

74289-1

04-01-2010

1/4



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 1, 2010

Ms. Jean Killoren, Authorized Agent for
CoreTex Products, Inc.
c/o Killoren Regulatory Consulting
316 Highland Avenue
Hartford, WI 53027-1318

**Subject: Amended Labeling, Addition of Multi-Pack Size, Updates for Per PR Notice 2007-4 & DEET RED
BugX® 30 Insect Repellent, EPA Reg. No. 74289-1
Your Submission Dated January 5, 2010**

Dear Ms. Killoren:

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

General Comment(s):

1. Delete all text throughout the label marked with "strikethrough."
2. The words "**INSECT REPELLENT**" must be displayed prominently on the front panel of this label, immediately after the brand name, in capital lettering, with large, contrasting, **bold-faced** type.
3. In order to facilitate inclusion of a missing label comment that was included in the original Notice of Registration for the subject product, dated July 6, 2005 (copy enclosed), you must delete all use directions and references for products packaged in a towelette form. If CoreTex Products, Inc. desires to market a DEET towelette product, they are required to submit a separate registration. Please note that the "Me-Too" comparison product (Morflex DEET Insect Repellent 30, EPA Reg. No. 51147-7) (copy of label enclosed), which was referenced on behalf of your client's (CoreTex Products, Inc.) "Me-Too" application contains no towelette use directions/references. To include towelette use directions/references on the subject label would be a direct contradiction to the conditions of registration and must be removed for that reason.

Precautionary Statements, Hazards to Humans subsection comment(s):

4. Revise the existing 5th sentence to read "Wash hands thoroughly with plenty of soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."

First Aid Statement section comment(s):

5. Delete the existing 3rd line ("If you suspect a reaction to this product:") within this section since revised/updated language has been incorporated into the Directions for Use section.
6. Revise the "**HOTLINE NUMBER**" subsection to read "Have the product label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx."¹

Directions for Use, [Pump:] subsection comment(s):

7. In order to facilitate inclusion of revised label language that is required as part of the RED for DEET, revise the existing 3rd and 4th sentences to read "If used on the face, spray on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face."

¹ Please note that the "1-800-xxx-xxxx" telephone 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.

Directions for Use, [Tube, squeeze bottle:] subsection comment(s):

- 8. In order to facilitate inclusion of revised label language that is required as part of the RED for DEET, revise the existing 2nd and 3rd sentences to read "If used on the face, spray on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face."

Directions for Use section comment(s):

- 9. In order to facilitate inclusion of revised label language that is required as part of the RED for DEET:
 - Revise the existing 6th and 7th sentences of the 1st main paragraph to read "Do not apply to children's hands. Do not allow children to apply this product."
 - Insert the following text immediately following the existing 9th sentence of the 1st main paragraph: "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."

Storage and Disposal section comment(s):

- 10. Replace the existing "STORAGE:" subsection with "PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals."
- 11. In order to facilitate inclusion of language from PR Notice 2007-4, replace the existing "DISPOSAL:" subsection with "CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. *If empty:* Place in trash or offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."

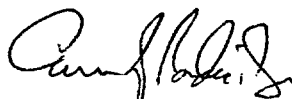
Optional Marketing Claims section comment(s):

- 12. Partially revise optional marketing claim #9 and delete optional marketing claim #19, since DEET in itself does have a scent. Alternatively, optional marketing claim #19 can be revised to read "Low Odor Formula."
- 13. Within optional marketing claims #24, #25, #26 and #30, replace the words "Over 7 hours" and "over 7 hours" with the words "Up to 7 hours" and "up to 7 hours."
- 14. Revise optional marketing claim #29 to read "Up to 7 hours of insect repellent protection."

A copy of your label stamped "Accepted with Comments" is 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 Rodia 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"
Copy of Conditions of Registration for EPA Reg. No. 74289-1, dated July 6, 2005
Copy of SAL for EPA Reg. No. 51147-7, dated October 25, 2004

January 5, 2010

Master Label

ACCEPTED
With COMMENTS
In EPA Letter Dated:

April 1, 2010

BugX® 30

Insect Repellent

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

| | | |
|---------------------|----------------|---------|
| ACTIVE INGREDIENTS: | <u>74289-1</u> | 30.0 % |
| DEET | | |
| OTHER INGREDIENTS: | | 70.0 % |
| TOTAL | | 100.0 % |

Keep Out of Reach of Children

WARNING

See additional precautions on back panel

Net Weight: oz (g)

