

706-83

02/14/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 14, 2013

Mrs. Kimberlee Young, CC, APC, Manager
Consultant/Agent for
Claire Manufacturing Company
c/o RegWest Company, LLC
30856 Rocky Road
Greeley, CO 80631-9375

**Subject: Amended Labeling, Submission of Acute Inhalation Study to Address CRP Requirement per Pre-Reregistration Labeling Review Dated August 29, 2012
Claire® Down & Out II Flying Insect Killer, EPA Reg. No. 706-83
Your Submission Dated September 21, 2012**

Dear Mrs. Young:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision provision(s):

General Comment(s):

1. The submitted/cited acute inhalation study (MRID 48892001) was determined to be acceptable. As a result, CRP is no longer required for the subject product.
2. Delete all text throughout the subject label marked with "strikethrough."
3. This subject label must not be split into 2 separate sub-labels which separately list "Occupational" and "Consumer/Residential" uses of this product. As you know, this label contains required PPE and other worker protection statements that must appear within all use sections of the label, and not just within the "Occupational" use section. As a result, your intended split of the subject label does not contain the required PPE and other worker protection statements within the "Consumer/Residential" use section of the label. As specified in Chapter 10.V. of the Agency's Label Review Manual, if your client wishes to market a separate product solely for "Consumer/Residential" use, without the required PPE and other worker protection statements, I would suggest that your client submit a new product application under PRIA 3.

First Aid Statements section comment(s), middle of page 1:

4. To facilitate incorporation of required label language from the acute toxicity reviews completed in support of the subject product, you must make the following changes within this subsection:
 - Since this subject product contains petroleum distillates, you must replace the existing "If Inhaled:" subsection with the following subsection:

If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • 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.
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- Revise the 2nd sentence within the "HOTLINE NUMBER" subsection to read "For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-866-836-8855, twenty-four (24) hours per day, seven (7) days per week."

Precautionary Statements, Hazards to Humans and Domestic Animals subsection comment(s), bottom of page 1:

5. To facilitate incorporation of required label language from the acute toxicity reviews completed in support of the subject product, since this product contains petroleum distillates, you must revise this subsection to read as follows:

"CAUTION: Contains Petroleum Distillate. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves."

Precautionary Statements, Environmental Hazards subsection comment(s), middle of page 2:

6. To facilitate incorporation of required label language from the REDs for d-Phenothrin and tetramethrin, you must revise this subsection to read as follows:

"This product is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not contaminate water when disposing of equipment wash-water or rinsate. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. See Directions for Use for additional precautions and requirements.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

Directions for Use, Precautions and Restrictions subsection comment(s), bottom of page 2 to top of page 3:

7. To facilitate incorporation of required label language from the REDs for d-Phenothrin and tetramethrin, you must make the following changes within this subsection:

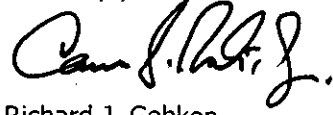
- Revise the existing subsection heading "**Precautions and Restrictions**" to read "**Use Restrictions**".
- Within the 1st paragraph in this subsection, insert the following text immediately following the existing 2nd sentence to read "Only protected handlers may be in the area during application."
- Within the existing 4th sentence of the 1st paragraph in this subsection, replace the words "people or pets" with the words "adults, children, or pets."
- Revise the existing 3rd paragraph in this subsection to read "Do not apply when food is present. In the home, all food processing surfaces and utensils should be covered during treatment, or thoroughly washed before reuse. Exposed food should be covered or removed."

Should Claire Manufacturing Company wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, Claire Manufacturing Company may refer consumers to the company's phone number or e-mail address.

Copies of your label stamped "Accepted with Comments" and the acute toxicity review completed in support of this amendment are enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,

FOR


Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated February 14, 2013*
Acute Toxicity Review, dated February 14, 2013
000706-00083 D427168, D436088 & D470014

{Subpart A Label For Occupational Use}



Down & Out II Flying Insect Killer

[[Select marketing claims from "Marketing Claims" section below]]

For Use in Non-Food Areas of Commercial, Industrial and Institutional Buildings and in Households

Active Ingredients:

Tetramethrin (CAS No. 7696-12-0).....	0.2%
Sumithrin (CAS No. 26002-80-2)	0.2%

Other Ingredients*	99.6%
Total	100.0%

*Contains petroleum distillates

Keep Out of Reach of Children

CAUTION

See back panel for First Aid and additional Precautionary Statements.

[Si usted no entiende la etiqueta, busque a alguien para que la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail).]

EPA Reg. No. 706-83

EPA Est. **ACCEPTED**
With COMMENTS
In EPA Letter Dated:

Net Wt. oz. / g
{5 ounces through 1 pound}

February 14, 2013
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

{Back Panel}

First Aid

If Inhaled:	<ul style="list-style-type: none"> • 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.
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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-866-836-8855 for emergency medical treatment information.	
Note to Physician: Contains petroleum distillate -- vomiting may cause aspiration pneumonia.	

(Note: The grid format for the First Aid statements will be used if market label space permits, otherwise, a paragraph format will be used.)

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wear long sleeved shirt and long pants, socks, shoes and chemical-resistant gloves.

