



Proposed Acceptability for Continuing Registration

PACR2004-08

Re-evaluation of Capsaicin

The purpose of this document is to inform the registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of capsaicin. The PMRA has determined that capsaicin is acceptable for continued registration provided that the proposed mitigation measures are adopted.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for capsaicin. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address below.

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Capsaicin has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient itself and its main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of the USEPA review, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of capsaicin and concluded that, on the basis of a health and environmental risk assessment, capsaicin was eligible for reregistration with implementation of mitigation measures. The PMRA's conclusions on the capsaicin re-evaluation were based on the RED document for capsaicin¹, with consideration of the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substance Management Policy [TSMP]).

¹ The USEPA RED document for capsaicin is available from the Chemical Status List on the Office of Pesticide Programs webpage at www.epa.gov/pesticides/reregistration

2.0 Re-evaluation of capsaicin

Active substance: 8-methyl-N-vanillyl-6-nonenamide or *N*-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methyl-6-nonenamide

Common name: Capsaicin

CAS number: 404-86-4

Capsaicin was first registered in Canada in 1968. It is a biochemical pesticide used to repel aggressive bears and dogs; to deter dogs, squirrels, cats, raccoons, skunks and groundhogs from damaging treated areas outdoors; and to deter pets from soiling indoor areas. Canadian registered products containing capsaicin are listed in Appendix I.

The USEPA assessment described in the RED document for capsaicin is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are outlined in the USEPA RED for capsaicin.

The federal TSMP² and Regulatory Directive DIR99-03³ were taken into consideration during the review of capsaicin, and it was determined that capsaicin is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in DIR98-04 or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for capsaicin, addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of capsaicin that are also registered in Canada. Based on the USEPA RED, and in consideration of the Canadian use pattern, the PMRA has determined that capsaicin is acceptable for continued registration, provided that the mitigation measures specified below are adopted.

² The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics

³ Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca or through our website at www.hc-sc.gc.ca/pmra-arla

It should be noted that end-use products that contain several active ingredients under re-evaluation will not be considered acceptable for continued registration until the re-evaluation of all active ingredients is complete.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

4.0 Proposed regulatory action

Based on recommended USEPA mitigation measures and in consideration of Canadian use patterns and basic hygiene practices, the Canadian label for end-use products containing capsaicin must include the following statements.

- (i) In the “Precautions” section of all pressurized spray products:
 - “Avoid touching eyes and face until you have washed your hands.”
- (ii) In the “Precautions” section of all pressurized spray bear repellent products:
 - “This product is for spraying the face of aggressive bears only and is not to be used against domestic animals or human beings.”
 - “Do not spray objects/areas for use as a repellent.”
- (iii) In the “Precautions” section of all products except pressurized sprays:
 - “Wear rubber gloves when handling this product and avoid touching eyes and face until you have removed gloves and washed your hands.”

The label amendments presented above do not include all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions is required within 90 days of finalization of the re-evaluation decision.

Registrants of end-use products that are not associated with a registered technical active ingredient are required to submit a request to register a technical source. This is required within 24 months of finalization of the re-evaluation decision.

5.0 Additional data requirements

The registrants of technical grade active ingredients are required to submit the following within 24 months of finalization of the re-evaluation decision:

- All data (as they relate to Canadian use pattern) submitted to the USEPA in response to the United States data call-in prior to the United States reregistration, and/or USEPA data evaluation reports (DERs).
- The registrant will be required to prepare and submit a comprehensive summary on the health and safety information available for the active ingredient. The summary should be based on a contemporary literature review and any available studies conducted on the active ingredient. As per normal practice, the PMRA will accept for review, sound, scientifically based waivers and rationales to address any of the data elements.

**Appendix I Canadian capsaicin products currently registered
(as of 31 December 2003)**

Product Name	Registrant	Registration Number	Guarantee	Class
Snyder Capsicum #1	Squirrel Proof Inc.	26477	0.60% (+ related capsaicinoids 0.48%)	T
Snyder Capsicum #2	Squirrel Proof Inc.	26478	0.07% (+ related capsaicinoids 0.06%)	T
Snyder Capsicum #3	Squirrel Proof Inc.	26852	2.30% (+ related capsaicinoids 2.20%)	T
Pred-it Bear Repellent	Pred-it Industries Inc.	23686	1.0%	R
Pepper Spray Pressurized Dog Repellant	Pepper Plus Inc.	23308	0.5%	D
Bear Gone Bear Deterrent	Pepper Plus Inc.	23507	1.0%	R
Pitbull Dog Repellent	Brandon Industries Canada Inc.	23547	0.5%	D
The Original Black Max Dog Repellent	Brandon Industries Canada Inc.	23548	0.5%	D
Bearguard Bear Deterrent	Bodyguard Canada LLC	24202	0.75%	R
Bodyguard Dog Repellent	Bodyguard Canada LLC	24203	0.35%	D
Defiance Pepper Spray Dog Repellent	Defiance ITM, Inc.	23115	0.35% (minimum)	D
Outdoorsman Bear Repellent	Personal Safety Corp.	23797	1.0%	R
The Original Black Max Bear Repellent	Brandon Industries Canada Inc.	24901	0.78%	R
Bearshield Bear Spray	North Pacific Supply Corp.	25126	0.75%	R
UDAP Bear Deterrent	Bodyguard Canada LLC	25589	0.75%	R
Tactical O.C. Bear Deterrent	Bodyguard Canada LLC	25590	0.75%	R
Bon-zai Animal Repellent (CAU, CAT, CAS)	Passion Krafts Int'l	25789	0.003% (+ 0.48% oil of black pepper, 0.018% piperine)	D

Product Name	Registrant	Registration Number	Guarantee	Class
Chemfree Critter Ridder Animal Repellent (CAU, CAT, CAS)	Woodstream Canada Corp.	25829	0.003% (+ 0.48% oil of black pepper, 0.018% piperine)	D
Squirrel Proof Chili Treat Wild Bird Seed	Squirrel Proof Inc.	26479	0.013% (+ related capsaicinoids 0.011%)	D
Squirrel Proof Seed Saver	Squirrel Proof Inc.	26480	0.60% (+ related capsaicinoids 0.48%)	D
Bearier Bear Deterrent	Axtrom Industries Inc.	26521	0.80% (+ alcohol 58%)	R
Guard Alaska Bear Repellent	McNeil River Enterprises Inc.	26529	0.75%	R
MSI Mace Aerosol Dog Repellent	R. Nicholls Distributors Inc.	26690	0.35%	D
Frontiersman Bear Attack Deterrent	Security Equipment Corp.	26619	0.857%	R
Squirrel Proof Chili Treat Wild Bird Suet	Squirrel Proof Inc.	26853	0.09% (+ 0.08% related capsaicinoids)	D
Bearier Bear Deterrent	Axtrom Industries Inc.	26871	0.75% (+ alcohol 58%)	R
Sabre Dog Attack Deterrent	Security Equipment Corp.	27051	0.50%	D

T = Technical; D = Domestic; R = Restricted.