

United States Environmental Protection Agency

Mr. Stuart McArthur
Senior Registration Specialist
S. C. Johnson & Son, Co.
1525 Howe Street
Racine, WI 53403-2236

NOV - 2 2007

Subject: Response to Label Revisions and addition of alternate CSFs
Product Name: NORM I
Registration No.: 4822-542
Date of Submission: 6 August 2007

Dear Mr. McArthur;

The proposed alternate confidential statement of formulas (CSF) dated 6 August 2007, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. These CSFs have been added to the registration file for the aforementioned product.

The label modifications submitted are acceptable, unless identified below.

The following marketing claims are not supported by product performance data and must be removed from the label, or modified as indicated:

A. Efficacy claims:

- Repels mosquitoes
2. (Tested) (Proven to) (repel Mosquitoes) (work)
4. (Provides a) 5' X 5' Area of protection (from mosquitoes) for up to 12 hours
13. Proven effective

B. Longevity Claims:

- 1. (Provides) (Enjoy) (A 5' X 5" area of) (Effective) (Protection) (from mosquitoes) For (Up To) (6), (7), (8), (9), (10), (11), (12) (Hour)(s) (of protection) (from Mosquitoes).

D. "Technology" Claims:

- 1. (Patented) (Laboratory) (Field) (Tested) (fan-aided) (innovative) Technology
2. New
5. (Quiet) (Built-in) fan (disperses) (circulates) (a new kind of) (the) (repellent) (all around you).

E. "Convenience/Portability" Claims:

- 2. (Unsurpassed) (Superior) (Comfort) (Convenience) (and) (Portability) compared to OFF!® (Insect Repellents) (skin applied repellents)

F. "No Skin Application" Claims

- 7. Effective mosquito protection you don't put on your skin.

G. Usage Claims:

CONCURRENCES

Table with 9 columns and 3 rows. Row 1: H7505P, empty, empty, empty, empty, empty, empty, empty, empty. Row 2: MSUAREZ, empty, empty, empty, empty, empty, empty, empty, empty. Row 3: Nov 2, 2007, empty, empty, empty, empty, empty, empty, empty, empty.

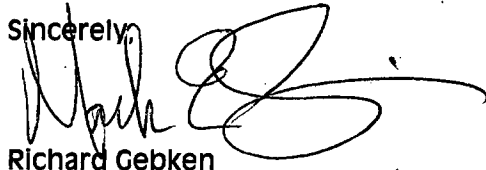
4. Device may also be placed on a table, (bench) (or other suitable surface) away from food, *drink*, and sources of heat, ignition or moisture.

The label amendment submitted is accepted conditionally.

Submit two (2) copies of the revised final printed label for the record.

If you have any questions, you may contact Mark E. Suarez, at (703) 305-0120.

Sincerely,



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

enclosures

004822-00542 D385712
004822-00542 S814570-ER

EPA Master Name: **NORM 1** (Version 8/6/07)
OFF!® (Personal) Insect Repellent [alternate brand name]

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV - 2 2007

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
4822-542**

GENERAL CLAIMS:

Efficacy claims:

1. Repels mosquitoes
2. (Tested) (Proven to) (repel Mosquitoes) (work)
3. (Portable) Protection
4. (Provides a) 5'X5' Area of protection (from mosquitoes) **for up to 12 hours**
5. Protection for (outdoor occasions)
6. Tested in the Everglades
7. **Effective** (protection) (repellency) no mess
8. Repels (Mosquitoes), (not people)
10. As you move (from place to place), [Product Name] rebuilds its protection in a few minutes
11. In just a few minutes, [Product Name] creates a(n) area of personal protection from mosquitoes.
12. Environmental factors such as wind may affect the area of protection
13. Head-to-Toe Protection
14. **Proven effective**

Longevity Claims:

1. (Provides) (**Enjoy**) (A 5' X 5" area of) (Effective) (Protection) (**from mosquitoes**) For (Up To) (6), (7), (8), (9), (10), (11), (12) (Hour)(s) (of protection) (from Mosquitoes).

Refill Claims:

1. (**Replace**)(Each) (refill) (provides) (effective) (personal space) (protection) (lasts) (up to) (**after**) (6), (7), (8), (9), (10), (11), (12) hours (protection) (per refill) (**or**) (**xx hours after opening**) (**or**) (**when blue indicator is gone**).
2. Replace refill and battery (ies) (at the same time) after (6), (7), (8), (9), (10), (11), (12) hours
3. Sample inside
4. Free refills
5. Added refills inside
6. (Do not) (Don't) forget (to purchase) (product name) (your) refills
7. Works with (product name) (repellent) (fan) (device) (unit)
8. For best results, we recommend that the refill be used within (#) (weeks) (months) of opening
9. **Refills available**
10. (**Multiple-use**) (**reusable**) **refills (up to 12 hours)**
11. **Use each refill multiple times (up to 12 hours)**
12. **Remainder of (6), (7), (8), (9), (10), (11), (12) hour refill can be used at a future time.**

