

4822-605

5/21/2014

1/11



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAY 21 2014

Jean M. Fugate
S.C. Johnson & Son, Inc.
1525 Howe St.
Racine, WI 53403-2236

Subject: Notification to Correct Typos and Add Optional Marketing Claims
Product Name: San Diego
EPA Registration Number: 4822-605
Submission Date: April 29, 2014
Decision Number: 491317

Dear Ms. Fugate:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated April 29, 2014 for the product 4822-605. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10.

If you have any questions, please call me directly at 703-305-6701 or Carlyn Petrella of my staff at 703-347-0439.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard Gebken".

Richard Gebken
Product Manager / Team Leader (10)
Insecticide Branch
Registration Division (7505P)
Office of Pesticide Programs



Unit States
Environmental Protection Agency
 Washington, DC 20460

- Registration (REGFEE)
- Amendment
- Other

OPP Identifier Number
NOTIFICATION 2/11
MAY 21 2014

Application for Pesticide - Section I

1. Company/Product Number S.C. Johnson & Son, Inc./4822-605	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) S.C. Johnson & Son, Inc./San Diego	PM# 10	
5. Name and Address of Application (Include ZIP Code) S. C. Johnson & Son, Inc. 1525 Howe St. Racine, WI 53403-2236 <input type="checkbox"/> Check if this is a new address.	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	

Section II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
--	---

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Notification of minor label changes per PR Notice 98-10.
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms or PR Notice 98-10 and 40CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes * <input checked="" type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.00485 – 0.0727 oz	No. Per container 1-12	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.	No. Per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Laminated pouch)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.00485 – 0.8724 ounces		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Jean M. Fugate	Title Lead, Regulatory Affairs Registration	Telephone No. (Include Area Code) (262) 260-2871
Certification		6. Date Application Received (Stamped)
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title Lead, Regulatory Affairs Registration	
4. Typed Name Jean M. Fugate	5. Date 29 April 2014	

29 April 2014

Mr. Richard Gebken
Product Manager 10
Document Processing Desk
Registration Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Via courier

cccc
cccc
cccc
e
e e e
eo ee
eooo
eooo
o
oooo
oooo
oooo
oooo

***Re: San Diego, EPA Reg. No. 4822-605
Notification of Minor Label Changes per PR Notice 98-10***

Dear Mr. Gebken:

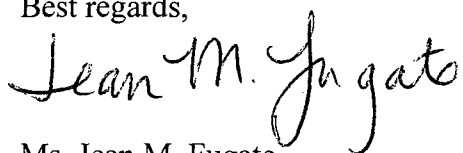
S.C. Johnson & Son, Inc. (SCJ) would like to notify the Agency of minor changes to the subject product label. First, we have incorporated labeling feedback provided per the Notice of Registration issued March 28, 2014 to add the assigned EPA Reg. No. "4822-605" and delete "sanctuary" from an optional marketing statement. We have also enhanced a referral statement and corrected a couple of typographical errors. An optional marketing statement was added that is a truncated version of several other currently-approved statements. Lastly, we have also added options to include references to SCJ branding and sub-branding and listed as optional marketing statements the names of the various components for this product - "Caddy", "Diffuser", "Candle", and "Lamp."

No data are being submitted in support of this action, and we believe no PRIA fee is due. Attached for your review please find the following:

- Completed application form
- One copy of the label with additions marked in *bold blue italics and highlighted in yellow* and deletions marked in ~~red strikethrough and highlighted in yellow~~

Thank you for your assistance with this action. Should you have any questions please do not hesitate to contact me.

Best regards,



Ms. Jean M. Fugate
Lead, Regulatory Affairs Registration
Phone: (262) 260-2871
Fax: (262) 260-4716
Email: jmfugate@scj.com

4/11

[Information in brackets is notes to Reviewer]
(Information in parentheses is optional language)

San Diego

ACTIVE INGREDIENT:

Metofluthrin 9.10%
OTHER INGREDIENTS..... 90.90%
Total..... 100.00%

NOTIFICATION

MAY 21 2014

KEEP OUT OF REACH OF CHILDREN AND PETS

CAUTION:

See additional (precautions) (and instructions) on (back) (side)(and)(bottom)(panel(s)) (outermost package).
Do not use indoors or in enclosed spaces.

