

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.13 Application

Application Number: 2015-7027
Application: New EP / Product Chemistry – Guarantee/ Identity of Formulants/
Proportion of Formulants; New Product Label - Precautions
Product: Vibrance Flexi Canola
Registration Number: 32624
Active ingredients (a.i.): Difenoconazole, Fludioxonil, Metalaxyl-M and S-isomer,
Sedaxane
PMRA Document Number: 2716576

Purpose of Application

The purpose of this application was to register Vibrance Flexi Canola for commercial seed treatment of canola, rapeseed and mustard (condiment and oilseed) to control seed and soil-borne diseases.

Chemistry Assessment

Vibrance Flexi Canola is formulated as a suspension concentrate containing sedaxane at a nominal concentration of 8.4 g/L, difenoconazole at a nominal concentration of 40 g/L, metalaxyl-M and S-isomer at a nominal concentration of 12.5 g/L, and fludioxonil at a nominal concentration of 4.2 g/L. This end-use product has a density of 1.14 g/mL and pH of 8.3. The chemistry requirements for this product have been fulfilled.

Health Assessments

Vibrance Flexi Canola is of low acute oral, dermal and inhalation toxicity. It is non-irritating to the eye or skin of the rabbit and not a dermal sensitizer in the mouse.

The use of Vibrance Flexi Canola on canola, rapeseed, and mustard (condiment and oilseed) is not expected to result in potential occupational or bystander exposure over the registered use of sedaxane, difenoconazole, fludioxonil, and metalaxyl-M (and S-isomer). No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue data were submitted to support the registration of Vibrance Flexi Canola, containing difenoconazole, metalaxyl-M and S-isomer, fludioxonil, and sedaxane. As all active ingredients are currently registered for seed treatment use on canola, rapeseed and mustard (condiment and oilseed) at the same application rates and conditions, the registration of Vibrance Flexi Canola will not result in an increase in dietary exposure to these active ingredients and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The reported levels of impurities for Vibrance Flexi Canola are not of environmental concern. The use of Vibrance Flexi Canola is not expected to pose environmental risks of concern when used in accordance with the label directions.

Value Assessment

As long as the coverage of the seed surface is similar, it is expected that Vibrance Flexi Canola and a registered precedent product will have comparable efficacy since the same amount of difenoconazole, metalaxyl-M and S-isomer, sedaxane and fludioxonil will be applied to control the same diseases on the same crops. Based on the weight of evidence, disease claims on the Vibrance Flexi Canola label are supported as proposed. There is value in registering a multiple active ingredients seed treatment to broaden the disease spectrum and, in some cases, lower the risk of resistance. In addition, since Vibrance Flexi Canola is a fungicide-only product, users will have more flexibility to use the insecticide of their choice, if needed.

Conclusion

The Pest Management Regulatory Agency has completed an assesment of the information submitted, and has found the information sufficient to support the registration of Vibrance Flexi Canola for commercial seed treatment of canola, rapeseed and mustard (condiment and oilseed).

References

PMRA Document Number	Reference
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2594324	2015, A21458B Document J Product Chemistry Volume, DACO: 3.1.2,3.2.1,3.2.2,3.2.3,3.3.1 CBI
2594325	2015, A21458B Document H, DACO: 3.2.1 CBI
2594326	2015, Analytical Method SF-798/1, DACO: 3.4.1 CBI
2594327	2015, Validation of SF 798/1, DACO: 3.4.1 CBI
2594328	2015, Analytical Method SFA-798/1, DACO: 3.4.1 CBI
2594329	2015, Validation of Analytical Method SFA-798/1, DACO: 3.4.1 CBI
2594330	2015, A21458B Physicochemical 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
2594331	2015, A21458B Physicochemical properties, 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
2606471	2016, A21458B - Content of Active Ingredient(s) and Corrosion Characteristics in Packaging Made of Stainless Steel after Storage for 2 weeks at 54C, DACO: 3.5.10 CBI
2594333	2015, A21458B Acute Oral Toxicity- Up and Down Procedure in Rats, DACO: 4.6.1
2594334	2015, A21458B Acute Dermal Toxicity in Rats, DACO: 4.6.2
2594335	2015, A21458B Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2594336	2015, A21458B Primary Eye Irritation in Rabbits, DACO: 4.6.4
2594337	2015, A21458B Primary Skin Irritation in Rabbits, DACO: 4.6.5
2594338	2015, A21458B Local Lymph Node Assay in Mice, DACO: 4.6.6
1571553	2007, Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy, DACO: 5.4
2594339	2015, Use description for A21458B Canola, DACO: 5.2
2594433	2015, Value Summary A21458B, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.7.1, 10.7.2

ISSN: 1911-8082

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