



Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 Application

Application Number: 2019-2606
Application: New EP Product Chemistry - Guarantee, Identity and Proportion of Formulants
New to Product Labels - Application Rate Increase or Decrease
Product: Tilmor 240 EC Fungicide
Registration Number: 33825
Active ingredients (a.i.): Tebuconazole and Prothioconazole
PMRA Document Number: 3127925

Purpose of Application

The purpose of this application was to register Tilmor 240 EC Fungicide, containing prothioconazole and tebuconazole, for use on wheat (spring, winter and durum), barley and oats based on precedents.

Chemistry Assessment

Tilmor 240 EC Fungicide is formulated as an emulsifiable concentrate containing tebuconazole at a concentration of 160 g/L and prothioconazole at a concentration of 80 g/L. This end-use product has a density of 0.96–1.00 g/mL and pH of 6.1 (1% solution). The required chemistry data for Tilmor 240 EC Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Tilmor 240 EC Fungicide was of low acute toxicity in rats via the oral, dermal, and inhalation routes of exposure. In rabbits, it was severely irritating to the eyes and mildly irritating to the skin. It was a skin sensitizer in mice.

The registration of Tilmor 240 EC Fungicide, containing the registered active ingredients prothioconazole and tebuconazole, was supported from an occupational exposure perspective.

The quantitative mixer/loader/applicator and postapplication worker risk assessments for tebuconazole, as well as the postapplication worker risk assessment for prothioconazole were updated. In addition, the previously conducted quantitative mixer/loader/applicator risk assessment for prothioconazole is adequate to cover the exposure from the use of Tilmor 240 EC Fungicide. As such, no health risks of concern were identified for workers handling or applying Tilmor 240 EC Fungicide provided that the appropriate personal protective equipment is worn and that all label directions are followed.

No new residue data for prothioconazole and tebuconazole in wheat, barley and oats were submitted to support the registration of Tilmor 240 EC Fungicide. The use of prothioconazole and tebuconazole in Tilmor 240 EC Fungicide on wheat, barley and oats fits within the registered use pattern of these active ingredients. Therefore, residue data on file are adequate to support the uses and established MRLs are acceptable to cover the level of residues expected in/on the crops following treatment with Tilmor 240 EC Fungicide. No health risks of concern for acute or chronic dietary exposure (food and drinking water) have been identified for any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of Tilmor 240 EC Fungicide, containing 160 g/L tebuconazole + 80 g/L prothioconazole, to control or suppress various diseases of wheat (spring, winter and durum), barley and oats, does not pose any additional risk to the environment.

No additional data was required for the environmental assessment. Environmental concerns are addressed in the environmental label statements.

Value Assessment

To register Tilmor 240 EC Fungicide for the suppression or control of cereal diseases on wheat, barley and oats, the applicant submitted a rationale to extrapolate claims from a precedent product containing tebuconazole, as well as the results of twenty eight field trials conducted on wheat and barley. Trials demonstrated the performance of Tilmor 240 EC Fungicide or its solo active ingredients against several wheat or barley diseases as well as the reduction of mycotoxin levels and fusarium damaged kernels in wheat. As Tilmor 240 EC Fungicide and the tebuconazole-containing product exerted similar levels of disease control in these trials, the trial results supported the extrapolation of claims to the Tilmor 240 EC Fungicide label.

Cereal diseases reduce yields and may also contaminate grains with a harmful mycotoxin, deoxynivalenol. Tilmor 240 EC Fungicide will provide commercially acceptable levels of cereal disease control to growers of wheat, barley and oats and may help to delay the development of resistance to azole fungicides in pathogen populations.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Tilmor 240 EC Fungicide.

References

PMRA Document Number	References
3003231	2019, Validation of analytical method 2001-0052801-01 - Determination of prothioconazole + tebuconazole, in the formulation prothioconazole + tebuconazole EC 240 (80+160 g/L), DACO: 3.4.1
3003233	2001, Determination of JAU 6476 and tebuconazole in formulations, DACO: 3.4.1
3003234	2007, Physical, chemical and technical properties of prothioconazole + tebuconazole EC 240 (80+160) g/L, DACO: 3.1
3003235	2007, Safety relevant technical properties of prothioconazole + tebuconazole EC 240 (80 + 160) g/L -Final report, DACO: 3.7
3003236	2012, Storage stability at elevated temperature and cold stability of prothioconazole + tebuconazole EC 240 (80+160 g/L) - [Packaging material: COEX/EVOH] - Final report (2 weeks) - PTZ+TBZ EC 240 (80+160) G, DACO: 3.5.10,3.5.14
3003237	2014, Shelf life of prothioconazole + tebuconazole EC 240 (80+160 g/L) - Packaging material: COEX/EVOH - Final report (2 years), DACO: 3.5.10
3003273	2019, Formulation process, DACO: 3.2
3003238	2007, Prothioconazole + tebuconazole EC 240 (80+160) G - Acute toxicity in the rat after oral administration, DACO: 4.6.1
3003239	2007, Prothioconazole + tebuconazole EC 240 (80+160) G - Acute toxicity in the rat after dermal application, DACO: 4.6.2
3003240	2007, Prothioconazole + tebuconazole EC 240 (80+160) G (Project: Prothioconazole (JAU 6476)) - Evaluation of corrosive properties by using an artificial 3D-skin model, DACO: 4.6.5
3003241	2007, Prothioconazole + tebuconazole EC 240 (80+160) G - Acute inhalation toxicity in rats, DACO: 4.6.3
3003242	2007, Prothioconazole + tebuconazole EC 240 (80+160) G - Acute eye irritation on rabbits, DACO: 4.6.4
3003243	2007, Prothioconazole + tebuconazole EC 240 (80+160) G - Acute skin irritation/corrosion on rabbits, DACO: 4.6.5
3003244	2007, Prothioconazole + tebuconazole EC 240 (80+160) G (Project: Prothioconazole (JAU 6476)) - Local lymph node assay in mice (LLNA/IMDS), DACO: 4.6.6
3003264	2019, Value Assessment of Tilmor 240 EC Foliar Fungicide for control of foliar and head diseases of wheat, barley and oats, DACO: 10.1
3031657	2019, Efficacy trials, DACO: 10.2.3
3031658	2019, Crop tolerance, DACO: 10.3.2(B)
3046730	2019, Resistance risk of the DMI fungicides prothioconazole and tebuconazole used in wheat for control of brown rust, head blight and powdery mildew, DACO: 10.5.3

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2021

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.