



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 4, 2024

J. Todd Frank  
Senior Regulatory Affairs Consultant  
Elanco US Inc.  
2500 Innovation Way  
Greenfield, IN 46140

Subject: Registration Review Label Mitigation for Permethrin and Diflubenzuron  
Product Name: Clean Up II Pour-On Insecticide with IGR  
EPA Registration Number: 11556-186  
Application Dates: 10/28/2022 and 9/13/2023  
Decision Numbers: 572573 and 594483

Dear J. Todd Frank:

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 Permethrin and Diflubenzuron Interim Decisions 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. You must 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.

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EPA Reg. No. 11556-186  
Decision No. 572573 and

If you have any questions about this letter, please contact Carolyn Smith by phone at (202)566-2273, or via email at [smith.carolyn@epa.gov](mailto:smith.carolyn@epa.gov).

Sincerely,



Jordan D. Page

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Senior Regulatory Advisor, RMIB3  
Pesticide Re-evaluation Division  
US EPA Office of Pesticide Programs

Enclosure

Reason to Issue: Add pictograms and minor revisions, phone #.

Date: 08/09/2023

Supersedes: 03/24/21

NOTE TO REVIEWER: Braces “{ }” indicate note to reviewer. Brackets “[ ]” indicate optional language.

### Clean-Up™ II Pour-On Insecticide with IGR

**Ready-to-Use Suspension for Control of Flies and Lice on Lactating and Non-Lactating Dairy Cattle, Beef Cattle, Calves and Horses and Prevents Emergence of Horn Fly Larvae in the Manure of Treated Cattle**

<b>DIFLUBENZURON</b>	<b>GROUP</b>	<b>15</b>	<b>INSECTICIDE</b>
<b>PERMETHRIN</b>	<b>GROUP</b>	<b>3A</b>	<b>INSECTICIDE</b>

{Box will be in the upper right corner of front panel.}

[Selected OPTIONAL MARKETING pictograms from page 5]

[Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS from page 5]

<b>ACTIVE INGREDIENTS:</b>	<b><u>% by Weight</u></b>
Diflubenzuron [CAS # 35367-38-5] .....	3.0%
Permethrin [CAS # 52645-53-1] .....	5.0%
<b>OTHER INGREDIENTS*:</b> .....	<u>92.0%</u>
<b>TOTAL</b> .....	100.0%

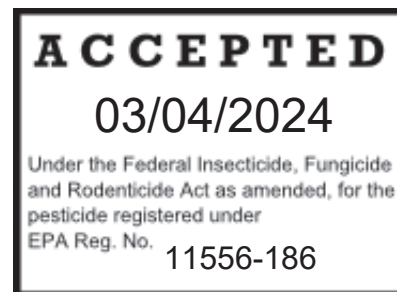
\*Contains petroleum distillate  
SHAKE WELL BEFORE USE.

**EPA Reg. No. 11556-186**

**EPA Est. No. TBD**

**NET CONTENTS:** [0.5 gallon (64 fl. oz)] [ 2.5 gallons (9.5L)]

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



**STOP - Read the label before use**

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See [location on package] for [Precautionary Statements] [and] [First Aid] [and] [Storage and Disposal] [and] [Directions for use]

<b>FIRST AID</b>	
<b>If Swallowed:</b>	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give any liquid to the person.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If on Skin or Clothing:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in Eyes:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>HOTLINE NUMBER</b>	
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. [For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), you may call 1-800-428-4441, twenty-four (24) hours per day, seven (7) days per week.] .] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product &amp; Veterinary Support at 1-800-428-4441. [or CHEMTREC at 1-800-424-9300, 24 hours per day, 7 days per week.]]</p>	
<p><b>Note to Physician:</b> May pose an aspiration pneumonia hazard. Contains petroleum distillate.</p>	

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

### **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Some materials that are chemical-resistant to this product are barrier laminate, nitrile rubber, neoprene rubber, and viton.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants, shoes plus socks.
- Chemical-resistant gloves made of barrier laminate, nitrile rubber, neoprene rubber or Viton; and
- Chemical-resistant apron for persons cleaning equipment, and for handlers performing animal dip applications.

### **USER SAFETY REQUIREMENTS**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched (except as required by directions for use) or heavily contaminated with this product's concentrate. Do not reuse them.

## USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

## ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help ensure that wind or rain does not blow or wash pesticide off the treatment area.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively foraging the treatment area.

## DIRECTIONS FOR USE

For both indoor and outdoor use.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**IMPORTANT:** Read the entire Directions for Use, Conditions of Sale and Disclaimer of Limited Warranty and Limitations of Damages before using this product.

## RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, **Clean Up II** contains a **Group 15** insecticide. Any insect population may contain individuals naturally resistant to **Clean Up II** 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 resistance-management 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.

## USE RESTRICTIONS:

- Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
- Not for use in outdoor residential misting systems.
- Not for use in metered release systems.
- Not for use in commercial animal premise automatic misting systems.
- Not for broadcast application.
- Do not make outdoor applications during rain.
- Do not apply when food or feed is present.
- Remove or cover food processing equipment and food preparation surfaces or wash them before use.
- Do not apply by high pressure hand wand, handheld foggers, or fog/mist generators.
- Do not apply the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur.

- Do not allow the product to enter any drain during or after application.
- Do not apply or irrigate to the point of runoff.
- Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours).
- Rainfall within 24 hours after application may cause unintended runoff of pesticide application.
- When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.

**READY-TO-USE: NO DILUTION NECESSARY**

TARGET ANIMAL	TARGET PEST	APPLICATION INSTRUCTIONS
Lactating and non-lactating dairy cattle, beef cattle, calves and MATURE horses	Sucking Lice, [(Biting) (Chewing)] Lice, House Flies, Stable Flies, Horse Flies, Black Flies, Horn Flies, Deer Flies, and Cattle Ticks.	<b>Pour-On:</b> Apply 3 mL per 100 lbs. body weight of animal up to maximum of 30 mL for any one animal. Pour along back line and down face. Product may be either administered directly from graduated tip-and-pour container, graduated applicator gun, or graduated ladle/dipper. Do not use this method of application on foals.
Horses and Foals	Sucking Lice, [(Biting) (Chewing)] Lice, House Flies, Stable Flies, Horse Flies, Black Flies, Horn Flies, Deer Flies, and Cattle Ticks.	<p><b>Wipe-On:</b> Apply 3 mL per 100 lbs. body weight of animal up to maximum of 30 mL for any one animal. Dampen an applicator mitt, cloth or toweling with Clean-Up II Pour-On Insecticide with IGR. Rub over hair with special attention to the legs, shoulders, neck and facial areas where pests appear or tend to congregate. Apply directly onto attached ticks.</p> <p><b>Ready-To-Use Spray:</b> Use Clean-Up II Pour-On Insecticide with IGR undiluted in a mist sprayer, applying 3 mL per 100 lbs. body weight of animal up to maximum of 30 mL for any one animal. Direct spray to the legs, shoulders, neck and facial areas where pests appear or tend to congregate. Apply directly onto attached ticks.</p>

**Instructions for all methods of application:** Keep away from eyes and mucous membranes of animal being treated. Repeat treatment as needed, but do not apply more than once every two weeks.

Product is not effective in controlling cattle grubs: therefore, the product can be used on cattle at any time of the year without fear of host-parasite reactions commonly associated with grub treatment products.

[A [[0.5 gallon] [64 fl. oz.]] container will treat up to 63 animals.]

[A [[2.5 gallon] [9.5L]] container will treat up to 315 animals.]

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Keep container sealed when not in use. Do not store near food or feed.

**Pesticide Disposal:** Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Handling:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ 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. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by 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 MERCHANTABILITY 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, incidental or consequential damages resulting from the use of handling of this product.

{{Optional marketing claims appearing on any location:}}

1. Provides control of [[biting] [chewing]] and sucking lice.
2. [[Prevents louse eggs [nits]] from hatching] [Kills louse eggs [nits] before they hatch] [Controls louse eggs [nits]].
3. One application controls lice.
4. Has a zero day pre-slaughter interval and milk discard time.
5. May be used as a component of an integrated pest management program, either alone or in combination with other insecticides as an aid to prevent the development of insecticide resistance.
6. Prevents the emergence of horn flies in the manure [[of] [from]] treated cattle.

{{Optional marketing pictograms appearing on any location:}}

