Proposed Re-evaluation Decision

PRVD2022-14

Capsaicin and Related Capsaicinoids and their Associated End-use Products

Consultation Document

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Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental standards and continue to have value. The re-evaluation considers data and information from various sources such as information from pesticide manufacturers, incident reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches and policies to all re-evaluations.

This document presents the proposed regulatory decision for the re-evaluation of capsaicin and related capsaicinoids, including any proposed amendments (new risk mitigation measures and updated labels to meet the current labelling standard) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based.

Capsaicin and related capsaicinoids (dihydrocapsaicin and nordihydrocapsaicin) are the essential oil extracts from pepper fruit, and the actives are always co-formulated. In Canada, capsaicin and related capsaicinoids are registered as animal repellents. They act as vertebrate repellents through irritation when they come into contact with skin or mucous membranes.

Capsaicin and its related compounds are the only actives registered to repel bears. These are restricted class products formulated as pressurized spray to be used only by authorized customers. Similar products, at a lower concentration and smaller size, are also registered to deter aggressive dogs or coyotes in domestic settings. The actives, formulated as a suspension, are registered as commercial and domestic class products for use to protect trees and ornamentals from deer, rabbits and hares. Granular, dust and liquid domestic class products are also registered to deter dog, cat, raccoon, skunk, groundhog and squirrels to protect the residential areas or bird seeds.

Capsaicin and its related compounds are shown to have value in providing a pest management solution. Based on the current use pattern of capsaicin and related capsaicinoids, dietary exposure is not anticipated. The potential risk to human health (occupational and non-occupational) and the environment is considered acceptable with the proposed risk mitigation measures and label updates.

Risk mitigation:

- o domestic class to repel dogs and coyotes a new precautionary statement;
- o commercial class (suspension) product to repel deer, rabbit and hares update the personal protective equipment and add re-entry interval statement;
- o domestic class (suspension) products to repel deer, rabbit and hares to add personal protective equipment, re-entry interval and update spray drift statement;
- o domestic class products to deter dog, cat, raccoon, skunk, groundhog and squirrels add additional and update personal protective equipment, and re-entry interval statement;

- o domestic class product as dust to treat bird seeds to deter squirrels update the personal protective equipment statement;
- o add statements to mitigate potential risk to aquatic organisms on all product labels; and
- o update general statements to relevant product labels to improve clarify.

No additional risk mitigation measures are proposed for restricted class products to deter bears, and for domestic class products as pre-treated bird seeds or suet to deter squirrels.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. Under the authority of the *Pest Control Products Act*, and based on the evaluation of currently available scientific information, products containing capsaicin and related capsaicinoids (Appendix I) are being proposed for continued registration in Canada with the proposed new mitigation measures and updates to label directions (Appendix II).

All products containing capsaicin and related capsaicinoids registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation, during which written comments and additional information may be submitted to PMRA Publications. The final re-evaluation decision will be published taking into consideration of the comments and information received during the consultation period.

Next steps

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document, which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on capsaicin and related capsaicinoids (based on the Science Evaluation of PRVD2022-14). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room.

Additional scientific information

No additional data are required.

[&]quot;Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science evaluation

1.0 Human health

1.1 Human exposure and risk

Capsaicin and related capsaicinoids are essential oil extracts from pepper fruit and act as vertebrate repellents through irritation when they come into contact with skin or mucous membranes. The actives are known to be of low acute oral toxicity. They are irritating to the skin, eyes and upper respiratory tract on contact and are potential sensitizers (Canada, 2004b and USEPA, 2010). Precautionary statements alerting users are present on registered product labels; however updates are proposed to meet current labelling standard (Appendix II). There is a long history of safe use of these actives as a food additive. Health Canada has not established toxicological reference values for capsaicin and related capsaicinoids for risk assessment and a qualitative approach was used to assess the human health risk.

Capsaicin and related capsaicinoids are registered as animal repellents in Canada. The registered products are formulated as:

- pressurized spray, restricted class end-use products to deter bears;
- pressurized spray, domestic class end-use products to repel aggressive dogs and coyotes;
- suspension, commercial and domestic class end-use products to repel white-tailed deer, black-tailed deer, rabbit and hares to prevent feeding damage to outdoor ornamental plants;
- granular or liquid domestic class end-use products to deter dog, cat, raccoon, skunk, groundhog and squirrels to protect landscaped areas or particular sites;
- pre-treated seeds or suet, domestic class end-use products to deter squirrels;
- dust, domestic class end-use product to be used to treat the bird seeds (treat your own) to deter squirrels.

Restricted class end-use products containing capsaicin and related capsaicinoids are registered to repel aggressive bears in emergency situations only. The products are only for use by authorized customers and the vendors are required to maintain a record of sales and the name and address of the purchaser, amount purchased together with a signed Notice to Purchaser regarding the use restrictions. Risks to the user and bystanders are considered acceptable when these products are used according to the current label directions, precautions and restrictions (for example, avoid contact with skin and eyes and avoid inhalation of spray; not to be used against domestic animals or human beings) (Canada 2004a and 2004b). No further mitigation measures are proposed.

