

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 12, 2017

Micah T. Reynolds Regulatory Consultant Agent for Biosensory, Inc. c/o 1150 18TH STREET, NW, SUITE 1000 WASHINGTON, DC 20036

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Add optional

marketing claims, harmonized select text between sublabels, and add label language for

supplemental distributor labels. Product Name: Conceal® Candle EPA Registration Number: 70909-5 Application Date: May 05, 2017 OPP Decision Number: 529255

Dear Mr. Reynolds:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Page 2 of 2 EPA Reg. No. 70909-5 OPP Decision No. 529255

If you have any questions, please contact Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

Anchew L. kupcelon

Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

NOTIFICATION

70909-5

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

10/12/2017

Conceal® Candle

Master Label includes:

- Main label
- Optional label claims
- Label text for supplemental distributors

EPA Reg. No.: 70909-5

Manufactured by: BioSensory™ Inc. Belding Mill Complex

107 Providence Street, Putnam, CT 06260,

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Main label

Conceal® Candle

Active Ingredient:

Keep Out of Reach of Children CAUTION

See (bottom) (bottom label) (bottom inner panel) (side panel) (insert label) (outer carton) (back (of) label) (reverse of front label) for (complete) (directions for use) (usage instructions) (usage information).

(See bottom panel for safety information) (Note to PM: This referral statement part of ASTM F-2058.)

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EPA Reg. No.: 70909-5
EPA Est. No.: XXXXX-XX-XX

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[Superscript is first letter of lot number]

Net Contents: XX

(Includes: X (candles)) (Note to PM: For multiple candles sold in one container.)

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Manufactured by/Sold By:

BioSensory™ Inc.

Good Science. Better Solutions.

Belding Mill Complex

107 Providence Street, Putnam, CT 06260

www.biosensory.com

(BioSensory, Dragonfly, Mosquito 'Cognito, and Conceal are registered trademarks of BioSensory™ Inc. Protected by U.S. Patent Numbers 5,205,064; 5,799,436; 6,055,766; and 6,362,235. (U.S. and) International Patents Pending.)

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Conceal® Candle; EPA Reg. No. 70909-5

NOTIFICATION of minor label revisions and additional text for new subregistrant REDLINE, VERSION –Master Label (13) dated April 25, 2017, Page 2 of 10

DIRECTIONS FOR USE

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

For outdoor use or for use in semi-enclosed areas such as porches and patios. Place candles around the perimeter of the area to be protected. Use (1 candle per 13 square feet) (2 candles per 25 square feet) (3 candles per 38 square feet) (4 candles per 50 square feet) (5 candles per 63 square feet) (6 candles per 75 square feet) (7 candles per 88 square feet) (8 candles per 100 square feet) (9 candles per 113 square feet) (10 candles per 125 square feet). Place candle(s) on a heat-resistant surface, away from anything flammable, and out of reach of children and pets. Keep wick trimmed to ¼ inch (6 mm) at all times. (Container) (Candle) may become hot; handle carefully. (Do not blow out or extinguish with water,) smother flame to extinguish. Never leave a burning candle unattended.

For maximum protection light candles and allow a molten pool of wax to fully form around the wick, approximately 20 to 30 minutes. Mosquitoes are (blocked) (inhibited) (disoriented) by the inhibitor plume produced by the candle(s). If you can smell the fragrance from the candle, you are in the inhibitor plume. Burns (for) (up to) (XX) hours (burn time is dependent upon candle size). (Up to (XX) hours burn time.)

ASTM Standard F-2058

(Exclamation in triangle) WARNING To Prevent Fire:

- Burning within sight.
- Keep away from children.
- Keep away from things that catch fire.

STORAGE AND DISPOSAL

Storage: Store in original container in a cool, dry place.

Disposal: Do not reuse this container. Place in trash or offer for recycling if available.

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Optional label claims

General Claims:

- Great for Decks, Yards, Gardens, Around Pools, Patios, Table top(s)
- Light candles 20 30 minutes before going outside.
- Helps to keep mosquitoes away (from you) (and your family).
- Reduce annoyance from mosquitoes.
- (Blocks) (inhibits) your scent so mosquitoes can't (find) (see) you.
- (Blocks) (inhibits) (disorients) mosquito's sensor receptors so they can't find you.
- Patented technology that (blocks) (inhibits) (disorients) the mosquito's sensors, and helps to keep them away from you.
- (Scent) (Conceal Candle) helps to keep mosquitoes away by (blocking) (inhibiting) ability to detect humans.
- Candle contains a patented mosquito scent (blocker) (inhibitor).
- (Scent) (Conceal Candle) (blocks) (inhibits) (disorients) mosquito's receptors from sensing humans.
- (Conceal Candle) (blocks) (inhibits) (disorients) mosquitoes (including those) which may (transmit) (carry) (West Nile virus) (encephalitis) (disease(s)).
- Garden fresh (scent) (fragrance). (Note to PM: This claim relates to intrinsic fragrance of linalool.)
- DEET Free
- Outdoor Mosquito Candle
- Patented Technology
- (X) pack
- (Contains) (X) candles (in pack) (in box) (in package)
- Image(s) of target pest mosquito
- Image(s) of use sites: patio, deck, porch, outdoor table
- Up to X hours burn time (per candle) (Note to PM: burn time dependent on candle size.)

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Label text for Supplemental Distributor EPA Co. No. 82166

Optional Label Claims:

- Great for (table top) (patios) (decks)
- 2 piece patio pack
- 3 piece deck pack
- Outdoor mosquito candle
- Blocks mosquitoes
- Candles inhibit mosquitoes' tracking receptors, blocking their ability to find people.
- Smoke free
- Clean burning, like indoor candles
- Works fast!
- Patented (linalool) (technology) (formula)
- Candle made in the USA
- Each (product name) (candle) burns up to 30 hours
- Disposable candle bases included
- Melted wax pool releases mosquito blocking ingredient
- Linalool made in China
- Blocks mosquitoes from finding you and your family!*

*With their sensors blocked, mosquitoes can't find you and your family!

- Patented Formula released by candle binds to mosquito antenna sensors.
- Enjoy your night in comfort!
- No messy creams and sprays!
- Candles burn clean like indoor candles, with a fresh scent.

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Conceal® Candle; EPA Reg. No. 70909-5

Label text for Supplemental Distributor EPA Co. No. 83096

Directions for Use:

DIRECTIONS FOR USE

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

For outdoor use or for use in semi-enclosed areas such as porches and patios. Place candles around the perimeter of the area to be protected. Use 1 candle per 13 square feet. Never leave a burning candle unattended. Light candles 20 to 30 minutes Defore-going-outside. Mosquitoes are blocked by the inhibitor plume produced by the candle. If you can smell the fragrance from the candle, you are in the inhibitor plume. (Container) (Candle) may become hot; handle carefully. Smother flame to extinguish.

STORAGE AND DISPOSAL

Storage: Store in original container in a cool, dry place.

Disposal: Do not reuse this container. Place in trash or offer for recycling if available.

ASTM Standard F-2058

(Exclamation in triangle) WARNING To Prevent Fire:

- Burning within sight.
- Keep <u>away from</u> children.
- Keep away from things, that catch fire.

Optional Label Claims:

- Garden fresh (scent) (fragrance). (Note to PM: This claim relates to intrinsic fragrance of linalool.)
- Yankee Candle® a passion for fragrance®.
- Does not contain citronella.
- DEET free.
- Mosquitoes find you by tracking the carbon dioxide you exhale.
- When they can't sense you, they can't find you!
- This package is 100% recyclable.

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Conceal® Candle; EPA Reg. No. 70909-5

NOTIFICATION of minor label revisions and additional text for new subregistrant REDLINE, VERSION – Master Label (13) dated April 25, 2017, Page 6 of 10

Label text for Supplemental Distributor EPA Co. No. 239

Directions for Use:

DIRECTIONS FOR USE

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

For outdoor use or for use in semi-enclosed areas such as porches and patios. Place candles around the perimeter of the area to be protected. Use 1 candle per 13 square feet. Never leave a burning candle unattended. Light candles 20 to 30 minutes before going outside. Mosquitoes are blocked by the inhibitor plume produced by the candle. If you can smell the fragrance from the candle, you are in the inhibitor plume. (Container) (Candle) may become hot; handle carefully. Smother flame to extinguish.

ASTM Standard F-2058

(Exclamation in triangle) WARNING To Prevent Fire:

- Burn within sight.
- Keep away from children.
- Keep away from things, that catch fire.

OR

For outdoor use or for use in semi-enclosed areas such as porches and patios. Place candles around the perimeter of the area to be protected. Use (1 candle per 13 square feet) (2 candles per 25 square feet) (3 candles per 38 square feet) (4 candles per 50 square feet) (5 candles per 63 square feet) (6 candles per 75 square feet) (7 candles per 88 square feet) (8 candles per 100 square feet) (9 candles per 113 square feet) (10 candles per 125 square feet) . Place candle(s) on a heat-resistant surface, away from anything flammable, and out of reach of children and pets. Keep wick trimmed to ¼ inch (6 mm) at all times. (Container) (Candle) may become hot; handle carefully. (Do not blow out or extinguish with water,) smother flame to extinguish. Never leave a burning candle unattended.

