4822-469

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

April 24, 2005

Kelly K. Naujock Registration Specialist S. C. Johnson & Son, Inc. 1525 Howe Street Racine, WI 53403

Subject: Re-submission of an amendment to product labeling in accordance with the Federal Fungicide and Rodenticide Act as Amended. Product Name: Repellent LMO Registration Number: 4822-469 Date of Submissions: July 2, 2004 and April 21, 2005 respectively OPP Identifier Number: none.

Dear Ms. Naujock;

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

- 1. Remove the marketing claim for the repellent LMO product that was submitted without verifying efficacy data to support this claim and therefore, is unacceptable for use with this pesticide product.¹
 - Tested in the most extreme mosquito conditions
- 2. The claim "**Doesn't use citronella**." must be removed from the table on page 2, because it is claim used in a false and misleading way.²

¹ SCJ may submit supporting data to add these claims for review under PRIA.

² CLAIMS ABOUT THE ABSENCE OF AN INGREDIENT: 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.

- 3. All statements regarding Bitrex, other than the Trademark reference, is limited solely to "Contains Bitrex." Therefore, remove the following statement entirely from all locations on the label:³
 - "Pad is designed to taste bitter to help prevent ingestion." Located on pages 3 (2 locations) and page 5 [3 locations]).

The attached master label shall supersede all previously submitted labels, and under 40 CFR Sec. 152.130 Distribution under approved labeling, SC Johnson may distribute or sell under the previously approved labeling for this product, for a period of 18 months after April 24, 2005.

If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

K: hand I lead

Richard Gebken Product Manager 10 Insecticide Branch Registration Division (7505C)

³ The Bitrex studies that we have examined have indicated that Bitrex does not prevent exposures of humans and animals and that the extent to which ingestion is limited by the presence of Bitrex seems to vary among individual humans and may be age related. With baits and other products used around the home, we are especially interested in protecting very young children who might not respond to Bitrex in the manner of older children and adults. Our expert in child-resistant packaging has indicated that the Consumer Product Safety Commission's analysis of the situation with respect to Bitex and humans was that there was no clear evidence that Bitrex makes products safer. Absolute or comparative safety claims on labels or labeling for pesticide products are not permitted within FIFRA and such claims are considered to be "false and misleading" [40 CFR, 156.10(a)(5)(ix).and (x)]. Regardless of the intention behind it, the claim implies that the products for which the claim is made are safer than others for which no such claim is made. A claim to the effect that something has been added to the product in order to make it less hazardous to children, pets, and/or other animals also would be likely to detract from required precautionary statements and would be false and misleading on that basis as well.

Labeling for the Outer Packaging for the Lamp, the Lantern, and the Refill Unit

Repellent LMO

Keep out of reach of children.

CAUTION: For detailed use directions and safety information, see (side) (back) (bottom) panel(s).

NET WT.: XX oz. SC Johnson A Family Company

CONTAINS: X Reusable Lamps X Mosquito Repellent Pads X Candles X Refills X Reusable Lanterns X Pole Segments

(Repellent LMO) Mosquito Repellent Pads (included) Mosquito protection for areas up to 15 feet by 15 feet Repels mosquitoes from an area up to 15 feet by 15 feet (225 SQ. FT.) Candle creates a pleasant glow while warming repellent pad for effective mosquito protection (in an area as large as 15 feet by 15 feet) Repellent LMO effectively repels mosquitoes from an average size patio for hours Repeis mosquitoes from an averaged size (deck)(patio) Each pad provides (effective) (fragrance free) protection for up to 4 hours Each pad lasts up to 4 hours Each candle and pad lasts up to 4 hours Up to 4 hours of protection No exposed flame when in use Convenient Easy to use Easy to assemble Portable No tools required for assembly pad technology repels mosquitoes? Don't forget to purchase Repellent LMO refills Works with Repellent LMO refills Also available Repellent LMO ACCEPTED Sample inside with COMMENTS Free refills In EPA Letter Baled: Added refills inside Heat activated repellent pad APR 2 4 2005 Contains X PowerPad refills Under the Federal Exceptible, Patented PowerPad technology Fungichie, and Rodemicida Ast, es amenied, for the peatieldo registered under LPA light No. 4822-469 Not just a candle, contains a repellent pad It's in the pad The power to repel is in the pad Enclosed flame No Scent

