Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 2.3, 3.12 Application

Application Number: 2021-0593
Application: Changes to EP Product Chemistry-Identity of Formulants; Changes to Product Labels-New Site or Host
Product: FORTENZA RED
Registration Number: 30898
Active ingredient (a.i.): Cyantraniliprole
PMRA Document Number : 3337211

Purpose of Application

The purpose of this application was to make updates to the chemistry specifications of the registered end-use product FORTENZA RED, as well as amend its label to add uses against seedcorn maggot in corn (field, pop and sweet); wireworm in cereal grains (barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale, sorghum, and wheat (all types)); and soybean aphids in soybean.

Chemistry Assessment

FORTENZA RED is formulated as a suspension containing cyantraniliprole at a concentration of 600 g/L. This end-use product has a density of 1.255 g/cm^3 and pH of 4.7. The chemistry requirements for this product have been fulfilled.

Health Assessments

A toxicology assessment was not required for this application.

A human health risk assessment was completed for FORTENZA RED for use as commercial (including mobile treaters) and on-farm seed treatments, and planting of treated cereal seeds. No health risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from wheat and barley field trials conducted in Canada were submitted to support the use of FORTENZA RED on cereal grains (crop group 15, except rice). Previously reviewed residue data from field trials conducted in/on corn were reassessed in the framework of this application. In addition, processing studies in treated wheat and barley were reviewed and reassessed in corn to determine the potential for concentration of residues of cyantraniliprole into processed commodities.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for cyantraniliprole was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. The

recommended MRL to cover residues of cyantraniliprole in/on crops and processed commodities are shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodities (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seeds)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Field corn grain	Seed treatment/0.53-0.57 mg a.i//seed	At maturity	<0.01	<0.01	No concentration in processed fractions	0.01	0.01 Cereals (Crop Group 15, except rice)
Popcorn grain	Seed treatment/0.57 mg a.i./seed	At maturity	<0.01	<0.01	No concentration in processed fractions	0.01	
Sweet corn kernels plus cob with husks removed	Seed treatment/0.48-0.55 mg a.i./seed	At maturity	<0.01	<0.01	Not applicable	0.01	
Barley	Seed treatment/28	92-124	<0.01	<0.01	No quantifiable residues observed at exaggerated rates	None	
Wheat	Seed treatment/30	86-141	<0.01	<0.01	No quantifiable residues observed at exaggerated rates	None	

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of cyantraniliprole. Risks from exposure to residues of cyantraniliprole in these crop commodities at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

Environmental Assessment

Use of FORTENZA RED on cereals is within the currently registered use pattern for cyantraniliprole. Risk to the environment is acceptable when the product is used according to the label directions.

Value Assessment

Submitted value information consisted of two trials for seedcorn maggot in corn, five trials for wireworm in wheat and barley, and four trials for soybean aphids on soybean. The value information was sufficient to support the addition to the FORTENZA RED label of claims for suppression of seedcorn maggot in corn (field, sweet and pop) at an application rate of 0.42 µL product/seed (167 mL /100 kg seed); suppression of wireworm at an application rate of 17 mL product per 100 kg seed or control of wireworm at an application rate of 33-50 mL product per 100 kg seed in small cereal grains (barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale, sorghum, and wheat (all types)); and early season reduction of soybean aphids in soybean at an application rate of 83 mL product per 100 kg seed.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the amendments to the label and specifications of FORTENZA RED.

References

PMRA Document Number	Reference
3183156	2020, Occupational Risk Assessment for Fortenza for Seed Treatment Use on Cereals in Canada. DACO: 5.1, 5.2, 5.3, 5.6
3183157	2020, Laboratory dust-off measurements of wheat seed treated with Fortenza, DACO: 5.15
3183160	2020, Cyantraniliprole FS (A17960B) - Magnitude of the Residues in or on Barley Raw Agricultural Commodities from a Seed Treatment Application, Canada 2019, DACO: 7.4.1,7.4.5
3183161	2020, Cyantraniliprole FS (A17960B) - Magnitude and Decline of the Residues in or on Wheat Raw Agricultural Commodities from a Seed Treatment Application, Canada 2019, DACO: 7.4.1,7.4.5
2978158	2019, FORTENZA DACO 10 Efficacy Data and Information, DACO: 10.1
2978160	2017, 10.2.3.3-1 - 2017-SCM-01, DACO: 10.2.3.3
2978161	2018, 10.2.3.3-2 - 2018-SCM-01, DACO: 10.2.3.3
3183149	2020, Value Summary for Fortenza in Cereal for control of wireworms, DACO: 10.1
3183151	2012, A18957L - Seed Care solution development against wireworms in winter cereals - EAME, DACO: 10.2.3.3
3183152	2019, Determine LER of Fortenza (CYNT) for the control of wireworms in Spring Wheat., DACO: 10.2.3.3

3183153	2019, Determine LER of Fortenza (CYNT) for the control of wireworms in Spring Wheat., DACO: 10.2.3.3
3183154	2019, Determine LER of Fortenza (CYNT) for the control of wireworms in Spring Wheat., DACO: 10.2.3.3
3183155	2019, Determine LER of Fortenza (CYNT) for the control of wireworms in Spring Wheat., DACO: 10.2.3.3
3188569	2020, Evaluate Fortenza for Soybean Aphids in Soybeans - Caged Field Studies (Controlled Field Environment), DACO: 10.2.3.3
3188570	2020, Evaluate Fortenza for Soybean Aphids in Soybeans - Caged Field Studies (Controlled Field Environment), DACO: 10.2.3.3
3188576	2019, Seed Treatment - Insecticide - Sales Support - 2019 US, DACO: 10.2.3.3
3188577	2020, Seed Treatment Insecticide - Development Support - 2020 Canada, DACO: 10.2.3.3
3188578	2021, Value Summary for Fortenza in Soybean for control of Soybean Aphid, DACO: 10.1