(Net Weight:) X oz (X grams)

((Starter Kit) (Contains)

[insert quantity] ([Product Name branding or sub-branding]) (mosquito) (repellent) (Lantern(s))
(Lamp(s)) (Light(s)) (Device(s)) (Unit(s)) (and) (holder(s)) (caddy(caddies)) (cradle(s))
[insert quantity] ([Product Name branding or sub-branding]) (mosquito) (repellent) (refill(s))
(diffuser(s))
[insert quantity] candle(s)

(Refill) (kit) Contains (1) (2) (3) ([Product Name branding or sub-branding]) (mosquito) (repellent) (refill(s))
(diffuser(s))
[insert quantity] candle(s)

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.

Use one (lantern) (lamp) (light) (device) (unit) in a (10' x 10' area) (100 square foot area) (10 foot by 10 foot area). Use two or more in larger areas.

For outdoor use only. Do not use in a tent or enclosed area.

Attention: (Repellent) (refill) (diffuser) surface is hot while burning, do not touch.

[Numbers or bullets may be used for the listed steps below]

(Lantern) (Lamp) (Light) (Device) (Unit) Set-up:

Lift the candle (holder) (caddy) (cradle) out of (lantern) (lamp) (light) (device) (unit) and place candle at the bottom before lighting (as shown).

Trim wick to (¼ inch) (¼ ") (or less) (before each lighting.)

Light the candle while in the (holder) (caddy) (cradle) and lower back into (lantern) (lamp) (light) (device) (unit).

Remove repellent (refill) (diffuser) from package and place on top of (holder) (caddy) (cradle).

When finished using lift (holder) (caddy) (cradle) and snuff out the candle flame.

((Hand Wash Logo) Wash hands after handling ((treated) puck) ((treated) sandcore) (repellent) (refill) (diffuser) (housing) (surface)).

Candle and heat-activated([insert branding or sub-branding]) (repellent) (refill) (diffuser) will last up to (8) (7) (6) (5) (4) (3) (2) hours. (Repellent) (refill) (diffuser) will last as long as one candle. When the candle is used up replace both candle & (repellent) (refill) (diffuser).

To Refill (Lantern) (Lamp) (Light) (Device) (Unit):

Be sure flame is out and (lantern) (lamp) (light) (device) (unit) is cool before handling. Replace ([Insert branding or sub-branding] candle and ([Insert branding or sub-branding]) (repellent) (refill) (diffuser).

Burn only [insert branding or sub-branding] Candles in [insert branding or sub-branding] (holder) (caddy) (cradle). Use of any other candle may cause injury or property damage.

To effectively repel mosquitoes, be sure to use the [insert branding or sub-brand name] (repellent) (refill) (diffuser) together with the supplied [insert Branding or sub-brand name] candle.

Storage and Disposal

Storage: Store in original container in a cool, dry place in an area inaccessible to children and pets.

Disposal: Before disposing, fully use up the product according to the label. Used (repellent) (refill) (diffuser) and (repellent) (refill pouch) (diffuser pouch): Place exhausted (repellent) (refill) (diffuser) and (repellent) (refill pouch) (diffuser pouch) in trash. Candle: After allowing exhausted candle to cool, place candle (container) (cup) in trash. Do not reuse or refill the candle (container) (cup). If (repellent) (refill) (diffuser) is partly used, call your solid waste agency or 1-800-529-3394 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Precautionary Statements

Hazards to Humans and Domestic Animals:

CAUTION: Harmful if swallowed or absorbed through the skin. Avoid contacting skin, eyes or clothing with ((treated) puck) ((treated) sandcore)(repellent) (refill) (diffuser) (housing) (surface). Do not use indoors or in enclosed spaces. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Use and store away from food, beverages and pet food.

