Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 2.3, 2.4 Application

Application Number: 2019-5988
Application: New End Use Product (Product Chemistry)-Identity of Formulants; Proportion of Formulants
Product: AZteroid FC 3.3
Registration Number: 34742
Active ingredient (a.i.): Azoxystrobin
PMRA Document Number : 3428395

Purpose of Application

The purpose of this application was to register the end-use product AZteroid FC 3.3, containing azoxystrobin, for in-furrow application on potatoes for control or suppression of listed soil-borne diseases.

Chemistry Assessment

AZteroid FC 3.3 is formulated as a suspension concentrate containing azoxystrobin at a concentration of 390 g/L. This end-use product has a density of 1.13-1.15 g/cm^3 and pH of 7.5. The required chemistry data for AZteroid FC 3.3 have been fulfilled.

Health Assessments

AZteroid FC 3.3 is of low acute oral, dermal and inhalation toxicity. It is mildly irritating to the eyes and slightly irritating to the skin. It is not considered to be a dermal sensitizer.

An occupational exposure and risk assessment for AZteroid FC 3.3, and its use on potatoes as an in-furrow treatment was conducted. No risks of concern are expected provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in Canada were submitted to support the use of AZteroid FC 3.3 on potatoes. Azoxystrobin was applied to potatoes at the labelled rate, and harvested according to label directions. Furthermore, previously reviewed residue data from field trials conducted in/on potatoes were reassessed in the framework of this application. In addition, a processing study in treated potato was also reassessed to determine the potential for concentration of residues of azoxystrobin into processed commodities.

Following the review of all available data, residues of azoxystrobin resulting from the in-furrow use on potatoes will be covered under the current maximum residue limit (MRL) of 8.0 ppm for Crop Subgroup 1C (Tuberous and Corm Vegetables), which was established to cover residues of azoxystrobin from a post-harvest use on Crop Subgroup 1C. Dietary risks

Canada

from exposure to residues of azoxystrobin in these potatoes at the registered MRL are acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues of azoxystrobin are considered safe to eat.

Environmental Assessment

The uses and application rates of azoxystrobin in AZteroid FC 3.3 are within those registered. The formulation of AZteroid FC 3.3 has also been reviewed and is not expected to result in increased environmental risks for the uses.

Value Assessment

Six bridging trials conducted on potato demonstrated that AZteroid FC 3.3 can be expected to perform similarly to a precedent product when applied as an in-furrow treatment at seeding for the control of silver scurf and suppression of black scurf and stem and stolon canker. In addition, these trials demonstrated no loss of efficacy when AZteroid FC 3.3 was applied in mixture with liquid fertilizer.

The registration of AZteroid FC 3.3 provides Canadian potato growers an additional fungicide product to manage certain diseases on potato with the option to apply it in mixture with a liquid fertilizer, water or both at seeding.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of AZteroid FC 3.3.

