

Evaluation Report for Category B, Subcategory 2.4 Application

Application Number: 2007-8367

Application: B.2.4 (Changes to Product Chemistry-Proportion of Formulants)

Product: Proxel GXL Microbiostat Solution

Registration Number: 14683

Active ingredients (a.i.): 1,2-benzisothiazolin-3-one

PMRA Document Number: 1624693

Purpose of Application

The purpose of this application is to amend the percentage w/w of the technical grade active ingredient (TGAI), 1,2-benzoisothiazolin-3-one in the end-use product, Proxel GXL Microbiostat Solution to reflect the changes in the TGAI. The guarantee of TGAI in the amended formulation will remain the same at 19.3% for the end-use product.

Chemistry Assessment

Proxel GXL Microbiostat Solution is formulated as a solution containing 1,2-benzisothiazolin-3-one at a nominal concentration of 19.3%. This end-use product has a density of 1.13 g/cm³ and pH of 12. The chemistry requirements for Proxel GXL Microbiostat Solution are complete.

Health Assessments

A toxicology assessment was not required as there are no significant changes to the end-use product formulation.

Environmental Assessment

An environmental assessment was not required for Proxel GXL Microbiostat Solution as the application did not involve any change to the uses or use pattern.

Value Assessment

A value assessment was not required for Proxel GXL Microbiostat Solution as the application did not involve any change to the uses or use pattern.



Conclusion

The PMRA has completed an assessment of the application and has found the information sufficient to support the changes in the product chemistry of the technical active (Application No. 2007-8027) which are also reflected in end-use product, Proxel GXL Microbiostat Solution.

References

None

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2008

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.