

Evaluation Report for Category B, Subcategory 3.4, 3.13 Application

Application Number: 2016-3377
Application: Changes to Product Label – Precautions and Application Method
Product: Concise
Registration Number: 32342
Active ingredient (a.i.): Uniconazole-P
PMRA Document Number: 2778766

Purpose of Application

The purpose of this application was to amend the end-use product, Concise, by removing the precautionary statements from the label and to increase the maximum container size for the product.

Chemistry and Value Assessments

Chemistry and value assessments were not required for this application.

Health Assessments

The precautions and restrictions of Concise were reassessed, taking into account the new toxicology data. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label. The change in container size from 4L to 10L is not expected to increase occupational exposure.

Concise was of low acute toxicity in rats via the oral and dermal routes. It was non-irritating to the skin and eyes of rabbits. It was not a dermal sensitizer in the mouse.

A dietary exposure assessment was not required for this application.

Environmental Assessment

An environmental assessment was conducted and the changes to this product do not pose an increased risk to the environment. Environmental concerns are mitigated through environmental precautionary statements on the label. No additional environmental data were required.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the amendment of Concise.

References

| PMRA Document Number | References |
|-----------------------------|--|
| 2656820 | 2005, Uniconazole-P SL Formulation: Acute Oral Toxicity Study in the Female Rat (Acute Toxic Class), DACO: 4.2.1 |
| 2656821 | 2005, Uniconazole-P SL Formulation: Acute Dermal Toxicity Study in the Rat, DACO: 4.2.2 |
| 2656823 | 2005, Uniconazole-P SL Formulation: Eye Irritation Study in the Rabbit, 4.2.4 |
| 2656824 | 2005, Uniconazole-P SL Formulation: Dermal Irritation Study in the Rabbit, DACO: 4.2.5 |
| 2656822 | 2005, Uniconazole-P SL Formulation: Local Lymph Node Assay in the Mouse (Individual Method), DACO: 4.2.6 |

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2017

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.