

Evaluation Report for Category B, Subcategory B.2.1, B.2.4 and C.8.1 Application

Application Number: 2003-2202
Application: B.2.1 New EP Product Chemistry - Guarantee
B.2.4 New EP Product Chemistry - Proportion of Formulants
Product: Lonza Formulation DC-103F
Registration Number: not assigned yet
Active ingredients (a.i.): Octyl decyl dimethyl ammonium chloride (QDF)
Dioctyl dimethyl ammonium chloride (QDE)
Didecyl dimethyl ammonium chloride (QAK)
Alkyl (40% C₁₂, 50% C₁₄, 10% C₁₆) dimethyl benzyl ammonium chloride (QAC)
PMRA Document Number: 1654654

Background and Purpose of Application

The purpose of this submission is to register a new formulation of sanitizer for indoor hard surfaces and structural uses.

Lonza Formulation DC-103F is a dilution of a formulation of products which had been previously reviewed and accepted for registration under the Pest Control Products Act, Lonza Formulation R-82-54 Disinfectant Cleaner (PCP # 19274) and Lonza Formulation R-8F Disinfectant Cleaner (PCP # 23270). These two products are currently registered in Canada under the Therapeutic Products Directorate due to disinfectant claims.

Lonza Formulation DC-103F is proposed for use as a sanitizer for hard non-porous surfaces and is not proposing disinfectant claims. Lonza Formulation DC-103F contains the active ingredients Alkyl (40% C₁₂, 50% C₁₄, 10% C₁₆) dimethyl benzyl ammonium chloride (QAC), Didecyl dimethyl ammonium chloride (QAK), Dioctyl dimethyl ammonium chloride (QDE), Octyl decyl dimethyl ammonium chloride (QDF). This mixture of active ingredients is currently registered in Canada for Indoor Hard Surfaces and Structural uses in several other end-use products (i.e. Kay Liquid Sanitizer, Reg. No. 25054; Kay Surface Sanitizer, Reg. No. 25703, Econo-cide B1002, Reg. No. 26362).

Chemistry Assessment

Lonza Formulation DC-103F, is a solution containing the quaternary ammonium chlorides, octyldecyl ammonium chloride, dioctyl dimethyl ammonium chloride, didecyl dimethyl ammonium chloride and alkyl (40% C₁₂, 50% C₁₄, 11% C₁₆) dimethyl benzyl ammonium chloride at 0.0060, 0.0024, 0.0036 and 0.0080% respectively. This end-use product has a specific gravity of 1.0 and pH between 9.5 to 11.0. The chemistry requirements for Lonza Formulation DC-103F are complete.

Health Assessments

Lonza Formulation DC-103F is of low toxicity to rats via the oral (LD₅₀ > 5000 mg/kg), dermal (LD₅₀ > 2000 mg/kg), and inhalation routes. It is mildly irritating to the eye of rabbits. It is not a dermal sensitizer in guinea pigs and it is not irritating to the skin of rabbits.

Based on the very low concentrations of the active ingredients (QAC, QDF, QDE and QAK) in the end-use product (Lonza Formulation DC-103F) and the use pattern which involves air drying of all treated equipment and utensils, it is expected that transfer of residues to food in contact with treated surfaces or direct exposure via use of treated utensils is expected to be negligible.

The proposed uses for Lonza Formulation DC-103F are not expected to result in an increase in exposure to workers handling or re-entering treated areas over the currently registered products containing the four active ingredients QAC, QAK, QDE and QDF.

Environmental Assessment

As stated above, Lonza Formulation DC-103F contains the same active ingredients as other products that are currently registered in Canada for similar uses. Use of Lonza Formulation DC-103F for cleaning, sanitizing and malodour control on indoor hard non-porous surface uses does not result in an unacceptable risk to the environment.

Value Assessment

Eleven laboratory studies, adapted from standard protocols for sanitizers and disinfectants, were submitted as part of the efficacy data package. The provided data shows that Lonza Formulation DC-103F meets the performance standard for a sanitizer, when used on indoor hard non-porous surfaces. In addition, a Letter of No Objection was submitted from the Food Directorate of Health Canada, in support of the use of Lonza Formulation DC-103F on equipment, food contact surfaces and utensils in food plants provided that 1) the food contact surfaces are previously cleaned and rinsed with potable water prior to sanitizing; 2) the use concentration of the product does not exceed 200 ppm; 3) the surfaces are hard, non-porous in nature and thoroughly drained prior to re-use. Therefore, from a value stand point, the use of Lonza Formulation DC-103F, as a sanitizer, on hard non-porous food contact and non-food contact surfaces is acceptable.