[Boxed format or bullets may be used in First Aid section if label space permits]

First Aid

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 by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on Skin: If treated ((treated) puck) ((treated) sandcore) (repellent) (refill) (diffuser) (housing) (surface) touches skin or clothing, 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.

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 ((treated) puck) ((treated) sandcore) (repellent) (refill) (diffuser) (housing) (surface)).

Physical or Chemical Hazards

To Prevent Fire or Injury: (! [*in triangle*])- Burn within sight. Never burn candle on or near anything that can catch fire. Keep out of reach of children and pets. Place on level, stable surfaces. Trim wick to (¼ inch) (¼") (or less) (before each lighting.) Keep candle free of matches and all foreign material. Never touch or move while in use or until wax hardens. Do not extinguish with water. Do not store near heat or open flame.

Environmental Hazards

Do not apply to water.

Questions? Comments? Call 800-558-5252 or write Helen Johnson

Sold by: ©20XX S.C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A.

EPA Reg. No. 4822-605

EPA Est. No. XXX-XX-XXX (Lot number suffix indicates appropriate establishment number.)

(US Pat. (Patent) [numbers]).

(All Rights Reserved)

((Mosquito) (repellent) (treated) (refill) (diffuser) made in [insert country].)

(Candles made in [insert country].)

((Holder) (caddy) (cradle) made in [insert country].)

((Lantern) (Lamp) (Light) (Device) (Unit) made in [insert country].)

[Labeling for (refill) (diffuser) pouch or wrap:]

[Insert Product Name]

ACTIVE INGREDIENT:

Metofluthrin 9.10%

OTHER INGREDIENTS..... 90.90%

Total..... 100.00%

KEEP OUT OF REACH OF CHILDREN AND PETS

CAUTION:

See additional precautions and instructions on (outer) (outermost) package.

Do not use indoors or in enclosed spaces.

Wash hands thoroughly after handling the (refill) (pouch) (packaging) (and) ((treated) puck) ((treated) sandcore) (repellent) (refill) (diffuser) (housing) (surface)).

Net Contents X oz (X grams)

Questions? Comments? Call 800-558-5252 or write Helen Johnson

Sold by: ©20XX S.C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A.

7/11

[Information in brackets is notes to Reviewer]
(Information in parentheses is optional language)

EPA Reg. No. 4822-605
EPA Est. No. XXX-XX-XXX (Lot number suffix indicates appropriate establishment number.)
(US Pat. (Patent) [numbers]) (All Rights Reserved)
((Mosquito) (repellent) (treated) (refill) (diffuser) made in [insert country].)
(Candles made in [insert country].)

[Labeling for bottom of (lantern) (lamp) (light) (device) (unit)]

[Insert Product Name]

ACTIVE INGREDIENT:

Metofluthrin 9.10%
OTHER INGREDIENTS..... 90.90%
Total..... 100.00%

KEEP OUT OF REACH OF CHILDREN AND PETS

CAUTION:

See additional precautions and instructions on (outer) (outermost) package.
Do not use indoors or in enclosed spaces.

To Prevent Fire or Injury: (! [in triangle]) - Burn within sight. Never burn candle on or near anything that can catch fire. Keep out of reach of children and pets. (See additional information inside.) [for booklet type bottom stickers.] Place on level stable surfaces. Trim wick to ¼ inch (") (or less) (before each lighting.) Keep candle free of matches and all foreign material. Never touch or move while in use or until wax hardens. Do not extinguish with water. Do not store near heat or open flame.

EPA Reg. No. 4822-605

(US Pat. (Patent) [numbers])

Questions? Call 800-558-5252 (or write Helen Johnson)

Sold by: ©20XX-S.C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A.

(All Rights Reserved)

((Holder) (caddy) (cradle) made in [insert country].)