Pressurized spray domestic class products (at lower concentration of actives and smaller container size than the restricted products) are registered as a direct spray to repel aggressive dogs and coyotes. The current labels contain appropriate precautionary statements, thus risks to the users and bystanders are considered acceptable when these products are used according to the current label directions and precautions (Canada 2004a and Canada 2004b). For consistency, a precautionary statement, "Do not spray this product on objects or humans." is proposed.

There is only one commercial class (suspension) end-use product containing capsaicin and related capsaicinoids (co-formulated with seven other non-conventional active ingredients). There is a potential for occupational exposure for users while mixing, loading and spraying the product on ornamental plants and while performing clean-up and maintenance activities, and postapplication exposure. The current personal protective equipment requires workers to wear a long-sleeved shirt, long pants, chemical-resistant gloves, safety goggles, and socks plus shoes during diluting and mixing of the product (concentrate suspension), and spraying the diluted product on the dry plants, and when performing clean-up and maintenance activities (Canada 2016). To meet the current labelling standard, the personal protective equipment is proposed to be updated. There is currently no re-entry interval statement on the label, thus, a re-entry interval statement of, "DO NOT enter or allow entry into treated areas until sprays have dried" is proposed to minimize the postapplication exposure. A spray drift statement is present on the current label to minimize bystander exposure. Thus, risks to workers and bystanders are considered acceptable when this product is used according to the proposed additional risk mitigation measures and updated labels (Appendix II).

There are two domestic class end-use products (ready to use spray and concentrated suspension) containing capsaicin and related capsaicinoids (co-formulated with seven other non-conventional active ingredients) registered to repel white-tailed deer, black-tailed deer, rabbits and hares to prevent feeding damage to outdoor ornamental plants (Canada 2012a, 2015a and 2015b). The products are sprayed on the dry plants by using a "ready to use spray" product or by diluting and mixing a concentrate suspension, and apply with a sprayer. There is potential for user exposure while mixing and/or spraying and clean-up activities. There are no personal protective equipment currently included in the labels. Therefore, the PMRA is proposing that the user wears a long-sleeved shirt, long pants, waterproof gloves, socks and shoes, when mixing/loading/applying (spraying) these domestic products. A re-entry interval statement (DO NOT enter or allow entry into treated areas until sprays have dried) is proposed to minimize the postapplication exposure. A spray drift statement is present on the current labels to minimize bystander exposure, but it is proposed to be updated to meet the current labelling standard. Thus, risks to users and bystanders are considered acceptable when these two products are used according to the proposed additional risk mitigation measures and updated labels.

In addition, there are domestic class (granular) end-use products containing capsaicin and related capsaicinoids (co-formulated with two other non-conventional active ingredients). They are formulated as granular products, which are registered to deter dog, cat, raccoon, skunk and groundhog to protect residential landscape areas such as flower beds and particular sites, such as garbage bags, ornamental plants, trees or buildings (for example, garages, verandas, sheds). The granular products are applied by hand, manual or motorized spreaders. The users are required to wear waterproof gloves on the current labels (Canada 2004a). Additional mitigation measure is proposed to include a long-sleeved shirt, long pants, socks and shoes, while applying these products. Sufficient precautionary statements are currently on the labels, such as "avoid ingestion and contact with eyes or skin" and "keep out of reach of children". A re-entry interval statement to restrict entry into treated areas until dusts have settled is proposed to minimize the postapplication exposure. Risks to users and bystanders are considered acceptable when these products are used according to the proposed additional risk mitigation measures and updated labels.

There are also domestic class (liquid) end-use products containing capsaicin and related capsaicinoids (co-formulated with two other non-conventional active ingredients). They are formulated as liquid products, which are registered to deter dog, cat, raccoon, skunk, groundhog and squirrels for outdoor use only to protect residential landscape areas such as gardens and lawns, and garbage bags, garbage containers and bird feeders. The liquid products are applied as ready to use spray or by diluting and mixing the concentrate and spraying by hand or power sprayer. Current personal protective equipment for the liquid products is waterproof gloves, a long-sleeved shirt, pants, shoes and socks, while mixing and/or spraying. To meet the current labelling standard, this personal protective equipment statement is proposed to be updated. Sufficient precautionary statements are currently on the labels, such as "avoid ingestion and contact with eyes or skin" and "keep out of reach of children". A re-entry interval statement to restrict entry into treated areas until sprays have dried is proposed to minimize the postapplication exposure. Risks to users and bystanders are considered acceptable when these products are used according to the proposed additional risk mitigation measures and updated labels.

Domestic class end-use products, formulated as pre-treated bird seeds and suet containing capsaicin and related capsaicinoids are registered to deter tree squirrels. There is a potential for user exposure as a result of using these pre-treated seeds or suet when filling feeders or scattering seeds on the ground. Appropriate precautionary statements are present on the labels (to warn the user of eyes, nose and skin irritant potential; "avoid contact with eyes or clothing" and "keep out of reach of children") (Canada 2004a and 2004b). Risks to the users are considered acceptable when these two products are used according to the current label instructions.

