

Evaluation Report for Category B Subcategory 2.1, 2.3, 2.4, 3.1, 3.12 Application

Application Number: 2008-4125
Application: New product chemistry: guarantee, identity of formulants, proportion of formulants; New product label: application rate increase, new site or host
Product: Nuosept W Concentrate
Registration Number: 29949
Active ingredients (a.i.): Bronopol, 2-methyl-4-isothiazolin-3-one, and 5-chloro-2-methyl-4-isothiazolin-3-one
PMRA Document Number: 1991047

Purpose of Application

The purpose of this application was to register a new commercial liquid in-can preservative to be added to paints, coatings and pigment slurries.

Chemistry Assessment

Nuosept W Concentrate is formulated as a solution containing 5-chloro-2-methyl-4-isothiazolin-3-one at a nominal concentration of 1.50% and 2-methyl-4-isothiazolin-3-one at a nominal concentration of 0.50%. This end-use product has a density between 1.1084 and 1.1182 g/cm³ and a pH between 3-5. The chemistry requirements for Nuosept W Concentrate are complete.

Health Assessments

Nuosept W Concentrate is considered to be of moderate toxicity via the oral route, low toxicity via the dermal route, slightly irritating to the skin and a potential skin sensitizer. A risk assessment was not performed as the proposed use pattern fits within the existing use profile for the three active ingredients. The potential exposure to mixers, loaders, applicator and post-applicators is not expected to exceed that of other registered uses of the three active ingredients.

Environmental Assessment

An environmental assessment was not required.

Value Assessment

Laboratory studies were conducted to evaluate the ability of Nuosept W Concentrate to protect in-can paints, coatings and pigment slurries against bacteria and fungi. The studies were conducted in paint and slurries containers to simulate in-can conditions. The data demonstrated that Nuosept W Concentrate is effective against bacteria and fungi growth under representative use conditions.

Conclusion

The PMRA conducted an evaluation of the subject application and determined there was sufficient information to support full registration of Nuosept W.

References

PMRA Document Number: 1651189

Reference: 2008, Efficacy discussion for Nuosept W in paints and similar matrices (adhesives, caulks, grouts, pigment slurries, etc.), Data Numbering Code: 10.2, 10.2.3.2

PMRA Document Number: 1651240

Reference: 2008, Nuosept W Concentrate product chemistry, Data Numbering Code: 3.0 Confidential Business Information

PMRA Document Number: 1651241

Reference: Nuosept W Concentrate starting materials, Data Numbering Code: 3.2.1 Confidential Business Information

PMRA Document Number: 1651242

Reference: Nuosept W Concentrate analytical method, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1651243

Reference: Nuosept W Concentrate physical-chemical properties, Data Numbering Code: 3.5 Confidential Business Information

PMRA Document Number: 1651244

Reference: 2007, Nuosept W conc: acute oral toxicity study in the rat (up and down procedure), Data Numbering Code: 4.6.1

PMRA Document Number: 1651247

Reference: 2007, Nuosept W conc: acute dermal toxicity study in rats, Data Numbering Code: 4.6.2

PMRA Document Number: 1651248

Reference: 2008, Nuosept W conc: 4-hour acute inhalation toxicity study in rats, Data Numbering Code: 4.6.3

PMRA Document Number: 1651249

Reference: 2007, Nuosept W conc: primary skin irritation study in rabbits (4-hour semi-occlusive application), Data Numbering Code: 4.6.5

PMRA Document Number: 1651252

Reference: 2007, Nuosept W conc: local lymph node assay (LLNA) in mice (identification of contact allergens), Data Numbering Code: 4.6.6

PMRA Document Number: 1844207

Reference: 2009, Analysis of BN, MIT & CIT in: Nuosept W, Nuosept W Conc & CF-FI-17 intermediates by gradient RP-C8-HPLC-UV-ESTD, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1844210

Reference: 2009, Rationale for waiver of dielectric voltage breakdown test, Data Numbering Code: 3.5.15
Confidential Business Information

PMRA Document Number: 1868549

Reference: 2010, Validation of a modified analytical method for the determination of the active ingredients in the formulation of Nuosept W conc, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1868550

Reference: 2010, Storage stability and corrosion characteristics of Nuosept W conc, Data Numbering Code: 3.5.10, 3.5.14 Confidential Business Information

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2011

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.