((Lantern) (Lamp) (Light) (Device) (Unit) made in [insert country].)

[Labeling for on top of (repellent) (refill) (diffuser):]

HOT! Do not touch while burning (.)(!)

[OR]

Hot while burning!

[OR]

Hot Surface while burning (.)(!) Do not touch (.)(!)

[OR]

Hot Surface (.)(!) Do not Touch (.)(!)

[Optional marketing statements grouped by category of statement]

[Reusability/Portability]

- 1. Refillable holder
- 2. Refillable caddy

3. Refillable cradle
4. Refillable lantern
5. Refillable lamp
6. Refillable light
7. Refillable device
8. Refillable unit
9. Reusable holder
10. Reusable caddy
11. Reusable cradle
12. Reusable lantern
13. Reusable lamp
14. Reusable light
15. Reusable device
16. Reusable unit
17. Portable (mosquito) repellency
18. Portable (mosquito) repellent
19. Caddy
20. Diffuser
21. Candle
22. Lamp

[General Miscellaneous]

1. (S.C. Johnson) A Family Company
2. A Family Company since 1886
3. Fisk Johnson [signature]
4. Enjoy your (patio) (backyard) with OFF!
5. Heat-activated repellent
6. Get ready for summer
7. Easy to use
8. Single use
9. Affordable (mosquito protection) (mosquito repellency)
10. The OFF! brand, relied on for generations
11. OFF!

[Sensory perception – Scent]

[Note to reviewer: the following section is for when the candle contains fragrance.]

1. Candle scented with citronella (essence)

[Sensory perception – Lack of scent]

[Note to reviewer: the following section is for when the formulation and candle do not contain a fragrance]

1. Unscented
2. Non-fragranced

[General Use Occasions]

1. (For your) Tabletop
2. (For your) Patio & Deck
3. (For your) Backyard

4. (For your) Camp
5. (For your) Campsite
6. (For your) Campground
7. Great for (parties) (gatherings) (camping) (your outdoor adventures)

[Design/Aesthetics/Product Type]

1. Fit into your décor
2. Fits in with your decor!
3. Accent your summer while providing (protection) (repellency)
4. Accent your patio while providing (protection) (repellency)
5. Enjoy summer (in style) (with ambiance) (with a glow)
6. Design for your outdoor patio (area)
7. Add a glow to your (evening) outdoors
8. Candle glows for (8) (7) (6) (5) (4) 3) (2) hours
9. (Attractive) (inspired) design (fits your décor)
10. Create an (inviting) (welcoming)(attractive) (appealing) outdoor (space)(ambiance)
11. Provides ambiance for your backyard
12. (Add) (bring) ambiance to your outdoor (experience) (gathering)
13. Repel mosquitoes while providing a glow
14. Creates a (wonderful) glow
15. Just light it and relax

[Segmentation]

1. OFF! for every occasion
2. OFF! has a complete line of mosquito protection for every occasion

[Note to reviewer: Alternate Segmentation Options: to be used in conjunction with a reference to another OFF! product appropriate to the claim. "You" will be used in conjunction with a reference to an approved personal repellent. "Your gear" & "Your tent" will be used in conjunction with a reference to an approved repellent product for use on tent. "Your area" & "Your campsite" will be used in conjunction with a reference to an approved area repellent product.] [to be used with images of appropriate OFF! products]

3. For a (full) (complete) (range) (line) of (mosquito) (protection) (OFF! Outdoor) options, choose products for:
(you) (your (gear) (tent))(your (area) (campsite))
4. For you, for your (gear) (tent), for your (area) (campsite) (backyard) (patio)
5. Try our complete line of OFF! Outdoor products. [list to be chosen from the following, with images of appropriate products:]
(Personal repellents) (tabletop) (patio & deck) (backyard) (camp) (campsite) (campground)
6. Look for products in each of these categories to meet your outdoor needs. [list to be chosen from the following, with images of appropriate products:]
(Personal repellents) (tabletop) (patio & deck) (backyard) (camp) (campsite) (campground)
7. For you, your (area) (campsite) (backyard) (patio) [to be used with images of appropriate OFF! product.