A domestic class end-use product, formulated as dust containing capsaicin and related capsaicinoids, is registered to treat the bird seeds (treat your own) to deter tree squirrels. There is potential exposure for the users from treating the bird seeds and loading the treated seeds in the bird feeders or scattering seeds on the ground. Appropriate precautionary statements are present on the current label (to warn the users of eyes, nose and skin irritant potential; avoid contact with eyes or clothing" and "keep out of reach of children"). On the current label, the personal protective equipment for the users includes eye and face protection and rubber gloves (Canada 2004a). An update to the personal protective equipment is proposed to meet the current labelling standard (Appendix II). Risks to users are considered acceptable when the product is used according to the proposed updated personal protective equipment statement and the label direction.

Capsaicin and related capsaicinoids are not registered in Canada for food and feed uses. Contamination of drinking water sources is not expected based on the use pattern (Canada 2012a). Therefore, dietary exposure to capsaicin and related capsaicinoids is not anticipated under the current conditions of use.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Capsaicin and related capsaicinoids are not registered for food and feed uses and exposure to drinking water is not expected to occur from the registered use pattern.

Risks to residential users and bystanders are considered acceptable when the products containing capsaicin and related capsaicinoids are used according to the proposed additional risk mitigation measures and updated labels. As such, an aggregate assessment is not required.

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pesticides with a common mechanism of toxicity. While capsaicin and related capsaicinoids may share structural similarities to components found in essential oil-based pest control products, it is difficult to determine which constituents share a common mechanism of action as it is often not possible to fully identify and characterize the constituent(s) responsible for toxicity. However, based on the low toxicity profile, and given that dietary exposure to CAS (capsaicin) and RCS (related capsaicinoids) is not expected under the current conditions of use, there is no requirement for a cumulative risk assessment at this time.

2.0 Environmental assessment

Available mammalian toxicology data indicates lack of acute toxicity to mammals and was used to indicate that capsaicin and related capsaicinoids are expected to be nontoxic to terrestrial wildlife. Based on the current use pattern, environmental exposure is expected to be limited (Canada 2012a). In addition, as capsaicin and related capsaicinoids are used to repel mammals, it is expected that terrestrial organisms will avoid exposure to capsaicin and related capsaicinoids, thus further limiting exposure. To minimize aquatic exposure and meet current labelling standard, the PMRA is proposing to update the current labels. Thus, risks to the environment are considered acceptable when the products containing capsaicin and related capsaicinoids are used according to the proposed label update.

Capsaicin and related capsaicinoids are not considered to be Track 1 substances as they do not meet all of the criteria as per the Toxic Substances Management Policy.

3.0 Incident reports

As of 19 May 2022, one human incident report (involving packaging failure) and one environment incident report have been submitted to the PMRA.

In an incident classified as Human Minor and Packaging Failure, a can of Counter Assault Ultra Bear Deterrent (Reg. No. 22137; 2% capsaicin and related capsaicinoids) located in the back seat of the car accidentally discharged from the nozzle as well as leaked down the side of the can. Six individuals in total (2 adults and four children, ages unknown) were exposed to the spray, while driving. All individuals were reported to have suffered from burning eyes, nose, and lungs. The signs are highly consistent with exposure to capsaicin. The product label currently warns not to store the product in the passenger compartment of vehicles. No additional mitigation is recommended based on this incident.

In the one environmental incident, three cedar trees/shrubs were damaged following application of a product containing capsaicin and related capsaicinoids, along with a domestic class herbicide, to the neighbouring property. The incident was assessed as minor. The USEPA's EIIS database (updated to October 2015) also contains seven incident reports of plant damage following direct application of products containing capsaicin. The product label includes directions to test a small spray area for any damage to plants. No additional mitigation is required based on these incidents.

4.0 Value

Capsaicin and its related compounds are of value as two of the few active ingredients registered for use by domestic users to repel vertebrates in residential areas; in and around structures, landscaped areas including gardens (excluding food crops), ornamentals, paths, lawns, bird feeders, garbage bags and containers. Capsaicin and its related compounds are of value to commercial users to protect trees and ornamentals from deer in commercial settings. Capsaicin and its related compounds are of value as the only product registered to deter attacks from bears and aggressive dogs or coyotes.

To improve clarify, general label improvements regarding use directions for products containing capsaicin and related capsaicinoids are proposed (Appendix II).