24-Hour Medical Emergency 1-866-836-8855

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, nitrile rubber, neoprene rubber and Viton \geq 14 mils. Applicators must wear long-sleeved shirt, long pants, shoes and socks.

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 or heavily contaminated with this product's concentrate; do not reuse them.

User Safety Recommendations

Users should: thoroughly wash hands with soap and water after handling this product and before eating, drinking, chewing gum, using tobacco or using the toilet; immediately remove clothing/PPE if pesticide gets inside, then thoroughly wash and put on clean clothing; immediately remove PPE after handling this product. Wash the outside of gloves before removing. As soon as possible, thoroughly wash and change into clean clothing.

Physical or Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not store in direct sunlight. Do not smoke while using this product. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting. Incineration of container may cause explosion. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Environmental Hazards

This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not apply directly to water.

DIRECTIONS FOR USE

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

**Shake Well Before Use; Hold Container Upright.
Apply in Short Bursts.**

Precautions and Restrictions

Do not use in commercial food processing, preparation or storage areas. Do not apply this product in a way that will contact adults, children or pets, either directly or through drift. Do not enter or allow others to enter the treated area until the sprays have dried. Do not allow people or pets to enter treated areas until vapors, mists and aerosols have dispersed, and the treated area has been thoroughly ventilated. Do not use on humans, domestic animals or pets. Remove pets/birds and cover fish aquariums and ornamental fish ponds before spraying, and turn aquarium systems off.

~~Products solely for domestic/residential dwellings use may omit the following paragraph.~~

Do not use in food areas of food handling establishments, restaurants or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served, such as dining rooms, but excluding areas where food may be prepared or held. Non-food areas are areas such as garbage rooms, lavatories, floor drains (to sewers), entries, vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage areas (after bottling or canning). Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, bodies of water or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.

~~(Products solely for commercial use may omit the following paragraph.)~~

Do not apply when food is present. In the home, cover all food processing surfaces and utensils during treatment or thoroughly wash before use. Cover or remove exposed food.

To Kill Flies, Gnats, Mosquitoes and Small Flying Moths: Close all doors and windows, and direct spray upward into center of room with a slow sweeping motion. Spray 5-10 seconds for average room. Wait 2 hours after application, then open windows, vents and doors for 2 hours. If an odor is still detected, additional ventilation is required. Sweep up and discard fallen insects.

Storage and Disposal

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

Pesticide Storage: Store in a cool, dry (preferably locked) place inaccessible to children and pets and away from direct sunlight, windows and flames or other sources of heat or ignition. **Pesticide/Container Disposal:** Do Not Function or Incinerate! **If empty:** Place in trash or offer for recycling if available. [This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label.] **If partly filled:** Call your local solid waste agency for disposal instructions.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

{For Customer Support}



[Manufactured by:]
[A Product of:]



Claire Manufacturing Company
1005 S. Westgate Drive
Addison, IL 60101
[www.clairemfg.com]



{Enlargement:
No CFCs.

Contains no CFCs which deplete the ozone layer.
Federal regulations prohibit CFC propellants in aerosols.}

PLEASE RECYCLE
WHEN EMPTY



{Marketing Claims}

**Kills Common Pests:
House Flies • Mosquitoes
and Others Listed on Back Panel**



[Made in the U.S.A.]

{End of Marketing Claims}

- [] Denotes alternate/optional verbiage
- { } Denotes verbiage not printed on market labeling

8/10

(Subpart B Label: For Consumer/Residential Use)



Down & Out II Flying Insect Killer

[[Select marketing claims from "Marketing Claims" section below]]

For Use in Non-Food Areas in Households

Active Ingredients:

Tetramethrin (CAS No. 7696-12-0).....	0.2%
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**Keep Out of Reach of Children
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See back panel for First Aid and additional Precautionary Statements.

(Si usted no entiende la etiqueta, busque a alguien para que la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail).)

EPA Reg. No. 706-83

EPA Est. _____

Net Wt. ____ oz. / ____ g
{5 ounces through 1 pound}

(Back Panel)

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If Inhaled:	<ul style="list-style-type: none"> • 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.
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Hazards to Humans & Domestic Animals

CAUTION: Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wear long-sleeved shirt and long pants, socks, shoes and chemical-resistant gloves. Thoroughly wash with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

9/10

24-Hour Medical Emergency 1-866-836-8855

Physical or Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not store in direct sunlight. Do not smoke while using this product. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting. Incineration of container may cause explosion. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

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10/10

recycling, empty the can by using the product according to the label.] If partly filled: Call your local solid waste agency for disposal instructions.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

{For Customer Support}



**THE
NEXT LEVEL**
in **CLEANING & MAINTENANCE**

[Manufactured by:]
[A Product of:]



Claire Manufacturing Company
1005 S. Westgate Drive
Addison, IL 60101
[www.clairemfg.com]



[Enlargement:
No CFCs.

Contains no CFCs which deplete the ozone layer.
Federal regulations prohibit CFC propellants in aerosols.]

PLEASE RECYCLE
WHEN EMPTY



{Marketing Claims}

Kills Common Pests:
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and Others Listed on Back Panel



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{End of Marketing Claims}

[] Denotes alternate/optional verbiage
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