



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

11556-186

Date of Issuance:

11/10/15

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Clean-Up II Pour-On Insecticide
 with IGR

Name and Address of Registrant (include ZIP Code):

Mr. Douglas A. Spilker
 Manager, EPA Regulatory Affairs
 Bayer HealthCare LLC, Animal Health Division
 P.O. Box 390
 Shawnee Mission, KS 66201

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Jennifer Urbanski, Ph.D., Product Manager 04
 Invertebrate & Vertebrate Branch, Registration Division (7505P)

Date:

11/10/15

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Permethrin GDCI-109701-1252
 - b. Permethrin GDCI-109701-1113
 - c. Permethrin GDCI-109701-1281

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 11556-186.”
5. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/05/2015

If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Enclosure

Reason to Issue:

Propose Registration of a new product.

Date: 10/28/2015

Supersedes:
03/17/2015
Page 1 of 7

Note to Reviewer: Brackets [] and parentheses () denote 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

- Provides control of [(biting) (chewing)] and sucking lice
- [(Prevents louse eggs (nits) from hatching) (Kills louse eggs (nits) before they hatch) (Controls louse eggs (nits))]
- One application controls lice
- Has a zero day pre-slaughter interval and milk discard time
- 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

ACTIVE INGREDIENTS:

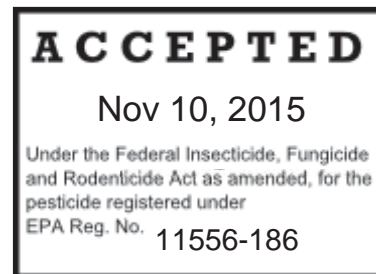
Diflubenzuron [CAS # 35367-38-5]	3.0%
Permethrin [CAS # 52645-53-1]	5.0%
OTHER INGREDIENTS*:	92.0%
Total:	100.0%

*Contains petroleum distillate	SHAKE WELL BEFORE USE.
EPA Reg. No. 11556-186	EPA Est. No. TBD

NET CONTENTS: [0.5 gallon (64 fl. oz) or 2.5 gallons]

Manufactured for:

Bayer HealthCare, LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201



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Date: 10/28/2015

Supersedes:
03/17/2015
Page 2 of 7

Note to Reviewer: Brackets [] and parentheses () denote optional language

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]

FIRST AID	
If Swallowed:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor for treatment advice.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
If On Skin or Clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If In Eyes:	<ul style="list-style-type: none">• 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.
HOTLINE NUMBER	
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 1-800-422-9874, twenty-four (24) hours per day, seven (7) days per week.	
Note to Physician: May pose an aspiration pneumonia hazard. Contains petroleum distillate.	

Reason to
Issue:

Propose Registration of a new product.

Date: 10/28/2015

Supersedes:
03/17/2015
Page 3 of 7

Note to Reviewer: Brackets [] and parentheses () denote optional language

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 butyl rubber, neoprene and polyvinyl chloride (PVC). If you want more options, follow the instructions for category A on EPA chemical-resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants, shoes plus socks.
- Chemical-resistant gloves; 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.

Reason to
Issue:

Propose Registration of a new product.

Date: 10/28/2015

Supersedes:
03/17/2015
Page 4 of 7

Note to Reviewer: Brackets [] and parentheses () denote optional language

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

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.

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, hand held foggers, or fog/mist generators.
- Application is prohibited directly into sewers or drains, or to any area like a 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.

Reason to Issue:

Propose Registration of a new product.

Date: 10/28/2015

Supersedes:
03/17/2015
Page 5 of 7

Note to Reviewer: Brackets [] and parentheses () denote optional language

- 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.	Pour-On: 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.	Wipe-On: 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. Ready-To-Use Spray: 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.

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.

Reason to
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Propose Registration of a new product.

Date: 10/28/2015

Supersedes:
03/17/2015
Page 6 of 7

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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 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: 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 Bayer HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

Limited Warranty and Limitation of Damages: Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO

Reason to
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Propose Registration of a new product.

Date: 10/28/2015

Supersedes:
03/17/2015
Page 7 of 7

Note to Reviewer: Brackets [] and parentheses () denote optional language

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 Bayer 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.