

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

September 29, 2025

Elizabeth Kile Vehring
Director, US Regulatory Affairs, R&D
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

Subject: Label Amendment - Registration Review Mitigation for Cyfluthrin

Product Name: Cylence Pour On EPA Registration Number: 11556-107 Application Date: October 28, 2022

Case Number: 477492

Dear Elizabeth Kile Vehring:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Cyfluthrin Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. You must

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submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Lauren Weissenborn via email at weissenborn.lauren@epa.gov.

Sincerely,

Cathryn Britton

Cathuy Sutter

Chief, Risk Management and Implementation

Branch V

Pesticide Re-evaluation Division (7508M)

Office of Pesticide Programs

ENCLOSURE: Stamped label

Reason to Issue: Interim Registration Review, add pictograms/pictures, updated phone numbers, address and minor revisions.

Date: 10/27/2022 Supersedes: 09/11/2009

NOTE TO REVIEWER: Braces "{ }" indicate notes to reviewer. Brackets "[]" indicate optional language.

CYLENCETM POUR-ON INSECTICIDE

For Control of Horn Flies, Face Flies, Biting Lice and Sucking Lice, on Beef and Dairy Cattle [Including Lactating]

{[Selected pictograms from page 4]}

ACTIVE INGREDIENT:	% by Weight
Cyfluthrin	1%
OTHER INGREDIENTS:	99%
Total	

EPA REG NO. 11556-107 EPA EST. NO. TBD

CYFLUTHRIN	GROUP	3A	INSECTICIDE

Note to reviewer: box will be in the upper right corner of front panel.

For outdoor use only.

Net Contents: [6 pints (2.839 L)] [1 pint (473 mL)]

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140 [U.S.A.]

ACCEPTED

09/29/2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 44550 407

11556-107

KEEP OUT OF REACH OF CHILDREN WARNING

[See [Rear] [side] [inside] [and] [inside booklet] [panel[s]] for [other] Precautionary Statements [Storage and Disposal] [and] First Aid]]

FIRST AID			
If in Eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 		

70 0					
If Swallowed:	• Call a poison control center or doctor immediately for treatment advice.				
	 Have a person sip a glass of water if able to swallow. 				
	• Do not induce vomiting unless told to do so by a poison control center or doctor.				
	 Do not give anything to an unconscious person. 				
If on Skin or	Take off contaminated clothing.				
Clothing:	 Rinse skin immediately with plenty of water for 15-20 minutes. 				
	 Call a poison control center or doctor for treatment advice. 				
If Inhaled:	 Move person to fresh air. 				
	• If person is not breathing, call 911 or an ambulance, then give artificial respiration,				
	preferably by mouth-to-mouth, if possible.				
	 Call a poison control center or doctor for further treatment advice. 				
HOT LINE NUMBER					

Have the product container or label with you when calling a poison control center or doctor or going for treatment. [You may also contact 1-800-428-4441 for emergency medical treatment information.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.] [or CHEMTREC at 1-800-424-9300, 24 hours per day, 7 days per week.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wear goggles, face shield or safety glasses. Wash hands thoroughly with soap and warm water after handling. Do not contaminate feed or food.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters. Apply this product only as specified on the label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, CyLence Pour-On contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to CyLence Pour-On and other Group 3A insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same sites. Appropriate resistancemanagement strategies should be followed.

Contact your local extension specialist advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific pest problems in your area.

For Control of Horn Flies, Face Flies, Biting Lice and Sucking Lice on Beef and Dairy Cattle [Including Lactating].

How to Apply: CyLence Pour-On Insecticide is a ready-to-use solution. [To use the package dispenser, hold the container upright, remove the cap from the dosage chamber and gently squeeze the sides of the bottle to fill the chamber to the desired dosage. *] Apply the required amount of solution directly along the top of the back and top of the head of the animal.

Amount to Use: Apply CyLence Pour-On Insecticide at the dosages shown on the following table. Due to the small amount of material required, care must be taken to apply the correct dosage.

	Horn and Face Flies		Biting and Sucking Lice	
Animal Waish4	Descent (ml)	Number of Animals This Container will	Description (ml)	Number of Animals This
Animal Weight	Dosage (ml)	treat	Dosage (ml)	container will treat
Less than 400 lbs.	4	709 [118*]	8	354 [59*]
400-800 lbs.	8	354 [59*]	16	177 [29*]
Over 800 lbs.	12	236 [39*]	24	118 [19*]

^{*}Substitutions for the 1 pint size.

CyLence Pour-On Insecticide can be used on beef and dairy cattle [including lactating] of all ages and sizes. Treatment for flies can be repeated as needed but not more often than once every 3 weeks. For optimal lice control, an initial application followed by a second treatment 3 weeks later is recommended.

CyLence Pour-On Insecticide does not control cattle grubs.

NOTICE TO VETERINARIANS

As with all synthetic pyrethroids, a small percentage of animals may experience a temporary skin sensation known as paresthesia within 24 hours after application. Paresthesia is characterized by one or more of the following signs: head tossing, tail twitching, restlessness, and irritability. Generally, affected animals return to normal within 48 hours without treatment.

STORAGE AND DISPOSAL Not for Use or Storage in or Around the Home

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If the container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose as directed for pesticides above.

Pesticide Disposal: Pesticide wastes are hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Offer for reconditioning, if appropriate. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ½ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow

begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, of if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans, and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather, conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Elanco US Inc. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

LIMITED WARRANTY AND LIMITATIONS OF DAMAGES

Elanco US Inc warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANT ABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of Elanco is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special consequential damages resulting from the use of handling of this product.

{[Optional marketing pictograms and pictures appearing on any location:]}



