

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

January 7, 2008

Ms. Olivia D. Laird, Agent/Consultant Tender Corporation c/o Laird's Regulatory Consultants, Inc. 17804 Braemar Place Leesburg, VA 20175-70469

Subject:

Renaming of Product

Ben's[®] Tick & Insect Repellent Wipes, EPA Reg. No. 56575-13

Your Submission Dated October 8, 2007

Dear Ms. Laird:

Please note that the primary product name for this product has been changed from "BFZeeTM Tick and Insect Repellent Wipes" to "Ben's[®] Tick & Insect Repellent Wipes." Further, 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 provision(s):

General Statement:

1. Delete all text throughout the label marked with "strikethrough."

<u>Ingredient Statement section comment(s)</u>:

2. Relocate the CAS number listed for DEET as a footnote on the front panel of the label or delete it.

General Comments at bottom of front panel:

- 3. Delete the marketing claim "Contains no alcohol." 1
- 4. Delete the marketing claim "Long-lasting protection." No data has been submitted to support this claim.

Net Contents/Net Weight Statement section comment(s):

5. The net contents must be expressed in terms of liquid measure (fluid ounces) per individual wipe and also total fluid ounces per package. ²

¹ Statements or claims that express the absence of certain ingredients are misleading statements prohibited by the Agency's labeling regulation. These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it could be misleading if it is used in a way to falsely suggest to the potential purchaser that the product is in some way less risky, better or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained the substance in the first place.

² For more detailed information, please refer to Chapter 17, Section III(A)(2) of EPA's Label Review Manual.

<u>Directions for Use section comment(s)</u>:

6. As required by PR Notice 2001-3, replace the existing section with: "Read and follow all directions and precautions on this product label. Tear open sachet near notched end. Remove and unfold wipe (towelette). Repellents should be applied only to exposed skin as directed on this product label. Do not use under clothing. Use just enough of this product to cover exposed skin. Heavy application and saturation is unnecessary for effectiveness. If biting insects do not respond to a thin film of repellent, apply a bit more. Do not apply near eyes and mouth, and apply sparingly around ears. Do not allow children to handle this product, and do not apply to children's hands. When using on children, apply product to your child yourself. Instruct older children in the proper use of this product. Do not apply more than 3 times per day to children ages twelve (12) and under. Reapply as necessary or after swimming or showering. Apply this product second if used in conjunction with a sunscreen product. After returning indoors, wash treated skin with soap and water or bathe. This is particularly important when repellents are used repeatedly in a day or on consecutive days. Also, wash treated clothing before wearing it again. NOTE: Do not apply on or near acetate, rayon, Spandex or other synthetic fabrics, nylon furniture, plastics (such as eyeglasses and watch crystals), leather and painted or varnished surfaces (including automobiles)."

Storage & Disposal section comment(s):

7. Replace the existing section with:

"STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **Pesticide Storage:** Store this product in a cool and dry (preferably locked) area inaccessible to children or pets and away from heat or open flame. **Pesticide Disposal: If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available."

<u>Precautionary Statements section, Hazards to Humans and Domestic Animals subsection</u> comment(s):

8. As required by PR Notice 2001-3, replace the existing section with: "Never use repellents over cuts, wounds or irritated skin. Causes substantial but temporary eye injury. Do not get in eyes. Do not apply to children's hands. Do not use on infants. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Use of this product may cause skin reactions in rare cases. If you suspect a reaction to this product, discontinue use, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent product with you."

<u>First Aid Statement (table) comment(s)</u>:

9. Replace the statement starting with "Have the product container...," with: "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 1-800-258-4696 or the National Pesticide Information Center at 1-800-858-7378.

³ Please note that the "1-800-258-4696" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

First Aid Statement (table) comment(s) cont'd.:

10. Insert the following text as a new row at the end of the existing First Aid section as follows:

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Physical and Chemical Hazards Statement comment(s):

11. Delete this section from the label. A revised version of the existing text from this section has been relocated to the Directions for Use section of the label under Item #6 above.

Company Name and Address Statement comment(s):

12. Delete the website "www.bens30.com" listed on the label since it is considered collateral labeling.

Tender Corporation should note that the Agency is in the process of developing and improving the current Efficacy Assessment Guidelines for repellent products. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines are complete. When the guidelines are finalized, the Agency expects to issue a Data Call-In to address the revised quidelines to all registrants with registrations for personal repellent products that have not previously submitted efficacy data sufficiently consistent with the revised quidelines.

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 FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions. A copy of your label for this product stamped "Accepted with Comments" is enclosed for your records. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via email at Rodia.Carmen@epa.gov.

> Richard J. Gebken Product Manager (10) Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 056575-00013 D385536



Don't Get Bitten - Get Ben's®

DIRECTIONS FOR USE

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

Read all directions and precautions on this product label Tear open sachet near notched end. Remove and unfold wipe (towelette), Apply to all exposed sidn. Apply sparingly around ears. Wash hands after applying: Do not use under clothing Avoid overexposure. Frequent reapplication and saturation is unnecessary for effectiveness. Do not apply to eyes, mouth or to the hands of young children. Do not allow children to handle this product. Apply product to your child yourself. Reapply as necessary or after swimming or showering. Apply this product second if used in conjunction with a sunscreen product. After returning indoors, washingted with sean and water. treated skin with soap and water.

Storage: Store in a cool, dry (preferably tocked) storage area inaccessible to children and pets and away from heat or open flame. Disposal: Do not reuse box or pouch. Place in trash or offer for recycling if available. Call your local solid waste agency (or 1-800-CLEANUP) for disposal instructions. Never place unused product down any indoor of outdoor drain.
PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals. WARNING ***

Do not apply over cuts, wounds or irritated skin. Causes substantial but temporary eye injury. Do not get in eyes. Do not let children rub their eyes if hands have been treated. Do not use on infants. Thoroughly wash skin with soap and water after use. May cause skin reactions in rare cases. If you suspect you or your child is reacting to this product, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent with you. Harmful if swallowed.

First Aid

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 missing eye Call a poison control center or doctor for treatment advice.
Immediately call a poison control center or doctor for treatment advice Have person sip a glass of water it unable to swallow Do not induce vomiting unless told to do so by a poison control center or doctor Do not give anything by mouth to an unconscious person

Have the product container or label with you when calling a polson control center or doctor or going for treatment (You may also contact 1-800-258-4698 for emergency medical

> Physical and Chemical Hazards Keep off synthetics, plastics, furniture and paints. May damage leather



PO Box 290 Littleton, NH 03561 Questions? Call 1-800-258-4696



02-2220RO

ACCEPTED with COMMENTS In EPA Letter Dated

January 7, 2008 Under the Federal Insecticide, Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Reg. No.

-3600217**07** printed

Approval date

1707/2006 11/13/2006

Tick & Insect Repellent WILL

Tick & Insect Repellent Repels insects that may carry West Nile Virus and other

biting insects

ick & Insec

Active Ingredient: DEET (CAS No. 134-62-3)....30%

Other Ingredients:...

Keep out of reach of children

WARNING: See back panel for additional precautionary statements.

Net Weight: 0.12 oz each Total Net Weight: 1.44 oz

Tick & Insect Repellent \![[:]