Appendix I Registered products containing capsaicin and related capsaicinoids

Table 1 Registered products containing capsaicin and related capsaicinoids active ingredients as of 9 February, 2022^a

Registration number	Class	Registrant	Product name	Formulation type	Active ingredient (%)
27929	Т	Bushwacker Backpack & Supply DBA Counter Assault	OC - Capsaicin	Suspension	RCS-8.92; CAS- 10.85;
27906	Т	Robertet Canada, Inc.	Oleoresin Capsicum 33% Manufacturing Concentrate	Suspension	RCS-15.25; CAS- 17.75;
27907	Т	Robertet Canada, Inc.	Oleoresin Capsicum 13.3% Manufacturing Concentrate	Suspension	RCS-6.22; CAS-7.08;
27908	Т	Robertet Canada, Inc.	Oleoresin Capsicum 6.6% Manufacturing Concentrate	Suspension	RCS-3.10; CAS-3.50;
27909	Т	Robertet Canada, Inc.	Oleoresin Capsicum 20% Manufacturing Concentrate	Suspension	RCS-8.94; CAS- 11.06;
26477	Т	Squirrel Proof Inc.	Snyder Capsicum #1	Suspension	RCS-0.48; CAS- 0.60;
26852	Т	Squirrel Proof Inc.	Snyder Capsicum #3	Suspension	RCS-2.20; CAS- 2.30;
29550	Т	Passion-Krafts Int'l	Passion Krafts Oleoresin of Red Pepper Technical	Liquid	RCS-3.1; CAS-3.5;
27837	Т	West Coast Aerosols Ltd.	IDP Oleoresin Capsicum	Liquid	RCS-5.08; CAS-7.00;
22137	R	Bushwacker Backpack & Supply DBA Counter Assault	Counter Assault Ultra Bear Deterrent	Pressurized Product	RCS-0.9; CAS-1.1;
27380	R	Parkland Aero- Fillers	Back-Off Bear Deterrent	Pressurized Product	RCS-0.84; CAS- 0.98;
27381	R	Parkland Aero- Fillers	Bear Beware	Pressurized Product	RCS-0.65; CAS- 0.75;
27382	R	Parkland Aero- Fillers	Bear Beware Plus	Pressurized Product	RCS-0.84; CAS- 0.98;
28950*	R	Parkland Aero- Fillers	Stay-Away Bear Deterrent	Pressurized Product	CAS-0.98;
28951*	R	Parkland Aero- Fillers	Stop! Bear Deterrent	Pressurized Product	CAS-0.98;
26619	R	Security Equipment Corporation	Frontiersman Bear Attack Deterrent	Pressurized Product	RCS-0.753; CAS- 0.857;

Registration				Formulation	Active	
number	Class	Registrant	Product name	type	ingredient (%)	
	_	Security Equipment	Frontiersman Xtra	Pressurized	RCS-0.84; CAS-	
28410	R	Corporation	Bear Attack Deterrent	Product	1.00;	
20114	-	Security Equipment	Sabre Wild Max Bear	Pressurized	RCS-0.84; CAS-	
29114	R	Corporation	Attack Deterrent	Product	1.0;	
20257	D	Security Equipment	Sabre Wild Bear	Pressurized	CAS-0.857; RCS-	
29357	R	Corporation	Attack Deterrent	Product	0.753	
27715	R	UDAP Industries,	UDAP Pepper Power	Pressurized	RCS-0.64; CAS-	
27713	K	Inc.	Bear Deterrent	Product	0.75;	
25590	R	West Coast	Ruger Bear Deterrent	Pressurized	RCS-0.54; CAS-	
23370	IX	Aerosols Ltd.	_	Product	0.75;	
		West Coast	Bear D'fense	Pressurized		
27685*	R	Aerosols Ltd.	Professional Bear	Product	CAS-1.00;	
		ricrosors Etc.	Deterrent	Troduct		
	_	West Coast	Bearguard	Pressurized		
27926*	R	Aerosols Ltd.	Professional Bear	Product	CAS-1.00;	
		W . C	Deterrent	D : 1		
28596*	R	West Coast	Yukon Magnum (TM)	Pressurized	CAS-1.0;	
		Aerosols Ltd.	Bear Deterrent	Product	f	
30571	R	West Coast	Ruger Extreme Bear	Pressurized	RCS-0.72; CAS-	
		Aerosols Ltd. West Coast	Repellent Bear Scare Bear	Product Pressurized	1.0; RCS-0.72; CAS-	
33903	R	Aerosols Ltd.	Deterrent	Product	1.0;	
		Guardian Protective		Pressurized	RCS0.9641;	
34369	R	Devices, Inc.	Bear Shield	Product	CAS- 1.0974	
		Devices, me.		Troduct	WNT-0.53; RCS-	
					0.0025; MTX-	
			Bobbex Commercial		1.10; GRO-0.028;	
32038	С	Bobbex, Inc.	Deer & Rabbit	Suspension	FSO-0.31; FMM-	
32030		Booten, me.	Repellent Concentrate	Suspension	6.13; EGS-2.32;	
			r		CST-0.33;	
					CAS-0.003;	
					WNT-0.53; RCS-	
					0.0025; MTX-1.1;	
			Bobbex Deer &		GRO-0.028;	
29804	D	Bobbex, Inc.	Rabbit Repellent	Suspension	FSO-0.31; FMM-	
			Concentrate	•	6.13; EGS-2.32;	
					CST-0.33;	
					CAS-0.003;	
					WNT-0.53; RCS-	
29805					0.001; MTX-0.3;	
	D		Bobbex Deer &		GRO-0.014;	
		29805 D	Bobbex, Inc.	Rabbit Repellent	Suspension	FSO-0.21; FMM-
			Ready-To-Use Spray		4.09; EGS-0.93;	
					CST-0.17;	
					CAS-0.001;	

