

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

Application Number: 2014-3339
Application: New EP Product Chemistry – Guarantee, Identity of Formulants and Proportion of Formulants
Product: Exempla
Registration Number: 32015
Active ingredients (a.i.): Difenoconazole, Azoxystrobin
PMRA Document Number : 2537179

Purpose of Application

The purpose of this application was to register a new fungicide, Exempla, for use on Canola and Crop Subgroup 20A, by ground or aerial application.

Chemistry Assessment

Exempla is formulated as a suspension concentrate containing difenoconazole at 225 g/L and azoxystrobin at 225 g/L. This end-use product has a density of 1.137 g/mL and a pH of 6.9. The chemistry requirements for this product have been fulfilled.

Health Assessments

Exempla is of high acute oral toxicity and low acute dermal and inhalation toxicity. It is non-irritating to the eyes and minimally irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

Use of the new co-formulation of difenoconazole and azoxystrobin in Exempla on Crop Subgroup 20A is within the registered use patterns of these active ingredients. Occupational exposures of mixers, loaders, applicators, post-application re-entry workers, and bystanders are not expected to exceed the current exposures to registered products. No risks of concern are expected when following label instructions and precautions, including wearing the personal protective equipment identified on the label.

No new residue data were submitted in support of the registration of the end-use product Exempla, which contains difenoconazole and azoxystrobin, for use on canola (Crop Subgroup 20A). Data on file support the use of Exempla, which is not expected to increase the magnitude of both difenoconazole and azoxystrobin residues in/on the crops of Crop Subgroup 20A. Therefore, the dietary exposures to difenoconazole and azoxystrobin are not likely to pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Maximum Residue Limits (MRLs)

The following MRL is proposed for azoxystrobin as a result of this submission:

Matrix	Current Canadian MRL	Proposed MRL¹
Rapeseed (Crop Subgroup 20A, Revised)	1.0 [Rapeseeds (canola)]	1.0

¹ The current established MRL of 1.0 ppm for rapeseeds (canola) is extended to Crop Subgroup 20A (Revised).

Environmental Assessment

The maximum rates of the two actives, difenoconazole and azoxystrobin, for Exempla are lower than the maximum registered rates. On this basis, the appropriate spray buffer zones were determined for ground and aerial application.

Value Assessment

Value information was provided in the form of scientific rationales based on precedent products and two experimental trials to support the claims on crop subgroup 20A.

All the disease claims were deemed acceptable with modifications to the crops being supported based on host susceptibility to the pathogens. Aerial application is also supported for crop subgroup 20A.

This product will provide an alternative to growers to control important diseases of canola with a dual active ingredient premix, which is a valuable tool for resistance management.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and supports the registration of Exempla, for use on Canola and Crop Subgroup 20A, by ground or aerial application.

References

PMRA Document Number	References
2449709	2014, Azoxystrobin/Difenoconazole - A20760B - Document H – Product Chemistry Volume, DACO: 0.9, 0.9.1, 3.2.1 CBI
2449714	2014, Azoxystrobin/Difenoconazole - A20760B - Document MIII, Section 1 Product Chemistry Volume, DACO: 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, 3.5.1, 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, 3.5.7, 3.5.9, 3.7 CBI
2449715	2014, Azoxystrobin/Difenoconazole - A20760B - Document J - Product Chemistry Volume, DACO: 3.2.2, 3.2.3, 3.3.1, 3.3.2 CBI
2449716	2014, Azoxystrobin/Difenoconazole - A20760B - Document MIII, Section 1 -

Product Chemistry Volume, DACO: 3.3.2 CBI

2449717 2014, A20760B - Analytical Method SF-700/1 Determination of ASF819, CGA169374 in A20760B, DACO: 3.4.1 CBI

2449718 2014, A20760B - Validation of Analytical Method SF-700/1, DACO: 3.4.1 CBI

2449719 2014, Azoxystrobin/Difenoconazole - A20760B - Document MIII Section 2 Product Chemistry Volume, DACO: 3.4.1 CBI

2449720 2014, Azoxystrobin/Difenoconazole - A20760B - Physico-Chemical Studies of the Formulation - Product Chemistry Volume, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.7 CBI

2449721 2014, Azoxystrobin/Difenoconazole SC - A20760B - DOCUMENT M-III, Section 3, DACO: 4.1

2449722 2014, Azoxystrobin/Difenoconazole SC (A20760B) - Acute Oral Toxicity Up-And-Down Procedure in Rats, DACO: 4.6.1

2449723 2014, Azoxystrobin/Difenoconazole SC (A20760B) - Acute Dermal Toxicity in Rats, DACO: 4.6.2

2449724 2014, Azoxystrobin/Difenoconazole SC (A20760B) Acute Inhalation Toxicity in Rats, DACO: 4.6.3

2449725 2014, Azoxystrobin/Difenoconazole SC (A20760B) - Primary Eye Irritation in Rabbits, DACO: 4.6.4

2449727 2014, Azoxystrobin/Difenoconazole SC (A20760B) - Primary Skin Irritation in Rabbits, DACO: 4.6.5

2449728 2014, Azoxystrobin/Difenoconazole SC (A20760B) Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6

2328624 2013, Note to Reviewer, DACO: 5.2,7.1

2459339 2014, Note to Reviewer, DACO: 5.2

2449732 2013, Value Summary, DACO: 10.1,10.2.3.1,10.3.1,10.3.2

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