



# Regulatory Decision Document

RDD2002-04

## **p-Menthane-3,8-diol**

The active ingredient, p-menthane-3,8-diol, and the associated end-use product, OFF! Botanicals Lotion Insect Repellent 1, containing p-menthane-3,8-diol, for use as a personal insect repellent against mosquitoes and black flies, are eligible for full registration under Section 13 of the Pest Control Products (PCP) Regulations.

These products were proposed for registration in Proposed Regulatory Decision Document [PRDD2002-02 p-Menthane-3,8-diol](#). This Regulatory Decision Document outlines this stage of the Pest Management Regulatory Agency's regulatory decision-making process concerning the use of active ingredient, p-menthane-3,8-diol, and the associated end-use product, OFF! Botanicals Lotion Insect Repellent 1, containing p-menthane-3,8-diol, for use as a personal insect repellent against mosquitoes and black flies.

*(publié aussi en français)*

**November 29, 2002**

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

**Publications Coordinator  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6605C  
Ottawa, Ontario  
K1A 0K9**

**Internet:** [pmra\\_publications@hc-sc.gc.ca](mailto:pmra_publications@hc-sc.gc.ca)  
[www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)

**Information Service:  
1-800-267-6315 or (613) 736-3799  
Facsimile: (613) 736-3798**



ISBN: 0-662-33189-3

Catalogue number: H113-6/2002-4E-IN

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2002**

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.

## **1.0 Introduction**

This Regulatory Decision Document outlines the Pest Management Regulatory Agency's (PMRA) regulatory decision-making process concerning the use of active ingredient, p-menthane-3,8-diol, and the associated end-use product, OFF! Botanicals Lotion Insect Repellent 1, containing p-menthane-3,8-diol, for use as a personal insect repellent against mosquitoes and black flies.

## **2.0 Background**

The PMRA carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations. The assessment found that there was sufficient information, pursuant to Section 18(*b*), to allow a determination of the safety, merit and value of p-menthane-3,8-diol, and the associated end-use product, OFF! Botanicals Lotion Insect Repellent 1, containing p-menthane-3,8-diol, developed by S. C. Johnson Canada Inc. The PMRA concluded that the use of OFF! Botanicals Lotion Insect Repellent 1 in accordance with the label accompanying the product has merit and value consistent with Section 18(*c*) of the PCP Regulations and does not entail an unacceptable risk of harm under Section 18(*d*).

These products were proposed for registration in Proposed Regulatory Decision Document [PRDD2002-02](#). One comment was received by the PMRA concerning [PRDD2002-02](#) and is addressed in Appendix I.

## **3.0 Regulatory decision**

Based on the considerations outlined above, p-menthane-3,8-diol, and the associated end-use product, OFF! Botanicals Lotion Insect Repellent 1, for use as a personal insect repellent against mosquitoes and black flies, are eligible for full registration, pursuant to Section 13 of the PCP Regulations.

## Appendix I Comments and Responses

A single comment was received by the PMRA concerning [PRDD2002-02](#), published on September 18, 2002. The comment was from the public and related to the International Union of Pure and Applied Chemistry (IUPAC) chemical name of p-menthane-3,8-diol. The member of the public had noted that there was an error in the IUPAC chemical name and that the correct name should be as follows: 2-(1-hydroxy-1-methylethyl)-5-methylcyclohexanol. PMRA agrees, and all further documentation for this active ingredient will be corrected accordingly.