

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2017-3616

Application: New End-Use Product Chemistry – New Combination of Technical

Grade Active Ingredients

Product: Vibrance Cinco

Registration Number: 33349

Active ingredients (a.i.): Azoxystrobin, Fludioxonil, Metalaxyl-M and S-

isomer, Sedaxane, Thiabendazole

PMRA Document Number: 2958748

Purpose of Application

The purpose of this application was to register the fungicide, Vibrance Cinco, for use as a seed treatment on corn.

Chemistry Assessment

Vibrance Cinco is formulated as a flowable concentrate for seed treatment containing thiabendazole at 256.2 g/L, azoxystrobin at 12.8 g/L, fludioxonil at 32.0 g/L, metalaxyl-M and Sisomer at 25.5 g/L, and sedaxane at 64.1 g/L. This end-use product has a density of 1.13 g/mL and pH of 6.5–8.5. The required chemistry data for Vibrance Cinco have been provided, reviewed and found to be acceptable.

Health Assessments

Vibrance Cinco is of low acute oral and dermal toxicity. It is of slight acute inhalation toxicity in rats. It is non-irritating to the eye of the rabbit and in the chicken in vitro eye irritation test. It is also non-irritating to the skin of the rabbit and in the in vitro EPISKINTM assay. It is not a skin sensitizer by the local lymph node assay in mice.

The use of Vibrance Cinco on corn seed is not expected to result in risks of concern for seed treaters, planters, and bystanders provided that the product is used according to the approved label directions.

No residue data for azoxystrobin, fludioxonil, metalaxyl-M and S-isomer, sedaxane, and thiabendazole were submitted to support the domestic registration of the end-use product Vibrance Cinco. Previously reviewed residue data from field trials conducted in/on field corn, sweet corn and popcorn were reassessed in the framework of this petition. In addition, previously reviewed processing studies were also reassessed to determine the potential for concentration of residues into processed commodities. Based on this assessment, exposure to residues of azoxystrobin, fludioxonil, metalaxyl-M and S-isomer, sedaxane, and thiabendazole in/on corn and animal commodities treated according to the approved directions for use for Vibrance Cinco will not pose an unacceptable health risk to any segment of the population,



including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Vibrance Cinco falls within the currently registered use pattern for all five active ingredients. No additional risk to the environment is expected from the registration of this end-use product provided that environmental label statements are followed.

Value Assessment

A scientific rationale was provided in support of the claims. The activity of all five fungicide active ingredients pre-mixed in the Vibrance Cinco formulation against listed 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 five fungicide active ingredients. The combination of the five fungicides provides an enhanced *Rhizoctonia* disease control on corn. The registration of Vibrance Cinco will offer Canadian growers another product to manage multiple seed- and soilborne fungal diseases in corn.

Based on the rationale, the registration of Vibrance Cinco is supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support registration of Vibrance Cinco.

References

PMRA Document Number	References
2787769	2017, Confidential information
	Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane A22180A -
	Document J Product Chemistry Volume, DACO:
	3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.2,4.8 CBI
2787770	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane -
	A22180A - Document MIII, Section 1 - Product Chemistry Volume, DACO:
	10.2.1,10.2.2,10.2.3.1,10.2.3.2,10.3.3,10.6,2.2,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.
	3.1,3.3.2,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,
	3.5.7,3.5.8,3.5.9,3.7,5.14,5.2,8.4.1,8.6 CBI
2787771	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane A22180A
	 Document H Product Chemistry Volume, DACO: 3.2.1 CBI
2787772	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane A22180A
	– Document MIII Section 2 - Analytical Methods, DACO: 3.4.1 CBI
2787773	2017, Thiabendazole, Azoxystrobin, Fludioxonil, Metalaxyl-M and Sedaxane FS
	(256.17 /012. 77 /031.98/025.54/064.07) A22180A- SF-915/1- Determination of

	MK360/ICI5504/CGA173506/CGA329351/SYN524464 in A22180A by UHPLC
	Analytical Method, DACO: 3.4.1 CBI
2787774	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane A22180A – Validation of Analytical Method SFA-915/1 Final Report, DACO: 3.4.1 CBI
2787775	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS (256.17 /012. 77 /031.98/025.54/064.07) A22180A- SF-915/1- Determination of CGA329351 and CGA351920 in A22180A by Chiral LC Analytical Method, DACO: 3.4.1 CBI
2787776	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/SedaxaneA22180A – Validation of Analytical Method SF-915/1Final Report, DACO: 3.4.1 CBI
2787777	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane A22180A – 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
2787779	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS
	(A22180A) - Acute Oral Toxicity Study in Rats (Up and Down Procedure) Final
2202200	Report Amendment 1, DACO: 4.6.1
2787780	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS
0707701	(A22180A) - Acute Inhalation Toxicity in Rats Final Report, DACO: 4.6.3
2787781	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS
	(A22180A) - Acute Eye Irritation Study in Rabbits Final Report Amendment 1, DACO: 4.6.4
2787782	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS
	(A22180A) - In Vitro Eye Irritation Test in Isolated Chicken Eyes Final Report, DACO: 4.6.4
2787783	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS
	(A22180A) - Primary Skin Irritation Study in Rabbits Final Report, DACO: 4.6.5
2787784	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS (A22180A) - In Vitro Skin Irritation Test in the EPISKINTM Model Final Report, DACO: 4.6.5
2787785	2017, Thiabendazole/Azoxystrobin/Fludioxonil/Metalaxyl-M/Sedaxane FS
	(A22180A) - Local Lymph Node Assay (LLNA) in Mice Final Report, DACO: 4.6.6
2803259	2017, Rationale to register the new product VIBRANCE CINCO Seed Treatment
	in Canada, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.2,10.2.3.3,
	10.2.3.4,10.3,10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3,10.5.4, 10.6,10.7.1,10.7.2

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