

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.13 Application

Application Number: 2017-1924
Application: B.2.3: New Identity of Formulants
B.2.4: New Proportion of Formulants
B.3.13: Amended Label Precautions
Product: Aprovia Top
Registration Number: 31526
Active ingredients (a.i.): Benzovindiflupyr + Difenoconazole
PMRA Document Number : 2929034

Purpose of Application

The purpose of this application was to register an alternate formulation for Aprovia Top and update precautionary label statements.

Chemistry Assessment

Aprovia Top is formulated as an emulsifiable concentrate containing benzovindiflupyr at 78 g/L nominal and difenoconazole at 117 g/L nominal. This end-use product has a density of 1.066 g/mL and a pH of 5.5. The required chemistry data for Aprovia Top have been provided, reviewed and found to be acceptable.

Health Assessments

Aprovia Top is of moderate acute oral and low acute dermal and inhalation toxicity. It is severely irritating to the eye and non-irritating to the skin of the rabbit. It is a skin sensitizer in the mouse by the LLNA method.

The alternate formulation of Aprovia Top with the same use pattern as currently the registered product is not expected to increase the potential occupational/residential exposure to difenoconazole or benzovindiflupyr. No health risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

No new dietary residue data for benzovindiflupyr or difenoconazole were submitted, or are required to support registration of an alternate formulation of Aprovia Top. Given that the registered and alternate formulation of Aprovia Top are both emulsifiable concentrates, and that the use directions for Aprovia Top remain unchanged, exposures to residues of benzovindiflupyr and difenoconazole in the diet should not increase and will not pose an unacceptable health risk of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

There are no unacceptable environmental risks expected associated with the

alternate formulation. The label includes the required environmental precautions and hazards statements, including the buffer zones information, which adequately mitigates risks to the environment.

Value Assessment

As the guarantee of the active ingredient for the alternate formulation remains the same, the alternate formulation changes are not expected to impact the performance of Aprovia Top Fungicide. The alternate formation is supported from a value perspective.

Conclusion

The PMRA has reviewed the information provided to support the alternate formulation of Aprovia Top. Based on the results of this review, the alternate formulation of Aprovia Top is acceptable.

References

2753140 2017, Efficacy Rationale APROVIA TOP, DACO: 10.1

2753127	2016, Difenoconazole /Benzovindiflupyr EC (A19334D) - Acute Oral Toxicity Study in Rats (Up and Down Procedure)DACO: 4.6.1
2753128	2016, Difenoconazole/Benzovindiflupyr EC (A19334D) - Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2753129	2016, Difenoconazole/Benzovindiflupyr EC (A19334D) - Acute (Four-Hour) Inhalation Study in Rats, DACO: 4.6.3
2753130	2016, Difenoconazole/Benzovindiflupyr EC (A19334D) - Acute Eye Irritation Study in Rabbits, DACO: 4.6.4
2753137	2016, Difenoconazole/Benzovindiflupyr EC (A19334D) - Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2757539	2016, Difenoconazole / Benzovindiflupyr EC (A19334D) - Local Lymph Node Assay in the Mouse, DACO: 4.6.6

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2018

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.