

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2017-3149
Application: New EP Product Chemistry-New combination of TGAIs
Product: Vibrance Ultra Potato
Registration Number: 33171
Active ingredients (a.i.): Difenoconazole, mandipropamid, sedaxane
PMRA Document Number : 2847433

Purpose of Application

The purpose of this submission was to register a new combination of active ingredients for use as a potato seed piece fungicide.

Chemistry Assessment

Vibrance Ultra Potato is formulated as a suspension containing sedaxane at a concentration of 77.2 g/L, difenoconazole at a concentration of 77.2 g/L and mandipropamid at a concentration of 154.3 g/L. This end-use product has a density of 1.094 g/cm³ and pH of 6.5. The required chemistry data for Vibrance Ultra Potato have been provided, reviewed and found to be acceptable.

Health Assessments

Vibrance Ultra Potato is of low toxicity to rats via the oral, dermal, and inhalation routes. It is a non-irritant to the eyes and the skin of rabbits. It is not a dermal sensitizer in mice.

An assessment was performed for potato seed piece treaters and planters that may be exposed to Vibrance Ultra Potato. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for sedaxane, difenoconazole, and mandipropamid in potatoes were submitted to support the registration of Vibrance Ultra Potato. Previously reviewed residue data from field trials conducted in/on potatoes were reassessed in the framework of this petition. Based on this assessment, exposure to residues of sedaxane, difenoconazole, and mandipropamid in/on potatoes treated according to the use directions for Vibrance Ultra Potato will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No increase in environmental risk is expected from the use of Vibrance Ultra Potato.

Value Assessment

A scientific rationale was provided in support of the proposed claims. The activity of three fungicide active ingredients pre-mixed in the Vibrance Ultra Potato formulation against certain pathogens is already well established. The use pattern is currently registered and the use rates are within the range of currently registered rates for all three fungicide active ingredients. The combination of the three fungicides provides a broad-spectrum disease control. The registration of Vibrance Ultra Potato will offer Canadian growers another product to manage multiple seed- and soil-borne fungal diseases in potato.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the end-use product Vibrance Ultra Potato.

References

PMRA Document Number	Reference
2777528	2017, Difenoconazole/Mandipropamid/Sedaxane - A22202A Document J - Product Chemistry Volume, DACO: 2.2,3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.2,4.8 CBI
2777530	2017, Difenoconazole/Mandipropamid/Sedaxane A22202A - Document H Product Chemistry Volume, DACO: 3.2.1 CBI
2777531	2017, Difenoconazole/Mandipropamid/Sedaxane - A22202A - Document MIII Section 2 - Analytical Methods, DACO: 3.4.1 CBI
2777532	2017, A22202A - SF-890/1 - Determination of CGA169374 (Including Cis and Trans Isomers), NOA446510 and SYN524464 (Including Cis and Trans Isomers) in A22202A by UHPLC, DACO: 3.4.1 CBI
2777533	2017, A22202A - Validation of Analytical Method SF-890/1, DACO: 3.4.1 CBI
2777534	2017, Vibrance Ultra Potato (A22202A) Physiochemical Studies Summary, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2777535	2017, Difenoconazole/Mandipropamid/Sedaxane A22202A - Physico-Chemical Studies of the Formulation, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,3.7 CBI
2777537	2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
2777538	2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2777539	2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - Primary Eye Irritation in Rabbits, DACO: 4.6.4
2777540	2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - In Vitro Eye Irritation Test in Isolated Chicken Eyes, DACO: 4.6.4
2777541	2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - Primary Skin Irritation in Rabbits, DACO: 4.6.5

2777542 2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - In Vitro Skin Irritation Test in the EPISKINTM (SM) Model, DACO: 4.6.5

2777543 2017, Difenoconazole/Mandipropamid/Sedaxane FS (A22202A) - Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6

2313626 2013, ADMIRE 240F - Determination of Dermal and Inhalation Exposure of Workers during On-Farm Seed Piece Treatment of Potatoes, DACO: 5.3,5.4

2557310 2015, Observational Study to Determine Dermal and Inhalation Post-Application Exposure of Workers to Difenoconazole during Handling and Planting of Treated Potato Seed Pieces, DACO: 5.6

2777544 2017, Vibrance Ultra Potato Use Description /Scenario, DACO: 5.2

2777732 2017, Rationale to register the new product Vibrance Ultra Potato Seed Treatment in Canada, DACO: 10.1

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