"Technology" Claims:

1. (Patented) (Laboratory) (Field) (Tested) (fan-aided) (innovative)Technology
2. New
3. (Fan powered) outdoor protection
4. (Fan) (activated) repellent (pad)
5. (Quiet) (Built-in) fan (disperses) (circulates) (**a new kind of**) (the) (repellent) (**all around you**).
6. **Scientifically engineered.**
7. (**Vents**) (**air exits**) **out the bottom to repel mosquitoes (from where they hunt).**

"Convenience/Portability" Claims:

1. Portable (Light) (Small)
2. (Unsurpassed) (Superior) (Comfort) (Convenience) (and) (Portability) compared to OFF!® (Insect Repellents) (skin applied repellents)
3. Easy to use
4. Portable protection
5. (Take) (the) (Portable) (Outdoor) Protection (with you) (that goes with you) (that stays with you) (that) (allows) (lets) (you) (to) (enjoy) (the outdoors) (your outdoor) (activities) (events) (fun).
6. (Easy to use) (Convenient) (No liquid) (refills)
7. Created for your (outdoor) (active) lifestyle
8. Protection (for people on the go) (that fits your) (outdoor) (active) lifestyle
9. (Place) (Carry) (Have) (take) **unused** (product name)(one): (everywhere) (in) (your) (purse) (glove compartment) (glove box) (golf bag) (tennis bag) (tackle box) (tent) (book bag) (backpack) (fanny pack) (beach bag) (boat) (summer cabin) (first-aid kit)
10. **Outdoor Usage (Occasions) (Locations)**
For use (in) camping, fishing, hunting, boating, (in) the backyard, on the go, at sporting events, (while) gardening, playing (outside), (entertaining), (relaxing on), patio or deck, (away-from-home) (activities) (events), **the beach**, (at) the park, (outside)

"No Skin Application" Claims

1. **No skin application**
2. **Portable Protection You Don't Have To (put on), (spray on), (rub on)**
3. **(The) OFF!® (Personal Protection) (Repellent) you (do not) (don't) (need to) (put) (spray) on)**
4. **Mosquito control for sensitive skin**
5. **Nothing to apply**
6. **(Not messy) (no mess)**
7. **Effective mosquito protection you don't put on your skin.**

Usage Claims:

1. Clip-on Insect Repellent
2. (Specially designed to) Clip(s) onto (your) (belt), (pants), (shorts) (waistband) (purse) (or) (sit on a flat surface).
3. Device may also be placed on a table, (bench) (or other suitable surface) away from food and sources of heat, ignition or moisture.
4. Battery (ies) (not) included
5. (Just) Clip-It
6. (Ergonomic) (comfortable) (light) (portable) design
7. For outdoor use only.
8. Do not use indoors
9. Battery operated
10. Does not (require) (use) heat (to operate)
11. Refillable (**replaceable disk**)
12. **Don't spray it on (,)(.) Clip it on.**

Disease carrying mosquito claims:

1. (Repel(s)) (Protect(s) Against) Mosquitoes That May Carry (West Nile Virus), (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) (**or**) (Venezuelan) (equine encephalitis)

Marketing Claims:

1. (Multi-pack) (twin) (Bonus) (Value) (Variety) (Backyard) (Barbeque) (Pack)
2. Buy one get one free
3. Money back (guaranteed) (guarantee)
4. Odorless
5. Unscented
6. Fragrance Free
7. Get the OFF!® mosquito protection that is right for you.
8. (Contains) (with) (Metofluthrin) (S1264)
9. Visit www.OFFprotects.com for more information
10. Keep(s) Bugs OFF! ®
11. **Up to 12 hours** of protection from mosquitoes
12. Additional Information (about) (Product Name) (repellent) (fan) (device) (unit)

RETAIL CONTAINER LABELING: STARTER KIT AND REFILL

[PRODUCT NAME]

CAUTION:

(KEEP OUT OF REACH OF CHILDREN)

(Do not allow children or pets to (handle) (play with) the unit.)

See additional (precautions) (and instructions) on back.

Do not use indoors or in enclosed spaces.

