

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

Application Number: 2009-5406
Application: New end-use product; guarantee, identify and proportion of formulants
Product: Fennosan H-12
Registration Number: 30317
Active ingredients (a.i.): Sodium hypochlorite
PMRA Document Number : 2104680

Purpose of Application

The purpose of this application was to register a new sodium hypochlorite-based end-use product, Fennosan H-12 containing 10.3% sodium hypochlorite, for use in paper and paper process water systems to control bacteria, algae and fungi. Fennosan H-12 is a repack of an existing registered manufacturing product, Lavo 12% Trade (Registration number 26684). This application is linked to a second related application (2009-5408) to register a new adjuvant product, Fennosurf 300, to be used in conjunction with Fennosan H-12.

Chemistry Assessment

Fennosan H-12 is formulated as a solution containing sodium hypochlorite with a nominal concentration of 10.3% w/w available chlorine present as sodium hypochlorite when packed. This end-use product has a density of 1.18 g/mL and a pH of 12.0-13.0. The chemistry requirements for Fennosan H-12 are complete.

Health Assessments

No acute toxicity studies were required for the product Fennosan H-12 as it is a repack of an existing product.

A qualitative health assessment has been conducted for Fennosan H-12, containing 10.3% sodium hypochlorite. The use pattern of sodium hypochlorite, within Fennosan H-12, is within the current registered use patterns for the active ingredient. Therefore, exposure to sodium hypochlorite and the by-product, free available chlorine, is not expected to increase over the exposure from the currently registered products.

Environmental Assessment

No environmental concerns were identified for the proposed use of Fennosan H-12.

Value Assessment

Laboratory and field studies were conducted to evaluate the ability of the blend of Fennosan H-12 and its adjuvant Fennosurf 300 to reduce bacterial activity in pulp and paper waters. The laboratory studies were conducted using microbial samples taken in various contaminated white waters to obtain representative challenge organisms. Aliquots of these contaminated samples were challenged with various concentrations/ratios of the biocide and the adjuvant and incubated at temperatures representative of the conditions that can be found in pulp and paper applications. The field studies were conducted in paper and board machines and the results were monitored throughout time. Scientific publications were provided as supplemental information to support the proposed uses and label claims. The data demonstrated that mixing Fennosan H-12 and Fennosurf 300 is a more effective method when compared to using sodium hypochlorite alone to reduce bacterial and fungal growth in pulp and paper processes.

Conclusion

The PMRA has completed an assessment of available information for Fennosan H-12 and has found the information sufficient to grant a full registration of Fennosan H-12 when used in conjunction with the adjuvant Fennosurf 300.

References

PMRA Document Number	Reference
1841029	2009, Product Identification, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
1841030	2009, Formulation process, DACO: 3.2, 3.2.1, 3.2.2, 3.2.3 CBI
1841031	2009, Chemical and Physical Properties, DACO: 3.5, 3.5.1, 3.5.11, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.9 CBI
1841033	2000, Sodium Hypochlorite - MSDS, DACO: 3.5.12, 3.5.8, 9.3.1, 9.5.1, 9.8.1
1841035	2009, Graphic stability Sod Hypo Decomposition at 20C, DACO: 3.5.10 CBI
1841036	1997, Sodium hypochlorite, DACO: 3.5.14
1841037	2007, Chlorine in Drinking Water, DACO: 3.4.1, 3.7, 4.6.1, 4.6.2, 4.6.3, 4.6.5, 4.6.8, 8.1, 8.2.3.1
1358564	Establishing Certified Limits, DACO: 2.12.1, 3.3.1, 3.4.1 CBI
1543639	Establishing Certified Limits, DACO: 2.12.1, 3.3.1, 3.4.1 CBI
1841496	2009, Description of Starting materials, DACO: 3.2.1 CBI
1841045	2009, Value Summaries/Pest problem/Mode of action, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.2.3.4(A), 10.3.1, 10.3.2, 10.5.1
1972093	2008, Emin Leydier NogentsurSeine Microbio Lab Data Files, DACO : 10.2.3.2

1972095	2008, Cascades PKF Lab Study Data Files Toxican eau blanche, DACO: 10.2.3.2
1972097	2008, Cascades PKF Lab Study Data Files Toxican eau frache, DACO: 10.2.3.2
1972098	2008, Cascades PKF Lab Study Data Files Toxican Amidon, DACO: 10.2.3.2
1972103	2009, Fennosurf 300 / Fennosan H-12 Lab Studies Report Cascade, DACO: 10.2.3.2
1972104	2009, Finnish Board Mill Fennosurf 300 Study Edited Data Files, DACO: 10.2.3.2
1972105	2009, Slime Control with Hypochlorite plus Fennosurf 300 in a Board Machine, Finnish Folding-Box Board Machine (2005-2009), DACO: 10.2.3.3
1972111	2010, Minimizing Corrosion Concerns with Oxidizing Biocides by a Targeted Biofilm Control Approach Author: Ken Keegan, Mark Nelson, Juhana Ahola and Marko Kolari, DACO: 10.2.3.4
1972112	2010, US Alkaline Fine Paper Mill, DACO: 10.2.3.4
1972113	2010, Alkaline Fine Paper Mill Fennosurf 150 Trial Data File Plate Counts Graphs, DACO: 10.2.3.4

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2012

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.