

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number:	2021-4768
Application:	New End-use Product (Product Chemistry) – New Combination of Technical Grade Active Ingredients
Product:	Zeltera Cereals
Registration Number:	34751
Active ingredients (a.i.):	Ethaboxam, Inpyrfluxam, Metalaxyl-M and S-isomer, and Metconazole
PMRA Document Number:	3428572

Purpose of Application

The purpose of this application was to register Zeltera Cereals, an end-use product for use as a seed treatment on barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale, and wheat to protect against labelled seed and seedling diseases.

Chemistry Assessment

Zeltera Cereals is formulated as a suspension containing metconazole at a concentration of 4.6 g/L, metalaxyl at a concentration of 9.2 g/L, inpyrfluxam at a concentration of 3.1 g/L, and ethaboxam at a concentration of 15.4 g/L. This end-use product has a density of 1.03 g/mL and pH of 7.15. The required chemistry data for Zeltera Cereals have been provided, reviewed and found to be acceptable.

Health Assessments

Zeltera Cereals is of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eyes and skin, and it is not a skin sensitizer.

The registration of Zeltera Cereals for use as a seed treatment on listed small grain cereals does not represent an expansion of use for ethaboxam and inpyrfluxam as these active ingredients are registered for use on all listed seed types and for all exposure scenarios. As such, previously conducted risk assessments are adequate to cover the proposed uses. However, for metalaxyl and metconazole, this submission represents an expansion of use since they are not registered for on-farm seed treatment of teosinte seeds. Therefore, updated quantitative risk assessments for on-farm seed treatment of teosinte seeds with metalaxyl and metconazole were conducted. Bystander exposure is expected to be minimal since the product will be used in commercial seed treatment facilities or on-farm settings, and there are negligible chances for drift during seed treatment or planting of treated seeds. No health risks of concern were identified provided that workers wear the appropriate personal protective equipment and follow all label directions.

No new residue data for ethaboxam, metconazole, inpyrfluxam, or metalaxyl in barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale, or wheat were submitted nor required to support the registration of these active ingredients on the Zeltera Cereals label. Previously reviewed residue data for each active ingredient from field trials conducted in/on cereals were reassessed in the framework of this application. In addition, processing studies in treated wheat were reassessed to determine the potential for concentration of residues of these active ingredients into processed commodities.

The anticipated residues in the above-mentioned crops and animal commodities from the labelled use will be covered by the existing maximum residue limits (MRLs) for ethaboxam, metconazole, inpyrfluxam, and metalaxyl and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses on the Zeltera Cereals label are within the currently registered use pattern of ethaboxam, metconazole, inpyrfluxam, and metalaxyl. Therefore, no additional risk is expected when Zeltera Cereals is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

Support for most disease claims was based on the same claims that are registered for one or more of three precedent fungicide products that contain either one or two of the four active ingredients contained in Zeltera Cereals. Support for the remaining disease claims was based on the biological similarity of causal pathogens to those for which claims are registered for at least one of the precedent products. Data from multiple field, greenhouse, and laboratory trials demonstrated that labelled cereal crops can be expected to be tolerant of Zeltera Cereals when applied to seed as directed.

The availability of Zeltera Cereals will serve as an additional option for growers of cereal crops to manage economically important seed and seedling diseases. Zeltera Cereals is also expected to play a role in mitigating the development of resistance of labelled disease pathogens that are susceptible to at least two of the four active ingredients, each of which belongs to a different mode of action group.

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 Zeltera Cereals.

References

PMRA Document Number	Reference
3267201	2021, Physical and Chemical Properties for Zeltera Fungicide Cereals: Applicant Information, Formulator Information, Product Names, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5
3267202	2021, V-10492 FS: Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Description of Formulation Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, Enforcement Analytical Method, Submittal of Samples, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.2
3267203	2021, V-10492 FS: Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Description of Formulation Process, Discussion of Formation of Impurities, Preliminary Analysis, Certified Limits, Enforcement Analytical Method, Submittal of Samples, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.2 CBI
3267204	2021, Physical and Chemical Properties of V-10492 FS, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3267206	2021, Validation of Enforcement Analytical Method for Determination of Inpyrfluxam, Ethaboxam, Metalaxyl, and Metconazole in V-10492 FS Alternate Formulation, DACO: 3.4.1
3340043	2022, Shelf-Life Storage Stability and Corrosion Characteristics of V-10492 FS, DACO: 3.5.10,3.5.14
3267209	2021, V-10492 FS: Acute Oral Toxicity- Up-And-Down Procedure in Rats, DACO: 4.6.1
3267210	2021, V-10492 FS: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3267211	2021, V-10492 FS: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3267212	2021, V-10492 FS: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3267213	2021, V-10492 FS: Primary Skin Irritation in Rabbits, DACO: 4.6.5
3267214	2021, V-10492 FS: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3267215	2021, Summary of Occupational Risk Assessment for Zeltera Fungicide Cereals, DACO: 5.1, 5.2, 5.4, 5.6
3267216	2021, Dust-Off Study in Support of Planting and Treating of Target Crops with Zeltera Fungicide Cereals, DACO: 5.15
2819653	2017, APPENDIX 1: Trial Reports for "Value Summary for S-2399 3.2 FS Fungicide, a Seed Protectant Containing Inpyrfluxam, for Control of Seed and Seedling Diseases of Canola, Cereals, Legumes, Corn, Soybeans and Sugar Beets", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3(D),10.3.1,10.5.1,10.5.2,10.5.3,10.5.4
3267197	2021, Value Summary for Zeltera Fungicide Cereals, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3,10.4,10.5.1,10.5.2,10.5.3,10.5.4

PMRA Document Number	Reference
3321031	2022, Value Deficiency Response for Zeltera Fungicide Cereals (Sub. No. 2021-4768), DACO: 10.3,10.3.2(A)
3321033	2022, APPENDIX 3: Trial Reports for "Value Deficiency Response for Zeltera Fungicide Cereals (Sub. No. 2021-4768)", DACO: 10.3,10.3.2(A)
3323316	2022, Re: Category B Submission – Value Deficiency Response for Zeltera Fungicide Cereals (Sub. No. 2021-4768), DACO: 10.3
3388786	2022, Value Deficiency Response for Zeltera Fungicide Cereals (Sub. No. 2021-4768), DACO: 10.2
3388787	Mishra, K.K., Gahtyari, N.C., and Kant, L., 2022, Common Bunt and Smuts in Wheat and Barley Genetics, Breeding, and Management: Current Status and Future Prospects, In <i>New Horizons in Wheat and Barley Research</i> , 1st ed., 331-357. Springer Singapore, https://doi.org/10.1007/978-981-16-4449-8 , DACO: 10.2
3388788	Nguyen, H.D.T., Sultana, T., Kesanakurti, P., and Hambleton, S., 2019, Genome Sequencing and Comparison of Five <i>Tilletia</i> Species to Identify Candidate Genes for the Detection of Regulated Species Infecting Wheat, <i>IMA Fungus</i> (2019) 10:11, https://doi.org/10.1186/s43008-019-0011-9 , DACO: 10.2
3388789	Pacific Northwest Plant Disease Management Handbook, 2022, Wheat (<i>Triticum aestivum</i>)-Common Bunt (Stinking Smut), https://pnwhandbooks.org/node/3686/print , DACO: 10.2

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