For maximum protection light candles and allow a molten pool of wax to fully form around the wick, approximately 20 to 30 minutes. Mosquitoes are (blocked) (inhibited) (disoriented) by the inhibitor plume produced by the candle(s). If you can smell the fragrance from the candle, you are in the inhibitor plume. Burns (for) (up to) (XX) hours (burn time is dependent upon candle size). (Up to (XX) hours burn time.)

STORAGE AND DISPOSAL

Storage: Store in original container in a cool, dry place.

Disposal: Do not reuse this container. Place in trash or offer for recycling if available.

Notice: To the extent consistent with applicable law, buyer assumes all responsibility for safety and use not in accordance with directions.

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Conceal® Candle; EPA Reg. No. 70909-5

NOTIFICATION of minor label revisions and additional text for new subregistrant REDLINE, VERSION - Master Label (13) dated April 25, 2017 Page 7 of 10

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Optional Label Claims:

- Garden fresh (scent) (fragrance). (Note to PM: This claim relates the intrinsic fragrance of linalool.)

Does not contain citronella.

- DEET free.
- Mosquitoes find you by tracking the carbon dioxide you exhale.
- When they can't sense you, they can't find you!
- This package is 100% recyclable.
 - Great for (table top) (patios) (decks)
- 2 piece patio pack
- 3 piece deck pack
- Outdoor mosquito candle
- Blocks mosquitoes
- Candles inhibit mosquitoes' tracking receptors, blocking their ability to find people.
- Smoke free
- Clean burning, like indoor candles
- Works fast!
- Patented (linalool) (technology) (formula)
- Candle made in the USA
- Each (product name) (candle) burns up to 30 hours
- Disposable candle bases included
- Melted wax pool releases mosquito blocking ingredient
- Linalool made in China
- Blocks mosquitoes from finding you and your family!*

*With their sensors blocked, mosquitoes can't find you and your family!

Conceal® Candle; EPA Reg. No. 70909-5

NOTIFICATION of minor label revisions and additional text for new subregistrant REDLINE, VERSION –Master Label (13) dated April 25, 2017, Page 8 of 10

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- Patented Formula released by candle binds to mosquito antenna sensors.
- Enjoy your night in comfort!
- No messy creams and sprays!
- Candles burn clean like indoor candles, with a fresh scent.
 - Great for Decks, Yards, Gardens, Around Pools, Patios
- Light candles 20 30 minutes before going outside.
- Helps to keep mosquitoes away (from you) (and your family).
- Reduce annoyance from mosquitoes.
- (Blocks) (inhibits) your scent so mosquitoes can't (find) (see) you.
- (Blocks) (inhibits) (disorients) mosquito's sensor receptors so they can't find you.
- Patented technology that (blocks) (inhibits) (disorients) the mosquito's sensors, and helps to keep them away from you.
- (Scent) (Conceal Candle) helps to keep mosquitoes away by (blocking) (inhibiting) ability to detect humans.
- Candle contains a patented mosquito scent (blocker) (inhibitor).
- (Scent) (Conceal Candle) (blocks) (inhibits) (disorients) mosquito's receptors from sensing humans.
- (Conceal Candle) (blocks) (inhibits) (disorients) mosquitoes (including those) which may (transmit) (carry) (West Nile virus) (encephalitis) (disease(s)).

Candle Burns for/up to XX hours/minutes

Up to XX hours/minutes of burn time

Ortho Guarantee – If for any reason you, the consumer, are not satisfied with this product, mail us your original proof of purchase to obtain a full refund of your purchase price.

QUESTIONS OR COMMENTS - [phone icon] 1-800-xxxxxxx <u>www.ortho.com</u> [Visit our website computer icon]

[Company] & Your Environment – Your yard is a place for family and pets to enjoy. That's why [company] products are designed with care to provide effective solutions to insect problems. Please follow instructions for appropriate usage, storage and disposal.

1 candle covers 13 sq ft/ square feet

2 candles covers 25 sq ft/ square feet

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Conceal® Candle; EPA Reg. No. 70909-5

NOTIFICATION of minor label revisions and additional text for new subregistrant REDLINE, VERSION – Master Label (13) dated April 25, 2017, Page 9 of 10

X candles cover/covers X sq ft/square feet (NOTE TO PM: X is determined by statements in the directions for use)

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X candle pack

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