Registration number	Class	Registrant	Product name	Formulation type	Active ingredient (%)
27771	D	Bushwacker Backpack & Supply DBA Counter Assault	Counter Assault Dog Deterrent Pepper Spray	Pressurized Product	RCS-0.42; CAS- 0.50;
26479*	D	Squirrel Proof Inc.	Squirrel Proof Chili Treat Wild Bird Seed	Granular	CAS + RCS- 0.023;
26480*	D	Squirrel Proof Inc.	Squirrel Proof(TM) Seed Saver(TM)	Dust	CAS + RCS - 1.08;
26853*	D	Squirrel Proof Inc.	Squirrel Proof Suet With Chili Treat (TM)	Solid	CAS + RCS - 0.17;
27383*	D	Parkland Aero- Fillers	Dog Beware	Pressurized Product	CAS-0.44;
28948*	D	Parkland Aero- Fillers	Stay-Away Dog Deterrent	Pressurized Product	CAS-0.44;
28949*	D	Parkland Aero- Fillers	Stop! Dog Deterrent	Pressurized Product	CAS-0.44;
25789	D	Passion-Krafts Int'l	Scentagone Animal Repellent	Granular	RCS-0.0015; CAU-0.480; CAT-0.018; CAS-0.0017;
25829	D	Woodstream Canada Corporation	Safer`s Critter Ridder	Granular	RCS-0.0015; CAU-0.480; CAT-0.018; CAS-0.0017;
29741	D	Woodstream Canada Corporation	Chemfree Critter Ridder Concentrate	Liquid	RCS-0.121; CAU-3.84; CAT- 1.48; CAS-0.136;
29743	D	Woodstream Canada Corporation	Safer`s Critter Ridder Ready to Use	Liquid	RCS-0.015; CAU-0.48; CAT- 0.185; CAS- 0.017;
29858	D	Woodstream Canada Corporation	Safer`s Critter Ridder Granular	Granular	RCS-0.0015; CAU-0.48; CAT-0.018; CAS-0.0017;
27051	D	Security Equipment Corporation	Sabre K9 Dog & Coyote Attack Deterrent	Pressurized Product	RCS-0.44; CAS- 0.50;
33884	D	Security Equipment Corporation	Sabre 2-In-1 K9 Dog & Coyote Attack Deterrent With LED Armband	Pressurized Product	RCS-0.44; CAS- 0.50;
27714	D	UDAP Industries, Inc.	UDAP Industries Pepper Power Dog Deterrent	Pressurized Product	RCS-0.29; CAS- 0.35;
27690	D	West Coast Aerosols Ltd.	Bodyguard Cone Dog Repellent	Pressurized Product	RCS-0.36; CAS-0.50;
29967	D	West Coast Aerosols Ltd.	Spike Stream Dog Repellent	Pressurized Product	RCS-0.36; CAS- 0.50;

Registration number	Class	Registrant	Product name	Formulation type	Active ingredient (%)
29967.02	D	West Coast	Bodyguard Stream	Pressurized	RCS-0.36; CAS-
29907.02	D	Aerosols Ltd.	Dog Repellent	Product	0.50;
20067.02	D	West Coast	Ruger Stream Dog	Pressurized	RCS-0.36; CAS-
29967.03	D	Aerosols Ltd.	Repellent	Product	0.50;

T = Technical grade active ingredient, R = Restricted, C = Commercial, D = domestic,

CAS = Capsaicin, RCS = Related capsaicinoids, CAU = Oil of black pepper; CAT = Piperine (from oleoresin of black pepper); WNT = Wintergreen oil; MTX = Meat meal mixture; GRO = Garlic oil; FSO = Fish oil mixture; FMM = Fish meal mixture; EGS = Dried eggs; CST = Castor oil;

^{*} Capsaicin is always co-formulated with related capsaicinoids, individual active ingredient (%) of capsaicin and related capsaicinoids should be updated by the registrants.³

^a As of 2022-02-09, excluding discontinued products or products with a submission for discontinuation.

^{2010,} Memorandum to Registrants, Applicants and their Representatives for Capsaicin Products - Capsaicin Statement of Guarantee and Labelling Allowances.

Label amendments **Appendix II**

To meet current standards, the following label amendments are proposed

- 1) For All products:
- A. On the principal display panel,

replace

"WARNING IRRITANT"

with

"WARNING EYE AND SKIN IRRITANT"

- B. The **FIRST AID** section must be updated as per DIR2007-01.⁴
- 2) Add to labels of all technical grade active ingredient products:
- A. DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.
- B. Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean up of spills, contact the manufacturer and the provincial regulatory agency.
- 3) Add to labels of all end-use products:
- "DO NOT apply to any body of water."
- 4) For the domestic class products, Reg. No. 27383, 27690, 27714, 27771, 28948, 28949, 29967, 29967.02, 29967.03, pressurized spray products, under the section entitled **PRECAUTIONS**, add the following statement:
 - "**Do not** spray this product on objects or humans"
- 5) For the commercial class product Reg. No. 32038, suspension product, under the section entitled **PRECAUTIONS**;

replace

"safety goggles"

with

"protective eyewear (goggles or face shield)"

^{2007,} Regulatory Directive DIR2007-01, First Aid Labelling Statements.

