

34797-3

1/28/2008

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

JAN 28 2008

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Mr. Paul Kittelson  
Qualis, Inc.  
4600 Park Avenue  
Des Moines, Iowa 50321

Dear Mr. Kittelson:

Subject: Flea & Tick Shampoo  
EPA Reg. No. 34797-3  
Label Amendment dated 1/17/07

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Move the statement "For External Use Only" to a subsection of the Directions for Use entitled "Use Restrictions".

In the Precautionary statements, revise the inhalation and skin contact statements to read as follows:

Do not inhale vapors. Do not get on skin.

Revise the "If Swallowed" first aid statement to read as follows:

If Swallowed. 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.

Move the statement about use on food producing animals to the Use Restrictions and revise it as follows:

Do not use on food producing animals or animals intended for slaughter.

Move the following statements from the Precautionary Statements to the Use Restrictions and revise them as follows:

For external use only.

Do not contaminate food, feed or drinking water.

Consult a veterinarian before using this product on debilitated, aged, medicated pregnant or nursing animals. Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.  
In case of infection or skin irritation, discontinue use and consult a veterinarian.

Move the instructions about animal ingestion so that they follow the first aid statements.

Add an emergency number to the end of the first aid statements, in accordance with PR notice 2001-1. Delete the bracketed statement that "additional emergency contact information may be added to fit company policy" as any such statements must be submitted as a label amendment.

Move the instructions about having product container or label with you to the end of the first aid statements, in accordance with PR Notice 2001-1.

Revise all claims to "control" fleas and ticks to read "kills fleas and ticks..."

Delete the following instructions which may permit misuse:  
Intended for use on dogs and cats;

Delete the statement "Repeat as required" as it detracts from the retreatment interval of one week.

Revise the "If Partly filled" disposal statements as follows:  
Never place unused product down any indoor or outdoor drain.

For containers of 5 gallons, the Environmental Hazards Statement must include the following:

Do not discharge effluent contain this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant 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.

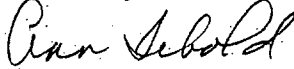
Delete from the Disposal instructions the following:  
"...except as specified by this label."

Note that additional changes may be required pursuant to PR Notices 2007-1 and 2007-4. Please note also that a notice of availability of EPA's reregistration eligibility document (RED) for products contain pyrethrins and piperonyl butoxide was published in the Federal Register on July 26, 2006. Additional data and/or labeling changes may be required for products containing pyrethrins and piperonyl butoxide. For more information, see the following website:  
<http://www.epa.gov/pesticides/reregistration/status.htm>.

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If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,



for

Richard Gebken

Product Manager 10

Insecticide Branch

Registration Division (7505P)

Flea & Tick Shampoo  
34797-3

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MASTER LABEL, FRONT PANEL:

Flea & Tick Shampoo

Label Claims (See Master Label Optional Claims)

ACTIVE INGREDIENTS:

Pyrethrins .....	0.06%
*Piperonyl Butoxide, Technical .....	0.60%
INERT INGREDIENTS: .....	99.34%
	100.00%

\* Equivalent to 0.48% (butylcarbityl) (6-propylpiperonyl) ether and 0.12 % related compounds.

FOR EXTERNAL USE ONLY

Keep Out of Reach of Children

CAUTION See Side [and/or] Back Panel for Additional Precautions

[Will Use One of the Following (may appear on front or side panel)]:

Manufactured (or Packaged) For: XYZ Company City, State Zip, USA

EPA Reg. No. 34797-3-XXXXX EPA EST. NO. 34797-IA-03

[OR]

Packaged By: Qualis, Inc Des Moines, IA 50321 USA

Distributed By: XYZ Company City, State Zip, USA

EPA Reg. No. 34797-3-XXXXX EPA EST. NO. 34797-IA-03

[OR]

Distributed By: XYZ Company City, State Zip, USA

EPA Reg. No. 34797-3-XXXXX EPA EST. NO. 34797-IA-03

NET CONTENTS Up to 5 Gallon (641 fl. oz.) 19 liters

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
JAN 28 2008

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
34797-3

MASTER LABEL, SIDE OR BACK PANEL:

**DIRECTIONS FOR USE** [NOTE - Directions may be continued on another side, back, or fold out label as required] It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**READ ENTIRE LABEL BEFORE EACH USE** [*This statement maybe found on front, side or back panel*]

**USE ONLY ON DOGS AND CATS. SHAKE WELL BEFORE USING.** Intended for use on dogs and cats; not intended for use on food producing animals. Do not use on dogs and cats under 12 weeks *of age*. Wet coat thoroughly with water. Rub Flea & Tick Shampoo into coat, working up a rich lather. Allow lather to remain 10 minutes, then rinse with clear water and towel dry. Repeat as required. Do not repeat treatment for 1 week.