~~(Contains 16 wipes, 8x6 inch (towel size))~~

PRECAUTIONARY STATEMENTS:

HAZARD TO HUMANS - WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Use of this product may cause skin reactions in rare cases. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

[Note to reviewer: Boxed format and bullets will be used in First Aid section if label space permits. If label space is limited a paragraph format will be used.]

| FIRST AID | |
|--|--|
| If swallowed: | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able 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. |
| 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. |
| If you suspect a reaction to this product: | <ul style="list-style-type: none"> • Discontinue use; • Take off contaminated clothing; • Rinse skin immediately with plenty of water for 15-20 minutes. |
| Call a poison control center or doctor for further treatment advice. Have the product label with you when calling a poison control center or doctor, or going for treatment. | |

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

[Note to reviewer: Alternate packaging for: tube, pump, squeeze bottle or towelettes.]

[Pump:]

Shake well before using. Evenly apply to skin before exposure to insects. To apply, to face, dispense (pump) on hands and then rub on face. Do not spray directly into face. Do not apply near eyes and mouth.

[Tube, squeeze bottle:]

Evenly apply to skin before exposure to insects. To apply to face, dispense (squeeze) into palm of hand and rub on. Do not apply near eyes and mouth.

~~[Towelette]~~

~~[Individual packs:]~~

~~Tear open envelope and unfold towelette. Wipe on a thin uniform film over all exposed skin except eye and mouth.~~

~~[Soft pack multi towelettes:]~~

~~Peel open label. Remove and unfold wipe. Reveal label (to save remaining wipes). Wipe on a thin uniform film over all exposed skin except eye and mouth.~~

Use just enough product (repellent) to cover exposed skin and/or clothing. Avoid over-application of this product. Do not apply over cuts, wounds or irritated skin. Do not use under clothing. Apply sparingly around ears. Do not apply to hands or near eyes and mouth of young children. Do not allow young children to apply this product. When using on children, apply to your own hands and then put the product on the child. Wipe palms after applying. After returning indoors wash treated skin with soap and water. Wash treated clothing before wearing it again.

[May damage certain synthetic fabrics, plastics, watch crystals, leather, and painted or varnish surfaces. Will not damage nylon, polyester, Dynel, Nalgene®, cotton or wool.]

[Note to reviewer: Boxed format will be used if label space permits. Paragraph format will be used if label is small.]

STORAGE AND DISPOSAL:

STORAGE: Store in a cool, dry place inaccessible to children. DISPOSAL: Non-refillable container. If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

4
4

Master Label

Made in the U.S.A.

Mfg. for:
CoreTex Products, Inc.
Bakersfield, CA 93308
1-877-684-5774

- ~~• 30% DEET in a water based formula~~
- 30% DEET
- ~~• Water based~~
- Insect repellent
- ~~Towelette~~ (Spray)
- Repels mosquitoes
- Repels biting insects for hours
- Repels mosquitoes, ticks, fleas, chigger, black flies, sand flies and deerflies
- Effective (~~scented/unscented~~) protection from mosquitoes, gnats, no-see-ums, sand flies, biting flies, deer flies, stable flies, black flies, ticks, chiggers, red bugs and fleas
- Just the right protection around the home and backyard
- Non-greasy
- Non-staining
- Resists perspiration
- Not greasy or oily
- Feels great on you, tough on bugs (too)!
- Effective dependable protection
- Pleasant (feel)
- Effective protection
- ~~• Fragrance free (Pleasantly scented)~~
- Repels mosquitoes that can carry west Nile Virus
- Great for picnics, barbecues, hiking, fishing and camping
- Easy to use
- Fits into pocket(s) (purse(s)) (fanny pack(s)) (backpack(s)) (tackle box(s)).
- Over 7 hours of maximum effective protection against mosquitoes
- Over 7 hours of protection against mosquitoes
- Over 7 hours of complete protection from mosquitoes bites
- BugX 30 is specially formulated, effective, dependable protection.
- Developed especially for travelers, campers, backpackers, fisherman, hunters, golfers, bikers, cyclist, hikers, trekkers, joggers, ball payers and active outdoors people who want the protection of DEET without the oily feeling.
- Provides hours of insect repellent action.
- Provides over 7 hours of mosquito repelling action.
- Does not feel greasy or oily, won't stain and resists perspiration.
- Perfect for: (home), (purse), (backpack(s)), (backpacking), (camping) and (traveling).

() optional text

Optional bullet points:

- Contains DEET