- 6) For the domestic class products Reg. No. 29804 and 29805, suspension product, under the section entitled **PRECAUTIONS**, add the following statement:
 - "Wear long-sleeved shirt, long pants, waterproof gloves, socks and shoes when diluting, mixing and applying the product."
- 7) For the domestic class products Reg. No. 25789, 25829, and 29858, granular products, under the section entitled **PRECAUTIONS**, add the following statement:
 - "Wear long-sleeved shirt, long pants, socks and shoes when diluting, mixing and applying the product."
- **8**) For the domestic class products Reg. No. 29741 and 29743, liquid products, under the section entitled **PRECAUTIONS**:

Replace

"pants, shoes and socks"

With

"long pants, socks and shoes"

9) For the domestic class products Reg. No 26480, dust product, under the section entitled **PRECAUTIONS**,

replace

"Wear eye and face protection and rubber gloves"

with

"Wear waterproof gloves and protective eyewear (goggles or face shield)"

- **10**) For the commercial class suspension product Reg. No. 32038, and the domestic class suspension products Reg. No. 29804 and 29805, under the section entitled **Directions for Use,** add the following statement of re-entry interval:
 - "DO NOT enter or allow entry into treated areas until sprays have dried."
- 11) For the domestic class granular products Reg. No. 25789, 25829 and 29858, under the section entitled **Directions for Use**, add the following statement of re-entry interval:
 - "DO NOT enter or allow entry into treated areas until dusts have settled."
- **12**) For the domestic class liquid products Reg. No. 29741 and 29743, under the section entitled **Directions for Use**, add the following statement of re-entry interval:
 - "DO NOT enter or allow entry into treated areas until sprays have dried."

13) For domestic class products Reg. No. 29804 and 29805, under the section entitled **PRECAUTIONS**,

Replace

"temperature"

with

"temperature inversions"

14) For all restricted class products: under the section entitled Directions for Use,

If there is any wording of the term "trained operators", it should be replaced with "certified applicators".

15) Following tables are proposed to all or individual products indicated:

Table 1 General label improvements for products containing Capsaicin and Related Capsaicinoids

Label element	Label improvement	Additional comments
	T 1 12	
General	Label improvements are required to ensure clarity and to	
	remove general terms.	
	Refer to the following PMRA regulatory policies and	
	guidelines listed below for more guidance on pest control product labelling:	
	Checklist of Labelling Requirements and	
	 LPS2011-02, Guidance to Improve Statements on Labels of Domestic Class Products. 	
Principal	On the principal display, remove "Guarantee" and replace	For example,
display	with "Active Ingredient".	ACTIVE INGREDIENT
panel:	with Tienve ingredient.	TICTIVE INCREDIENT
Active	The label must indicate the guarantee for both capsaicin	CapsaicinX%
Ingredient	and related capsaicinoids. As per the 2010 Memorandum	Related CapsaicinoidsY%
	to Registrants, Applicants and their Representatives for	_
	Capsaicin Products - Capsaicin Statement of Guarantee	
	and Labelling Allowances, the guarantee declaration on	
	the SPSF and label for products containing capsaicin must	
	include the capsaicin and the related capsaicinoids.	
Principal	For aggressive dog and coyote spray products, the net	
display	contents must be between 20 grams to 50 grams.	
panel: Net	For aggressive bear spray products, the net content must	
Contents	be between 225 grams to 500 grams.	
Principal	The general statement found on the principal display panel	
display	must reflect all the use patterns stated in the	
panel	DIRECTIONS FOR USE section of the secondary panel	
	of the label.	

		Аррепак п
Label element	Label improvement	Additional comments
Principal display panel	Add the product type if missing from the principal display panel.	The product type needs to be in the principal display panel as per the "Labelling Checklist".
Principal display panel and secondary display panel	The principal and secondary panel must clearly identify whether the product is "FOR INDOOR USE ONLY", "FOR OUTDOOR USE ONLY" and "FOR INDOOR OR OUTDOOR USE". Label instructions must be consistent with where the product is to be used throughout the label (for example, no references to outdoor uses if product is used indoors only).	As per the "Labelling Checklist".
Secondary display panel	For products applied to repel animals from outdoor areas containing a limitation of not applying to edible crops or where children play in the PRECAUTIONS, add the following in the DIRECTIONS FOR USE: "DO NOT apply in areas where plants are grown for food or feed (e.g., vegetables, fruit, herbs) or where children play."	
Secondary display panel	Remove unacceptable advertising statements as per Regulatory Directive DIR2016-01, <i>Guidelines for the Advertising of Pest Control Products</i> and non-pest control product claims. Any reference to a product being nontoxic to animals and the environment must be removed from the label. Non-pest control product claims must also be removed.	
Secondary display panel	For concentrate products that must be diluted before use, add the following statement in the directions for use: DO NOT apply undiluted.	
Secondary display panel	For general outdoor products with a specific re-treatment interval, vague statements indicating "reapply as necessary" or equivalent must be deleted from the label or replaced with the re-treatment interval statement followed by "Treatment must only be repeated if pest problem persist or reoccurs."	
Secondary display panel	Where there is a potential of damage, non-safety adverse effects statements should be added if not present such as "Users should test (treat) a small, inconspicuous area first to ensure there are no adverse effects such as staining or discolouration.", "Before treating large areas, test the potential damage of the repellent by first treating a small inconspicuous area" and "It is advisable to treat a small portion of plants to determine if damage will occur."	