**STORAGE & DISPOSAL [residential]:** Do not contaminate water or feed by storage and disposal.

**Pesticide Storage:** Store in original container at temperatures above 32°F and away from children.

If partly filled: Call your local solid waste agency (1-800-CLEANUP) for disposal instructions. Never place unused product down any indoor or outdoor drain except as specified by this label

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

[OR]

**STORAGE & DISPOSAL [non-residential]:** Do not contaminate water or feed by storage and disposal.

Pesticide Storage: Store product only in original container at temperatures above 32°F and away from children.. Store pesticide separately to prevent cross-contamination of other pesticides, fertilizers, food and feed.

**Pesticide Disposal:** Wastes resulting from use of this product must be disposed of on site or at an approved waste disposal facility

**Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**MASTER LABEL, SIDE OR BACK PANEL:**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Avoid contamination of feed and foodstuffs. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. For external use only. In case of infection or skin irritation, discontinue use and consult a veterinarian. In case of animal ingestion contact a veterinarian or call Animal Poison Control Hotline (1-800-548-2423) immediately.

**FIRST AID**

<u>Have product container or label with you when calling a poison control center or doctor or going for treatment. [Additional emergency contact information may be added to fit company policy]</u>	
<b>IF SWALLOWED:</b>	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless instructed by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
<b>IF ON SKIN OR CLOTHING:</b>	• 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.
<b>IF INHALED:</b>	• 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 immediately for further treatment advice.
<b>IF IN EYES:</b>	• 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. • Call a poison control center or doctor immediately for treatment advice.

**ENVIRONMENTAL HAZARDS:** [ Product for exclusive indoor(residential) use may omit the Environmental Statement (LRM 9-1) This product is toxic to fish. Do not apply directly to any body of water. Do not contaminate water when disposing of equipment washwaters.

**MASTER LABEL, OPTIONAL CLAIMS:**

- To control fleas & ticks on dogs & cats
- For use on cats and dogs to control fleas and ticks

**MASTER LABEL, MISCELLANIOUS:**

- [Label control number, revision date and UPC information will be placed onto side or back panel as a method of control and product identification.]
- [Residential – less than one gallon]
- [non-Residential – one gallon or more]

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Avoid contamination of feed and foodstuffs. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. For external use only. In case of infection or skin irritation, discontinue use and consult a veterinarian. In case of animal ingestion contact a veterinarian or call Animal Poison Control Hotline (1-800-548-2423) immediately.

**FIRST AID**

Have product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless instructed by a poison control center or doctor.</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 INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor immediately for further 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. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call a poison control center or doctor immediately for treatment advice.</li> </ul>

## Flea & Tick Shampoo

To control fleas & ticks on dogs & cats

**ACTIVE INGREDIENTS:**

Pyrethrin	0.06% w/w
*Pieronyl Butoxide, technical	0.60% w/w
<b>OTHER INGREDIENTS:</b>	99.34% w/w
	100.00% w/w

\* Equivalent to 0.48% (butylcarbityl) (6-propylpiperonyl) ether and 0.12 % related compounds.

**FOR EXTERNAL USE****KEEP OUT OF REACH OF CHILDREN****CAUTION:** See side panels for additional precautions

NET WT 8 oz (237 mL)

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

**READ ENTIRE LABEL BEFORE EACH USE**  
**USE ONLY ON DOGS AND CATS**  
**SHAKE WELL BEFORE USING.**

Intended for use on dogs and cats; not intended for use on food producing animals. Do not use on dogs and cats under 12 weeks of age. Wet coat thoroughly with water. Rub Flea & Tick Shampoo into coat, working up a rich lather. Allow lather to remain 10 minutes, then rinse with clear water and towel dry. Repeat as required. Do not repeat treatment for 1 week.

**STORAGE & DISPOSAL:**

Do not contaminate water or feed by storage and disposal.

**Pesticide Storage:** Store in original container at temperatures above 32° F and away from children.

**If partly filled:** Call your local solid waste agency (1-800-CLEANUP) for disposal instructions. Never place unused product down any indoor or outdoor drain except as specified by this label

**If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

Manufactured For:

XYZ Company City, State Zip

EPA Reg. No. 34797-3-XXXXX

EPA Est. No. 34797-IA-03

# UPC CODE