ACTIVE INGREDIENT:

Metofluthrin31.2%

OTHER INGREDIENTS..... 68.8%

Total.....100.0%

NET WT. (XXX) (OZ) (Grams)

(Starter Kit) Contains 1 [Product Name] (mosquito) (repellent) (fan) (device) (unit), (1) (2)

(mosquito) (repellent) Refill(s) (Discs) (Disks) (Cartridges), and 2 (battery type, e.g. AA) batteries

(Refill) Contains (1) (2) (3) [Product Name] (mosquito) (repellent) refill(s) (discs) (disks)

(cartridges)

Net Weight XX oz. (each)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

CAUTION: Harmful if swallowed, inhaled, or absorbed through the skin. Avoid contact with skin, eyes or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Store away from food, beverages and pet food. Do not use indoors or in enclosed spaces. Do not touch device with metal instruments or wet hands. Do not allow materials of any kind to cover the unit while it is in use. Replace refill only when unit is off.

(Note viewer: Boxed format or bullets may be used in First aid section if label space permits)

FIRST AID Call a poison control center or doctor immediately for treatment advice.

If Swallowed: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

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.

Page 4

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

For additional information in case of emergency call toll free 800-558-5252.

Hand Wash Logo:

Be sure to wash hands after handling.

ENVIRONMENTAL HAZARDS

Do not apply to water.

PHYSICAL & CHEMICAL HAZARDS – Do not pry open or probe into device with any instrument or tool. Use only with (Number) (Type) battery (ies). Do not cover the device when in use or place it near sources of heat or ignition. Do not store near heat or open flame. Do not put battery in fire or mutilate. **Battery(ies)** may burst or release toxic materials.

Supplemental (additional) Directions:

1. **Insert repellent disk.**
2. **Turn unit "On."**
3. **Clip unit onto waistband or place on table next to you.**
4. **Turn "Off" when finished. Remainder of 12 hour refill can be used at a future time.**

See inside for complete usage directions.

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.

Batteries are included.

To prepare (device) (unit) (To insert repellent (refill) (disk)):

1. For initial use **only**: **Open the battery door on the back of the device.** Pull red tab to activate batteries. **Replace the battery door.** [For Starter Instructions only]
2. Remove one mosquito repellent (refill) (disk) from its packaging and remove peel-off seal.
3. Open the **front cover and slide (refill) (disk) under the (locating) tabs, then snap the front cover latch closed.**

To operate unit:

1. Slide the ON/OFF switch to "ON" (**fan symbol**).
2. Clip the **unit** to your belt, pants/short waistband, purse or any other convenient location.
TIP: You can also place the unit next to you on a table, bench or other suitable (hard) surface (away from food and sources of heat, ignition or moisture.) (When placing unit on a surface, lay the unit on its **clip** to allow open circulation of repellent.
TIP: Within a few minutes [Product Name] (fan) (device) (unit) creates a 5' x 5' area of personal protection from mosquitoes for up to (6), (7), (8), (9), (10), (11), (12) hours. If you move, allow a few minutes for the [Product Name] (fan) (device) (unit) to rebuild **(an) (the) (its) (area of) (head-to-toe)** protection.
3. When finished using the product, turn the ON/OFF switch to ("OFF") (**off symbol**).
TIP: Between uses, close the unit to prolong the refill's life. Store [Product Name] (the unit) in the ("OFF") (**off symbol**) position in a cool, dry place – **never in a hot car, glove compartment, or trunk.**
TIP: For best results, replace the refill (within) (after) (#) weeks of opening or after 12 hours total use (when the blue indicator is gone). Repeat steps 1 and 2.

NOTE: When the fan no longer runs, replace with two new AA batteries. Batteries will last for up to (xx) hours of use.

NOTE (For Starter Instructions) (For Refill Instructions)(For Refill Pouch): Only (Product Name) refill disks should be used in the (Product Name) (unit) (device).

STORAGE: Store away from heat or flame in an area inaccessible to children.

DISPOSAL: Before disposing, fully use up the refill according to the label. Do not reuse the (refill) (cartridge). If Empty: Place in trash or offer the (refill) (cartridge for recycling if available. If refill remains partially unused: Call your local solid waste agency or 1-800-529-3394 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions? Comments? Call 800-558-5252 or Write Helen Johnson ©(YEAR) S.C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All Rights Reserved

EPA Reg. No. 4822-542

EPA Est. No. 4822-WI-1

FAN UNIT (Delivery Device) And REFILL POUCH:

[Product Name]

CAUTION

(KEEP OUT OF REACH OF CHILDREN)

(Do not allow children or pets to (handle) (play with) the unit.)

See additional precautions (and instructions) on refill (container) (box).

Do not use indoors or in enclosed spaces.

ACTIVE INGREDIENT:

Metofluthrin31.2%

OTHER INGREDIENTS..... 68.8%

Total.....100.0%

EPA Reg. No. 4822-542

EPA Est. No.

Net Weight

Questions? Comments? Call 800-558-5252 or Write Helen Johnson ©(YEAR) S.C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All Rights Reserved

EPA Reg. No. 4822-XXX

EPA Est. No. 4822-WI-1