[Underlined parenthesis sections in label to follow indicates optional language where a choice(s) of the underlined options will be included on the label and cannot be excluded]

[Performance/Efficacy]

1. Repels mosquitoes from an averaged size patio (10' x 10')
2. Pleasant, effective protection for your (backyard) (campsite) (patio) (deck)
3. Mosquito (protection) (repellency) for all occasions
4. Don't let mosquitoes ruin your summer
5. Proven active ingredient (for effective mosquito protection)
6. Active ingredient protects from mosquitoes
7. Long Lasting (up to 8 hours of repellency)
8. Acts as a mosquito screen for you and your family
9. Repellency from mosquitoes for your family
10. Repels mosquitoes before they get you
11. Protect (your family) (the ones you love) from mosquitoes
12. From the makers of [insert OFF! brand name]
13. Repels (annoying)(pesky) mosquitoes (from an area)(away from an area) up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
14. Provides repellency from (annoying)(pesky) mosquitoes (in an area) up to (10 ft. X 10 ft.)(10' X 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
15. (Effective) (Proven) mosquito repellency (in an area) up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
16. Creates an area that's proven effective at keeping mosquitoes (from an area)(away from an area) up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
17. Provides (an area) up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) of (outdoor) (backyard) (camp) (campsite) (patio) (campground) repellency from mosquitoes for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
18. Up to (2)(3)(4)(5)(6)(7)(8) hours of (proven) mosquito repellency up to (10 ft. x 10ft.)(10' x 10') (100 sq. ft.) (in the outdoors) (in the great outdoors) (on your patio) (for your patio) (on your deck) (in your backyard) (in the woods) (for your campsite) (per refill) (per diffuser)
19. Repels Mosquitoes
20. Provides Repellency From Mosquitoes
21. Provides (an area) up to (10 ft. x 10ft.)(10' x 10') (100 sq. ft.) of mosquito repellency
22. Up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) (per refill) (per diffuser)
23. Up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
24. Up to (10 ft. X 10 ft.)(10' x 10') (100 sq. ft.) of (outdoor) (backyard) (camp) (campsite) (campground) repellency from mosquitoes (per refill) (per diffuser)
25. Up to (2)(3)(4)(5)(6)(7)(8) hours of (proven) repellency up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) (for your patio) (in the outdoors) (in the great outdoors) (in your backyard) (in the woods) (for your campsite) (per refill) (per diffuser)
26. Enjoy up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) of repellency for your (backyard) (patio) (campsite) up to (2)(3)(4)(5)(6)(7)(8) hours of repellency (per refill) (per diffuser)

11/11

27. Each (refill) (diffuser) repels mosquitoes (in an area) up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.)
28. Each (refill) (diffuser) (and candle) lasts up to (2)(3)(4)(5)(6)(7)(8) hours
29. Each (refill) (diffuser) repels mosquitoes up to (2)(3)(4)(5)(6)(7)(8) hours
30. Repels (annoying) (pesky) mosquitoes (from an area)(away from an area) up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours while you enjoy the outdoors
31. Repels annoying)(pesky) mosquitoes (from an area)(away from an area) up to (10 ft. x 10ft.)(10' x 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours an area in your (outdoor living space) (campsite)
32. Provides an up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) area of (mosquito) repellency (per refill) (per diffuser)
33. Works for up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
34. Repel mosquitoes up to (10 ft. x 10 ft.)(10' x 10') (100 sq. ft.) for your (outdoor party)(backyard) (patio) (deck) for up to (2)(3)(4)(5)(6)(7)(8) hours (per refill) (per diffuser)
35. Repel(s) mosquitoes up to (10 ft. x 10 ft.)(10 x 10 ft.)(10' x 10') (100 sq. ft.)