3326819	2022, FLU+PEN 356 SC: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3326820	2022, FLU+PEN 356 SC: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3326821	2022, FLU+PEN 356 SC: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3326822	2022, FLU+PEN 356 SC: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6

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