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Repels mosquitoes in the (woods)(outdoors)(great outdoors)(backyard)(park)(forest) for up to 4hours **OFF! Protection That Glows** Repels mosquitoes that may carry West Nile Virus Stock up on Off! for the summer Off! for your next party Most trusted mosquito repellent America's favorite repellent Free Take back your backyard Contains no messy oil Stay out late with the product bugs hate Protection and ambiance Mosquito defense system Insects hate us people love us Great for (BBQs)(picnics) (Mosquito) Protection that you can enjoy Effective mosquito protection you don't have to put on This really works! Proven protection from mosquitoes Take the challenge A back yard necessity Perfect for parties Protect (your family)(the ones you love) from mosquitoes Party approved **OFF!** Defense Use with confidence Extends your (home)(outdoor) living area Enhances your outdoor experience Outdoor activity without annoying mosquitoes Maximize your outdoor experience Get ready for the summer (Family)(Camping)(Mosquito Protection) kit OFF! For every occasion Entomologist developed Free your family from (annoving) mosquitoes Repels mosquitoes before they get you OFF! is a complete line of mosquito protection for every situation (Multi-Pack)(Twin)(Bonus)(Value)(Variety)(Backyard)(Barbeque)(Pack) Buy One Get One Free Keep bugs OFF! without anything on Great protection no mess Great repellency no mess The OFF! that you don't put on Just light it and relax Light up your night Mosquito protection that lasts all evening The original Effective repellency against mosquitoes which may carry West Nile Virus Tested in the most extreme mosquito conditions Protection Chart OFF! ® PowerPad Does not use citronella. Uses heat activated repellent pad. √ Repels mosquitoes from an area up to 225 SQ, FT. $\sqrt{}$ Repels Mosquitoes that may carry West Nile Virus $\sqrt{}$

Each pad last up to 4 hours

Helpful Hints

Protection is not immediate.

Allow time for candle to heat (mosquito repellent) pad.

High humidity may increase time before repellent is released.

Pads are designed to release repellent when heated by candle.

Pad color will change during use.

Do not change pad until candle is used up.

When candle is used-up and will not relight, replace both candle and pad.

Expect a small amount of wax to remain in bottom of candle cup.

Change candle and pad at same time.

KEEP LEVEL

To avoid fire hazard, do not place pads, matches or other foreign matter on or in candle cup.

Use one (Repellent LMO) in an area as large as an average size deck or patio

Use one (Repellent LMO) in an area as large as 15' by 15'

Use two or more (Repellent LMO) in larger areas.

It is normal for the pad to emit some smoke when product is in use.

Pad is designed to taste bitter to help prevent ingestion.

Be sure to wash hands after handling.

Contains Bitrex.

Bitrex ® is a trademark of Macfarlan Smith, Ltd.

(For maximum protection) place product upwind.

To clear mosquitoes from under table, place underneath (table) for a few minutes.

Make sure pole is inserted securely and straight.

Test to ensure pole does not tip easily

Do not use hammer to insert pole.

If ground is too hard, use water to soften ground.

X-piece sectional pole included.

Assembles to (approximately) X feet (high).

Gently slide narrow end of pad into slot in top of unit

Precautionary Statements

Hazards to humans and domestic animals

Caution: Harmful if swallowed or inhaled. Avoid breathing vapors. Keep out of reach of children. For outdoor use only. Do not use indoors, in a tent or enclosed area. Attention, colored vent top is hot while in use.

Pad is designed to taste bitter to help prevent ingestion. Be sure to wash hands after handling.

First aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed: 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 told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Environmental hazards

This pesticide is highly toxic to fish. Do not apply directly to water. Drift from treated areas may be hazardous to organisms in adjacent aquatic sites.

Physical and chemical hazards

{Note: These physical and chemical hazards will be used when the product is sold as a lamp unit}

Place on level, stable surfaces. Do not cover lamp top with any foreign material while in use. Before lighting candle make sure wick is trimmed to ¼ inch. To avoid fire hazard, do not place pads, matches or other foreign matter near candle flame. Never cut, bend or alter shape of pad. Pads may cause staining – avoid contact with other surfaces. Do not place Repellent LMO near combustible materials such as dry vegetation, clothing, or fuels. NEVER BURN CANDLE UNATTENDED. Failure to follow these instructions could result in personal injury or property damage.