References

A. List of studies/Information submitted by applicant

PMRA Document Number	Reference
3047030	2019, AZteroid FC 3.3 Chemistry Requirements-Part A., 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, 3.4.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.4, 3.5.5
3047031	2018, Product Chemistry Testing and Accelerated Storage Stability / Corrosion Characteristics Testing of Azoxystrobin Formulation VCP-018, DACO: 3.5.1, 3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3047032	2019, Particle Size Determination of Formulated End-Use Product VCP-018 by Dynamic Light Scattering (DLS), DACO: 3.5.16
3220794	2021, AZteroid FC 3.3 Formulation Process and Storage Stability Data, DACO: 3.2.2,3.5.10
3220796	2021, Deficiency Response Summary, DACO: 3.2.2,3.4.1,3.5.10
3047034	2019, AZteroid FC 3.3 - Toxicology Summaries, DACO: 4.1
3047035	2018, 018-000: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3047036	2014, VCP-06-A: Acute Oral Toxicity - Up-And-Down Procedure in Mice, DACO: 4.6.1
3047037	2014, VCP-06-B: Acute Oral Toxicity - Up-And-Down Procedure in Mice, DACO: 4.6.1
3047038	2014, VCP-08: Acute Oral Toxicity - Up-And-Down Procedure in Mice, DACO: 4.6.1
3047039	2014, VCP-08-B: Acute Oral Toxicity - Up-And-Down Procedure in Mice, DACO: 4.6.1
3047040	2014, VCP-06 Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
3047042	2019, Acute Dermal Toxicity and Sensitization Data Waiver Rationale for AZteroid FC 3.3, DACO: 4.6.2,4.6.6
3047043	2018, 018-000: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3047044	2018, 018-000: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3047045	2018, 018-000: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3047046	2014, VCP-06 - Skin Sensitization Study in Guinea Pigs by Buehler Method (3 Induction), DACO: 4.6.6
3047047	2014, A 28-Day Inhalation Toxicity Study of VCP-03 in Sprague Dawler Rats, DACO: 4.7
3379885	2022, Single Dose Comparative Pharmacokinetic Study of Azteroid FC 3.3 and NCL Formulation Through Oral Gavage Administration in Wistar Rats, DACO: 4.5.9
3379886	2022, Acute Oral Toxicity Study Of [CBI removed] In Rats, DACO: 4.6.1
3379888	2022, Acute Eye Irritation Study Of [CBI removed] In Rabbits, DACO: 4.6.4
3379890	2022, Acute Dermal Irritation Study Of [CBI removed] In Rabbits, DACO: 4.6.5
3379892	Bihua Ma; Dan Hu; Meng Zhang; Xingyi Chen; Yu Chen; Liming Ye, 2020, Pharmacokinetic Study of Azoxystrobin and Isopyrazam in Rat by CL-MS/MS and Evaluation of its Toxicity, DACO: 4.8
3379893	2022, Expert Opinion on Pharmacokinetic Data for Azoxystrobin, DACO: 4.8 CBI
3416764	2022, Summary of information regarding the bioavailability and occupational exposure risk of AZteroid FC 3.3 and its formulants, DACO: 3.2.1,4.8,5.14 CBI
3430404	Abdulkadir Osman, Lucas Goehring, Alessandro Patti, Hugh Stitt, and Nima Shokri, 2017, Fundamental Investigation of the Drying of Solid Suspensions, Ind. Eng. Chem. Res. (56): 10506-10513, DACO: 5.14