Conclusion

The PMRA has completed an assessment of available information for Lonza Formulation DC-103F and has found the information sufficient to support full registration of this product.

References

Chemistry

PMRA Document Number	Reference
794165	2000. Product Identification Product Chemistry For Lonza Formulation DC-103F Lewis & Harrison; DC-103F.RTU/PC001 Volume 1 of 2 Non GLP, Unpublished, DACO: 3.1,3.2 CBI
794173	2000. Product Identification Product Chemistry For Lonza Formulation DC-103F Lewis & Harrison; DC-103F.RTU/PC001, DACO: 3.3.1,3.4.1 CBI
794174	2000. Lonza Formulation DC-103F - Chemical and Physical Characteristics, SP-00075-A, DACO: 3.5 CBI
794175	2001 Lonza Formulation DC-103F - Accelerated Storage Stability and Corrosion Characteristics, SP-00076-A, DACO: 3.5.10 CBI
919905	2003. Lonza Formulation DC-103F - One Year Storage Stability and Corrosion Characteristics, SP-00077-A, DACO: 3.5.10 CBI

Toxicology

PMRA Document Number	Reference
794166	1992. Primary Eye Irritation Study in Rats with DC-103. DACO 4.4.4
794167	1992. Primary Skin Irritation Study in Rabbits. DACO 4.6.5
794168	2003. Dermal Sensitization - Waiver Request. DACO 4.6.6
794169	2000. Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Bardac 208M. DACO 4.6.6
794176	Summary of Acute Toxicity Data for Lonza Formulation DC-103. DACO 4.1
794177	1992. Acute Oral Toxicity Study in Rats - Limit Test. DACO 4.6.1
794178	1992. Acute Dermal Toxicity Study in Rats - Limit Test. DACO 4.6.2
794179	2003. Acute Inhalation Request for Waiver Lewis & Harrison. DACO 4.6.3

Value

PMRA Document Number	Reference
794172	2003. Efficacy Summary, Mode of Action; Description of Pest Problem Dell Tech Laboratories Ltd. Non GLP, Unpublished, DACO: 10.1, 10.2, 10.2.3.1
794180	2003. DC103F Use-Dilution Testing - Pseudomonas aeruginosa, Lonza Inc., SP-02148-M, GLP, Unpublished, DACO: 10.2.3.2
794181	2003. DC103F Use-Dilution Testing - Staphylococcus aureus, Lonza Inc., SP-02150-M, GLP, Unpublished, DACO: 10.2.3.2
794182	2003. DC103F Use-Dilution Testing - Salmonella choleraesuis, Lonza Inc., SP-02149-M, GLP, Unpublished, DACO: 10.2.3.2
794183	2003. Germicidal and Detergent Sanitizing Action of Disinfectants - Listeria monocytogenes AppTec ATS; A01083 GLP, Unpublished, DACO: 10.2.3.2
794184	2002. AOAC Germicidal And Detergent Sanitizing Action of Disinfectants - Vibrio cholerae Hill Top Research Inc.; 02-120777-106 GLP, Unpublished, DACO: 10.2.3.2
794185	2001. Germicidal and Detergent Sanitizing Action of Disinfectants - Campylobacter jejuni Micro-BioTest Inc.; 163-140 GLP, Unpublished, DACO: 10.2.3.2
794186	2001. R-82F Food Contact Efficacy Testing - E.Coli Lonza Inc.; SP-01108-M GLP; Unpublished, DACO: 10.2.3.2
794187	2002. R-82F Food Contact Efficacy Testing - Yersinia enterocolitica Lonza Inc.; SP-02012-M GLP; Unpublished, DACO: 10.2.3.2
794188	2002. R-82 Food Contact Efficacy Testing - Shigella sonneii Lonza Inc.; SP-02062-M GLP; Unpublished, DACO: 10.2.3.2
794189	1980. Microbiological Test Report - Lonza Formulation R-82-54, Lonza Disinfectant Cleaner; Staphylococcus Aureus, Klebsiella penumoniae; Lonza Inc.; MB-723-80, GLP, Unpublished, DACO: 10.2.3.2
794190	2003. Adverse Effects; Non Safety Adverse Effects Dell Tech Laboratories Ltd. Non GLP; Unpublished, DACO: 10.3.1, 10.3.2

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2009

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.