

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2020-2650
Application: Changes to Product Labels - New Pests; New Site or Host
Product: Custodia
Registration Number: 33672
Active ingredients (a.i.): Azoxystrobin, Tebuconazole
PMRA Document Number: 3298356

Purpose of Application

The purpose of this application was to amend the registration of the end-use product Custodia to add the use on soybeans and oats to control various diseases.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of Custodia on oats and soybeans is not expected to result in potential occupational or bystander exposure over the registered use of azoxystrobin or tebuconazole. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for azoxystrobin and tebuconazole were submitted to support the addition of soybeans and oats to the label of Custodia. The two active ingredients are already registered for use on soybeans and oats. The use directions on the label of Custodia, including the formulation type, application methods (ground and aerial), number, rates and timing, are comparable to those on the labels of the precedent end-use products. As such, previously reviewed residue data from field trials conducted separately with azoxystrobin and tebuconazole in/on small grain cereal crops and soybeans were re-assessed in the framework of this application. Based on this assessment, azoxystrobin and tebuconazole residues are not expected to be greater than that for the currently registered uses and will be covered by the respective established maximum residue limits (MRLs). Consequently, dietary exposure to residues of these two active ingredients is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The amendment to the label of Custodia to include the use on soybeans and oats is not expected to increase risk to the environment when used according to label directions.

Value Assessment

Value information in the form of rationales were submitted in support of the use of Custodia on soybeans and oats in which registered single active ingredient products containing tebuconazole or azoxystrobin and co-formulated products of azoxystrobin plus a different active ingredient related to tebuconazole were cited as precedents. Based on these rationales, it was concluded that Custodia applied at 465-630 mL/ha can be expected to control Asian soybean rust and frogeye leaf spot while on oats, the rate of 465 mL/ha can be expected to control crown rust, stem rust and septoria leaf blotch.

The tolerance of soybeans to Custodia was demonstrated in field trials in which Custodia was applied at up to 1260 mL/ha, twice the maximum rate. Oats can be expected to be tolerant to Custodia applied at 465 mL/ha given that Custodia is already registered for use on two other small grain cereal crops, wheat and barley, at up to 630 mL/ha.

The availability of Custodia for use on soybeans and oats will present growers with a new option to manage economically important diseases in both crops while helping to mitigate the risk of resistance development.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the addition of soybeans and oats to the product label of Custodia.

References

| PMRA Document Number | Reference |
|-----------------------------|---|
| 3132558 | 2016, 31375616-SO - Custodia for Disease Control in Soybeans, DACO: 10.2.3.3(D), 10.3.2(B) |
| 3132559 | 2016, SOY 2-SoyADAMA2016HRS, DACO: 10.2.3.3(D),10.3.2(B) |
| 3132560 | 2017, Custodia in Soybeans, DACO: 10.2.3.3(D),10.3.2(B) |
| 3132561 | 2017, Custodia in Soybeans, DACO: 10.2.3.3(D),10.3.2(B) |
| 3132562 | 2017, SOY 5-SoyADAMACustodiaFungicide DH, DACO: 10.2.3.3(D), 10.3.2(B) |
| 3132563 | 2017, Custodia in Soybeans, DACO: 10.2.3.3(D),10.3.2(B) |
| 3132564 | 2018, Custodia in Soybeans, DACO: 10.2.3.3(D),10.3.2(B) |
| 3132565 | 2018, Evaluation of Disease Efficacy and Crop Tolerance of Custodia in Soybeans, DACO: 10.2.3.3(D), 10.3.2(B) |
| 3132566 | 2017, Custodia in Soybeans, DACO: 10.2.3.3(D),10.3.2(B) |
| 3132567 | 2017, Custodia in Soybeans, DACO: 10.2.3.3(D),10.3.2(B) |
| 3197646 | 2021, 2020-2650-Response to Custodia Deficiencies-01feb2021, DACO: 10.2.3.1, 10.4 |
| 3197647 | W. F. Pfender, 2006, Interaction of Fungicide Physical Modes of Action and Plant Phenology in Control of Stem Rust of Perennial Ryegrass Grown for Seed. Plant Dis 90:1225-1232, DACO: 10.2.3.1 |
| 3197648 | D. S. Mueller et al, 2005, Toxicity of Fungicides to Urediniospores of Six Rust Fungi That Occur on Ornamental Crops. Plant Dis 89:255-261, DACO: 10.2.3.1 |
| 3207479 | 2021, 2020-2650 DACO 10.2 Efficacy Rationale, DACO: 10.2, 10.2.1, 10.2.2 |

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.