

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5 and 3.1 Application

Application Number:	2005-0616
Application:	Category B, subcategory 2.1 (Guarantee), 2.3 (Identity of
	formulants), 2.4 (Proportion of formulants), 2.5 (Formulation
	type), 3.1 (Application rate increase)
Product:	Dantoguard Plus Liquid
Registration Number:	28822
Active ingredients (a.i.):	1,3-Bis(hydroxymethyl)-5,5-dimethyldantoin (DMY)
	1-(hydroxymethyl)-5,5-dimethyldantoin (MMY)
	3-Iodo-2-propynyl butyl carbamate (IPB)
PMRA Document Number: 1514251	

Background

The current application proposed the registration of Dantoguard Plus Liquid which is a combination of three active ingredients. The active ingredients were first registered in 1998 (1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin (DMY)), in 1990 (3-iodo-2-propynyl N-butylcarbamate (IPB)) and in 1998 (1-(hydroxymethyl)-5,5-dimethylhydantoin (MMY)). A comparable currently registered product, Dantogard Plus Preservative (Reg. No. 25757) contains the same combination of active ingredients as is proposed in this submission.

Purpose of Application

The purpose of this submission was to register a new commercial material preservative, Dantoguard Plus Liquid. This product is intended to prevent bacterial and fungal spoiling of various detergents and fabric softeners. For specific details of uses, application rates and methods, precautions, restrictions and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Dantogard Plus Liquid is a solution containing the active ingredients: 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin, 1-(hydroxymethyl)-5,5-dimethylhydantoin and 3-iodo-2-propynyl N-butylcarbamate at nominal concentrations of 26.9%, 25.5%, and 2.5%, respectively. This product has a specific gravity of 1.2 and pH of 7.1. The chemistry requirements for Dantogard Plus Liquid are complete.



Health Assessments

Dantoguard Plus Liquid is of low acute toxicity via the oral route to rats and the dermal route to rabbits and is of slight acute toxicity to rats via the inhalation route of exposure. It is mildly irritating to the eyes and skin of rabbits and is not considered to be a dermal sensitizer in guinea pigs.

A health assessment has been conducted for Dantogard Plus Liquid Preservative. An increased risk is not expected from the proposed use compared to the use of registered products containing DMY, MMY and IPB active ingredients.

Environmental Assessment

A comparable currently registered product, Dantogard Plus Preservative (Reg. No. 25757) is used for the same purposes and contains these same actives in different proportions. Use of the proposed new product instead of the currently registered product at the respective label rates will not significantly increase the amount of iodocarb released to the environment and will result in only an 18% increase in the release of the total amount of the dimethylhydantoins, which are structurally very similar and have similar toxic activity. The environmental risk from the use of these actives in material preservatives is expected to be minimal as all three active ingredients are readily transformed to less toxic, non-persistent compounds once diluted and introduced into an aquatic environment.

Value Assessment

The applicant submitted data which demonstrated that Dantogard Plus Liquid is an effective material preservative for various detergents and fabric softeners. The efficacy data package supports rates ranging from 200 to 2,500 ppm. Doses above 2,500 ppm did not demonstrate improved efficacy.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of available information for Dantoguard Plus Liquid and has found the information sufficient to allow for conditional registration, with registration being contingent upon fulfilling the following requirements:

1. Provide outstanding efficacy data.

References

- 1033428 Product Identification; Includes MSDS, DACO: 3.1
- 1033429 Description of Beginning Materials;, DACO: 3.2.1
- 1033430 Manufacturing process;, DACO: 3.2.2
- 1033431 Discussion of Potential Impurity Formation;, DACO: 3.2.3
- 1033432 Certification of Ingredient Levels;, DACO: 3.3.1
- 1033433 Analytical Method to Verifiy Certified Limits;, DACO: 3.4.1
- 1033434 Chemical and Physical Properties;, DACO: 3.5
- 1033435 1999, Liquid Dantogard Plus-One Year Storage Stability and Corrosion Characteristics, 38 pages,, SP-98032-A, DACO: 3.5.10
- 1104501 2004, Dantoserve. One Year Storage Stability and Corrosion Characteristics., Study No: SP-01057-A, DACO: 3.5.10
- 1104508 Establishing Certified Limits, DACO: 3.3.1
- 1104510 Discussion of the Formation of Impurities of Toxicological Concern., DACO: 3.2.3
- 1104515 Impurities of Toxicological Concern, DACO: 3.4.2
- 1033447 Efficacy Parity between Dantogard Plus Liquid and Dantogard Plus Solid in HI & I Formulations (2000), Lonza Inc, RR-00-08, DACO: 10.1
- 1259893 A Car Wash Formulation (2005), Lonza Research & Development, DACO: 10.2.3.2
- 1259894 A Floor Cleaner Product (2005), Lonza Research & Development, DACO: 10.2.3.2
- 1259901 Colgate-Palmolive, Glycoserve LAD, Dantoserve and Dantoserve Plus Liquid in Colgate-Palmolives Murphys Oil Formulation (2003), Performance Chemicals Technical Services Lonza Inc., DACO: 10.2.3.2
- 1259902 Unilever Home and Personal Care, Dantogard Plus Liquid in 6 Unilever Fabric Sofener Snuggle Variants (2002), Performance Chemicals Technical Services Lonza Inc., DACO: 10.2.3.2

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2006

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.