 Table 2
 Product specific label improvements

	Product specific label amendments	
Label element and Reg. Nos.	Label improvement	Comments
Dog/Coyote repellent products Reg. Nos. 27383 27690 27714 27771 28948 28949 29967 29967.02 29967.03 33884 Secondary display panel: Use Directions	On the capsaicin products used to protect people from dog and/or coyote attacks, the site claims must be amended to "aggressive dogs" and "aggressive coyotes". The Directions for Use section must include the following: "FOR OUTDOOR USE ONLY. Capsaicin sprays have been proven effective in repelling aggressive [insert target animal, i.e., dogs and/or coyotes] only when sprayed directly into the face, especially in the eyes or on the nose of the animal. This product is only to be used to deter aggressive [insert target animal, i.e., dogs and/or coyotes] that are attacking or about to attack people. DO NOT seek out encounters with [insert target animal, i.e., dogs and/or coyotes]. There is no guaranteed method of responding to an aggressive [insert target animal, i.e., dogs and/or coyotes] encounter because each encounter is unique. This product is a [insert target animal, i.e., dogs and/or coyotes] attack repellent that may protect users in some unexpected confrontations with these animals but may not be effective in all situations or prevent all injuries. This product must be used only as a last resort. DO NOT use this product against people or non-target animals. READ THIS ENTIRE LABEL BEFORE TAKING THIS PRODUCT INTO AREAS WHERE AGGRESSIVE [INSERT TARGET ANIMAL, I.E., DOGS AND/OR COYOTES] MIGHT BE ENCOUNTERED.	Do not remove product specific use directions such as "Depress top button, spraying into face and eyes of threatening dog. Spray in a series of short bursts. Spray is most effective at short range (up to 3m)." or text such as "When threatened by a dog, turn actuator 45 degrees to "Ready" position. Point nozzle directly toward dog's face. Depress actuator button for a burst of spray to a maximum range of 3 metres. Move away to avoid exposure to spray."
Bear repellent products Reg. Nos. 22137 25590 26619 27380 27381 27382	On the capsaicin products used to protect people from bear attacks, the site claims must be amended to "aggressive bears". Move use directions currently under Precautions section to Direction for Use section. Specifically, the Directions for Use section must include the following: "FOR OUTDOOR USE ONLY. Capsaicin sprays have been proven effective in repelling aggressive bears only when sprayed directly into the face, especially in the	Move use directions currently under Precautions section to Direction for Use section.
28950 28951	eyes or on the nose of the animal. This product is only to be used to deter aggressive bears that are attacking	

	Product specific label amendments	
Label	Label improvement	Comments
element and	•	
Reg. Nos.		
29114	or about to attack people. DO NOT seek out encounters	
29357	with bears. There is no guaranteed method of	
34369	responding to an aggressive bear encounter because	
	each encounter is unique. This product is a bear attack	
27685	• •	
27715	repellent that may protect users in some unexpected	
27926	confrontations with these animals but may not be	
28596	effective in all situations or prevent all injuries. Strict	
30571	attention to the advice of wildlife professionals on	
33903	safety is advised. This product must be used only as a	
	last resort. Capsaicin sprays will not repel bears from	
25789	treated objects or areas. DO NOT spray objects (e.g.,	
	tents, clothing) or areas with this product. DO NOT use	
Secondary		
display	this product against people or non-target animals.	
panel: Use	READ THIS ENTIRE LABEL BEFORE TAKING THIS	
Directions	PRODUCT INTO AREAS WHERE AGGRESSIVE	
and	BEARS MIGHT BE ENCOUNTERED."	
Precautions		
	And the PRECAUTIONS section must read as follows:	
	"PRECAUTIONS: KEEP OUT OF REACH OF	
	CHILDREN. Severe irritation to eyes, nose, respiratory and	
	skin areas can occur. Persons with respiratory problems or	
	wearing contact lenses should not use this product. Avoid	
	contact with skin and eyes and avoid inhalation of spray.	
	WHEN TRAVELLING DO NOT STORE IN PASSENGER	
	COMPARTMENT. Contact air carriers for regulations	
	concerning air transport. Contents under pressure. Container	
	may explode if heated. Do not place in hot water or near	
	radiators, stoves or other sources of heat. Do not use in the	
	presence of open flame or spark or while smoking. Do not leave	
	in hot vehicle. For safety and performance, do not store above	
	[Insert numerical value as found on registered label]°C or	
	below [Insert numerical value as found on registered label]°C.	
	Be careful not to puncture container. DO NOT INCINERATE	
	CONTAINER. Wash hands before touching eyes or face and	
	prior to using the washroom."	