3047051 2019, Magnitude of the Residue of Azoxystrobin in or on Potato Raw Agricultural Commodities Following In-Furrow Applications of Azoxystrobin (2018), DACO: 7.2.1,7.3,7.4.1
3047054 Melanie Kah, Helene Walch, Thilo Hofmann, 2018, Environmental fate of nanopesticides: durability, sorption and photodegradation of nanoformulated clothianidin, Environ. Sci. Nano. 5(4):803-1046. doi: 10.1039/c8en00038g, DACO: 8.2.3.3,8.2.4.2,8.2.4.6,8.6.2
3047055 2015, VCP-06-A (36-225-41): Ready Biodegradability in a CO_2 Headspace Test, DACO: 8.2.3.6
3047056 2015, VCP-06-B (10-246-108): Ready Biodegradability in a CO_2 Headspace Test, DACO: 8.2.3.6
3047057 2017, Adsorption/Desorption of a Bifenthrin Formulation (Formulation 03-004) in Two Soils, DACO: 8.2.4.2
3047058 2017, Adsorption/Desorption of a Bifenthrin Formulation (Formulation 03-005) in Two Soils, DACO: 8.2.4.2
3379894 2022, Determination Of Rate Of Release Of Azteroid FC 3.3 + NCL Formulation, DACO: 8.2.4.6
3379895 2022, Determination Of Solution Extraction Behaviour Of [CBI removed] Polymers In Water, DACO: 8.2.4.6
3379897 2022, Water Solubility Of Azteroid FC 3.3, DACO: 8.2.4.6
3379898 2022, Azoxystrobin Dissolution Rate Determination of Formulated End-Use Product NCL Formulation by Crossflow Filtration, DACO: 8.2.4.6
3379899 2022, Azoxystrobin Dissolution Rate Determination of Formulated End-Use Product VCP-801 by Crossflow Filtration, DACO: 8.2.4.6
3379900 2022, Azoxystrobin Dissolution Rate Determination of Formulated End-Use Product AZteroid FC 3.3 and NCL Formulation by Crossflow Filtration, DACO: 8.2.4.6
3379901 Karen Duis, Thomas Junker, Anja Coors, 2021, Environmental fate and effects of water-soluble synthetic organic polymers used in cosmetic products, Environ. Sci. Eur. 33(21). https://doi.org/10.1186/s12302-021-00466-2, DACO: 8.6,9.9
3379902 2022, Ready Biodegradability Of [CBI removed], DACO: 8.6.2
3047061 2014, VCP-06-A *Daphnia magna* 48-Hour Acute Toxicity Test, DACO: 9.3.2
3047062 2014, VCP-06-B *Daphnia magna* 48-Hour Acute Toxicity Test, DACO: 9.3.2
3047063 2015, Bifenthrin (Nano-Sized Polymer): A 10-Day Acute Toxicity Test With The Freshwater Amphipod (*Hyalella azteca*) Using Spiked Sediment, DACO: 9.3.4
3047064 2015, Bifenthrin (Conventional-Sized Polymer): A 10-Day Acute Toxicity Test With The Freshwater Amphipod (*Hyalella azteca*) Using Spiked Sediment, DACO: 9.3.4
3379904 2022, Acute Immobilisation Study Of [CBI removed] To *Daphnia magna*, DACO: 9.3.2,9.3.5
3379906 2022, Acute Immobilisation Study Of NCL Polymer To *Daphnia magna*, DACO: 9.3.2,9.3.5
3379908 2022, Alga (*Pseudokirchneriella subcapitata*), Growth Inhibition Test With [CBI removed], DACO: 9.8.2,9.8.6
3379910 2022, Alga (*Pseudokirchneriella subcapitata*), Growth Inhibition Test With NCL Polymer, DACO: 9.8.2,9.8.6
3047009 2019, Summary of Value for AZteroid FC 3.3, containing Azoxystrobin, for Control of Soil-Borne Diseases of Potato, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3(D), 10.3.1, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4

3047011	2018, Fungicidal performance of azoxystrobin in-furrow on potato, DACO: 10.2.3.3(D), 10.3.2(B)
3047012	2016, Fungicidal performance of azoxystrobin in-furrow on potato, DACO: 10.2.3.3(D),10.3.2(B)
3047013	2016, Vive 2016 potato trial VCP-F-2016-F-7, DACO: 10.2.3.3(D),10.3.2(B)
3047014	2019, Vive Rhizoctonia Report, DACO: 10.2.3.3(D),10.3.2(B)
3047016	2016, Vive Crop fertilizer rhizoctonia trial, DACO: 10.2.3.3(D),10.3.2(B)
3047017	2016, Vive Crop fertilizer rhizoctonia trial, DACO: 10.2.3.3(D),10.3.2(B)
3047018	2016, Vive 2016 potato trial VCP-F-2016-F-4, DACO: 10.2.3.3(D),10.3.2(B)
3047019	2016, Vive 2016 potato trial VCP-F-2016-F-5, DACO: 10.2.3.3(D),10.3.2(B)

B. Additional information considered

Published information

PMRA Document Number	Reference
3408570	Yueyang Zhang, Claudia Sheedy, Denise Nilsson, Greg G. Goss, 2020, Evaluation of interactive effects of UV light and nano encapsulation on the toxicity of azoxystrobin on zebrafish, Nanotoxicology. 14(2): 232-249, DACO: 9.5.2,9.5.4