Do not use anything other than Repellent LMO pads and candles in lamp. To the fullest extent permitted by law S.C. Johnson & Son, Inc. shall not be liable for damage, injury or poor performance caused by the use of other pads and candles.

{Note: These physical and chemical hazards will be used when the product is sold as a lantern unit}

Do not cover lantern top with any foreign material while in use. Before lighting candle make sure wick is trimmed to ¼ inch. To avoid fire hazard, do not place pads, matches or other foreign matter near candle flame. Never cut, bend or alter shape of pad. Do not move when lit. Use pole per instructions; do not use for any other purposes. Do not remove hanging lantern from pole. Make sure pole is inserted securely (and straight). Remove all pole segments from ground when not in use to minimize tripping hazard. TEST TO ENSURE POLE DOES NOT TIP EASILY. Do not place near underground wires or gas lines. Pads may cause staining – avoid contact with other surfaces. Do not place Repellent LMO near combustible materials such as dry vegetation, clothing, or fuels. NEVER BURN CANDLE UNATTENDED. Failure to follow these instructions could result in personal injury or property damage.

Do not use anything other than Repellent LMO pads and candles in lamp. To the fullest extent permitted by law S.C. Johnson & Son, Inc. shall not be liable for damage, injury or poor performance caused by the use of other pads and candles.

{Note: These physical and chemical hazards will be used when the product is sold as a refill unit}

Do not cover unit top with any foreign material while in use. Before lighting candle make sure wick is trimmed to ¼ inch. To avoid fire hazard, do not place pads, matches or other foreign matter near candle flame. Never cut, bend or alter shape of pad. Pads may cause staining – avoid contact with other surfaces. Do not place Repellent LMO near combustible materials such as dry vegetation, clothing, or fuels. NEVER BURN CANDLE UNATTENDED. Failure to follow these instructions could result in personal injury or property damage.

Do not use anything other than Repellent LMO pads and candles in lamp. To the fullest extent permitted by law S.C. Johnson & Son, Inc. shall not be liable for damage, injury or poor performance caused by the use of other pads and candles.

STORAGE: Prolonged storage of repellent pads in outdoor conditions may decrease effectiveness. Store unused pads in an area inaccessible to children and pets. DISPOSAL: Before disposing, empty package by using the product according to the label. Used Pad: Place exhausted pad in trash or offer for recycling if available. Candle: After allowing exhausted candle to cool, place cup in trash. Unused pads: Call your local solid waste agency or 1-800-529-3394 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Directions for Use: It is a violation of federal law to use this product in a manner that is inconsistent with its labeling.

{Note: These directions for use will be used when the product is sold as a lamp unit}

Locate lock tabs on unit base, press to release and lower frame. Remove enclosed contents. Firmly press candle cup onto base post. Light candle. Remove repellent pad from package being careful not to cut, bend, or alter pad shape. Insert OFF! PowerPad into middle slot on top. Pad is designed to taste bitter to help prevent ingestion. Raise frame base and snap into place. Move lamp only when cool and not in use. To avoid fire hazard, do not place pads, matches or other foreign matter on or in candle cup. When finished using, carefully remove frame base and blow out candle. Pad is designed to last as long as candle.

To replace pad/candle combination: _.

When candle is used up and will not relight, replace both candle and pad.

Remove lamp top. Make sure flame is extinguished and lamp is cool before changing pad. Pull out used pad and slide in new pad. Remove used candle cup and firmly press new candle cup with fresh candle onto base post. To avoid fire hazard, use only OFF! candles in lamp. Light candle. Raise frame base and snap into place. Avoid contamination of food.