	Product specific label amendments	
Label	Label improvement	Comments
element and		
Reg. Nos. General	General information:	Adding clarity on the
outdoor –	Replace	target pests, rates
granules	"GENERAL INFORMATION: Scent-a-gone contains	and non-food/non-
graniones	ingredients that irritate animals when they touch or taste the	feed and non-
Reg. Nos.	product. It can be used to repel animals such as dogs, cats,	children play areas
25789	groundhogs, skunks and raccoons from treated areas for about	only.
25829	30 days."	
29858		
G 1	With	
Secondary	"GENERAL INFORMATION: [Insert product name]	
display panel:	contains ingredients that irritate animals when they touch or taste the product. It can be used to repel dogs, cats, groundhogs,	
General	skunks and raccoons from treated areas for about 30 days."	
Information	skulks and laccools from treated areas for acoust 50 days.	
and	Directions for Use:	
Directions	Replace with	
for Use		
	"DIRECTIONS FOR USE:	
	DO NOT apply in areas where plants are grown for food or	
	feed (e.g., vegetables, fruit, herbs) or where children will play.	
	Indoors: Spread at a rate of 83 g/m ² (100 ml/m ²) on building	
	surfaces to be protected. Reapply after 30 days if animals	
	continue to be a problem. Treatment must only be repeated if	
	pest problem persist or reoccurs. A [Insert numerical value as	
	found on registered label with appropriate units (e.g., g or kg)]	
	kg product will treat [Insert numerical value as found on	
	registered label] m ² .	
	Outdoors: Apply on sunny, dry days. Spread by hand (gloves	
	are recommended) or using manual or motorized spreaders at a	
	rate of about 117g/m ² (125 ml/m ²). May be applied to lawns,	
	ornamental garden paths and flower beds. To protect garbage	
	bags, garbage cans, ornamental plants, trees or buildings (e.g.,	
	garages, verandas, sheds) apply on the ground as a protective	
	band 0.5 m for skunks, 2 m for raccoons, 0.3 m for groundhogs,	
	0.5 m for dogs and 0.3 m for cats. A quantity of [Insert numerical value as found on registered label with appropriate	
	units (e.g., g or kg)] will treat [Insert numerical value as found	
	on registered label] m ² . Reapply after 30 days if animals	
	continue to be a problem. Treatment must only be repeated if	
	pest problem persist or reoccurs."	

Label element and Reg. Nos. Suet product Reg. No. 26853 Principal display panel: Remove "A High-Energy, Health Dietary Supplement For Attracting Wild Birds Treated to Discourage Feeding by Tree Squirrels" Replace with "Treated to Discourage Feeding by Tree Squirels" Remove "Our products are non-toxic to animals and the environment." Remove "Our products are non-toxic to animals and the environment." Remove "Our products are non-toxic to animals and the environment." Remove "Our products are non-toxic to animals and the environment." Remove "Ireferences to gardens because it could imply that the product could be applied to food crops. Principal display panel: Remove "REPELS CATS, DOGS, GROUNDHOGS, RACCOONS, SKUNKS AND SQUIRRELS FOR UP TO 30 DAYS FROM LANDSCAPED AREAS INCLUDING ORNAMENTALS, GARBAGE CONTAINERS" Principal display panel Geplace with "REPELS CATS, DOGS, GROUNDHOGS, RACCOONS, SKUNKS AND SQUIRRELS FOR UP TO 30 DAYS FROM LANDSCAPED AREAS INCLUDING ORNAMENTALS, LAWNS, BIRD FEEDERS, GARBAGE BAGS AND GARBAGE CONTAINERS" Replace with "REPELS CATS, DOGS, GROUNDHOGS, RACCOONS, SKUNKS AND SQUIRRELS FOR UP TO 30 DAYS FROM LANDSCAPED AREAS INCLUDING ORNAMENTALS, LAWNS, BIRD FEEDERS, GARBAGE BAGS AND GARBAGE CONTAINERS" Replace with "REPLES CATS, DOGS, GROUNDHOGS, RACCOONS, SKUNKS AND SQUIRRELS FOR UP TO 30 DAYS FROM LANDSCAPED AREAS INCLUDING ORNAMENTALS, LAWNS, BIRD FEEDERS, GARBAGE BAGS AND GARBAGE CONTAINERS" Secondary display panel Directions for Use: Remove "Landscaped Areas, including lawns, gardens and ornamentals." Replace with "Landscaped Areas, including lawns and ornamentals."		Product specific label amendments			
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		Add "DO NOT apply in areas where plants are grown for food			
or feed (e.g., vegetables, fruit, herbs) or where children play."					

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