{Note: These directions for use will be used when the product is sold as a lantern unit}

Use connectors to assemble rods. Push pole into stable ground. Test to ensure pole does not tip easily. Locate lock tabs on unit base, press to release and lower frame. Remove enclosed contents. Firmly press candle cup onto base post. Light candle. Remove repellent pad from package being careful not to cut, bend, or alter pad shape. Insert OFF! PowerPad into middle slot on top. Pad is designed to taste bitter to help prevent ingestion. Raise frame base and snap into place. When finished using, carefully remove frame base and blow out flame. Pad is designed to last as long as candle. To avoid fire hazard, do not place pads, matches or other foreign matter on or in candle cup. Use one Repellent LMO in an area as large as 15' by 15'. Use two or more in larger areas. Allow time for candle to heat mosquito repellent pad. When candle is used up and will not relight, replace both candle and pad. Expect a small amount of wax to remain in bottom of candle cup. (Change candle and pad at same time.) Place product upwind for maximum protection.

To replace pad/candle combination:

When candle is used up and will not relight, replace both candle and pad. Lower lantern from base. Make sure flame is extinguished and lantern is cool before changing pad. Pull out used pad and slide in new pad. Wash hands. Remove used candle cup and firmly press new candle cup with fresh candle onto base post. To avoid fire hazard, only use OFF! candles in lantern. Light candle. Raise frame base and snap into place. Avoid contamination of food. Cleaning instructions:

Before cleaning lantern, extinguish flame and let lantern cool. Wash with a wet cloth only. Note: To avoid damaging product, be careful not to move or bend metal bar inside of lantern when cleaning. Be sure to wash hands after handling.

{Note: These directions for use will be used when the product is sold as a refill unit}

To replace pad/candle combination:

Pads are designed to release repellent when heated by candle. When candle is used up and will not relight, replace both candle and pad. Avoid contamination of food. Detach unit top from base. Make sure flame is extinguished and unit is cool before changing pad. Remove used pad from top of unit. Remove new repellent pad from package being careful not to cut, bend, or alter pad shape. Gently slide narrow end of pad into slot in top of unit. Pad is designed to taste bitter to help prevent ingestion. Important: Remove used candle cup and firmly press new candle cup with fresh candle onto base post. Light candle. Reattach unit top and base. Do not place repellent pad or matches on or in candle cup.

EPA Reg. No. 4822-469 EPA Est. No. XXXX-XX (...) Lot number suffix (...) indicates appropriate establishment number. US Pat.6,337,080 & 6,663,838 & 6,503,459 Questions? Comments? Call 800-558-5252 or write Helen Johnson Sold by: @2004 S.C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A. All Rights Reserved www.mosquitoes.com Pads made in Italy Candles made in Canada.

Labeling for the Vent Top

Attention Hot Surface Slide Pad in Center Slot

Labeling for the Lamp Base

KEEP OUT OF REACH OF CHILDREN

If pad is swallowed, call 1-800-558-5252. Do not use indoors, in a tent or enclosed area. Read Directions for Use and Precautionary Statements on outer package carefully. Use only OFF! pads and candles. NEVER BURN CANDLE UNATTENDED. Do not place near combustible materials such as dry vegetation, clothing or fuels. Place on a level, stable surface. Make sure pole is inserted securely. Do not remove hanging lantern from pole. Do not move when lit. Manufactured for: S.C. Johnson & Son, Inc., Racine, WI 53403-2236. US PAT.: (XXX), patent pending.

Labeling for the Pad Pouch

OFF! Repellent Pad OFF! PowerPad KEEP OUT OF REACH OF CHILDREN. CAUTION HARMFUL IF SWALLOWED OR INHALED SEE OUTER CARTON FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

Questions? Comments? Call 800-558-5252 or write Helen Johnson. Sold by:@2004 S.C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A. All rights reserved. Made in Italy. EPA Reg. No. 4822-469. EPA Est. No. 43917-ITA-1

Net Contents: 1 PAD Net Wt.: .057 oz. S.C. Johnson, A Family Company

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Bitrex (18) is a trademark of Macfarlon Smith, LTD. Contains Bitrex. Be sure to wash hands after handling.

Labeling for the Insert

. Be sure to wash hands after handling. Bitrex **®** is a trademark of Macfarlon Smith, LTD. Remove this insert before using. Pads are designed to release repellent when heated by candle.

Pad color will change during use. Do not change pad until candle is used up. When candle is used up and will not relight, replace both candle and pad. Expect a small amount of wax to remain in bottom of candle cup. Change candle and pad at same time.

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