



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 16, 2010

Combat Insect Control Systems
% Georgia Anastasiou, Agent
Lewis & Harrison
122 C Street, N.W., Suite 740
Washington, D.C. 20001

Subject: Amendment to add claims against large cockroaches.
Combat Small Roach Bait F.03
EPA Reg. Nos. 64240-33
Application dated January 25, 2010

Dear Ms. Anastasiou:

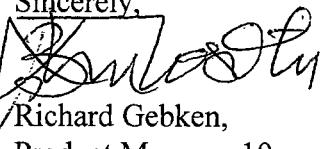
The above referenced submission in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(a), is acceptable subject to the following comments and/or terms for conditionally accepted amendment.

- The requested added claims for American cockroaches (large cockroaches) are acceptable for this product, provided that the stations allow for full access of large cockroaches to the fipronil treated bait.
Provide the Agency with evidence that the entry hole on this bait station is of adequate size to allow entry by the larger American cockroaches — either by sending a sample station to the Agency or providing a scaled picture for evaluation by the efficacy team/RM reviewer.
- Modify the claims “overnight [action] formula” and “kills overnight” to read “***starts killing overnight***”, “***starts working overnight***”, “***starts working as soon as cockroaches feed on bait***” or similar wordings that provide a more accurate representation of how the product works.
These claims imply 24 hour efficacy, but the bait product does not work within 1 day. Generally, baits are not fast acting and should not be marketed as something that would eliminate a cockroach infestation “overnight”.

Please note that we have approved the amendment for the subject product with the understanding that the labeling is consistent with the Agency's previously approved labels and with the labels for other identical products. Your failure to comply with the above stated conditions nullifies our conditional acceptance of the proposed labeling amendment.

Enclosed with this letter, see our review (dated April 05, 2010) of your submitted Efficacy data, and revise the labeling accordingly to reflect the comments stated in the DER. Submit final printed label to the Agency prior to releasing this product for shipment. See enclosed stamped label for your record. If you have any questions please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,

for 

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

Enclosure

Note: **Bold, Italicized text is information for the reader and is not part of the label.**
[Bracketed information is optional text]
Underlined text is new.

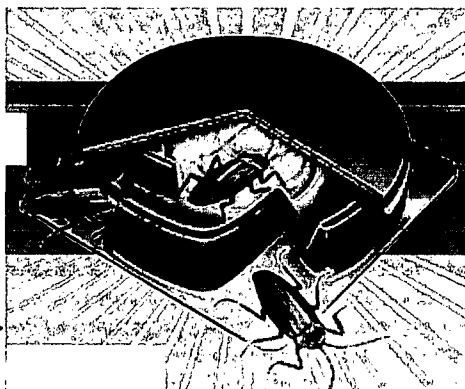
Master Label, JANUARY, 2010
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Combat Small Roach Bait F.03
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COMBAT® Small Roach Bait F.03

Approved Alternate Brand Names:

Combat Quick Kill Formula 1
Combat Plus^{Brand} Quick Kill Formula 1 Roach Baits
Combat Source Kill Max R1
Combat Defense System^{Brand} Source Kill Max R1

ACCEPTED
With COMMENTS
In EPA Letter Dated:
JUN 16 2010
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
64240-33



For [Large] [and] [Small] Roaches
Overnight [Action] Formula
Kills Overnight & Keeps on Killing for up to 6 Months

[ROACH]

ACTIVE INGREDIENT: Fipronil[†] 0.03%

OTHER INGREDIENTS:..... 99.97%

[†] CAS No. 120068-37-3

DO NOT ALLOW CHILDREN OR PETS TO PLAY WITH THE BAIT STATIONS.

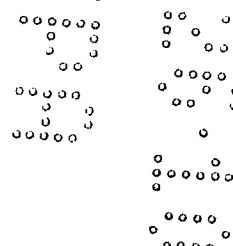
CAUTION:

See precautionary statements on back -or- side panel.

EPA Reg. No. 64240-33 EPA Est. No. _____

Distributed by & ©2010 Combat Insect Control Systems
[19001 N. Scottsdale Rd.,] Scottsdale, AZ [ARIZONA] 85255
[MADE IN U.S.A.]

[CONTAINS] [2] [4] [6] [8] [12] [18] [24] [30]
Child-resistant bait stations [for large and small roaches]
[TOTAL] NET WT. [0.07 oz. (2g)] [0.14 oz. (4g)] [0.21 oz. (6g)] [0.28 oz. (8g)]
[0.42 oz. (12g)] [0.63 oz. (18g)] [0.84 oz. (24g)] [1.06 oz. (30g)]



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Wash [hands] thoroughly with soap and water after handling bait stations.

STORAGE AND DISPOSAL: [Do not contaminate water, food or feed by storage or disposal.]

STORAGE: Store in cool, dry area out of reach of children.

DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is not available, place in trash. **If partially filled:** Call your local solid waste agency ~~for [toll free number] 1-800-CLEANUP~~ for disposal instructions. Never place unused product down any indoor or outdoor drain.

[U.S. Patent Nos. _____ and others pending.]

[Combat®] [Guaranteed to work [or your money back]!

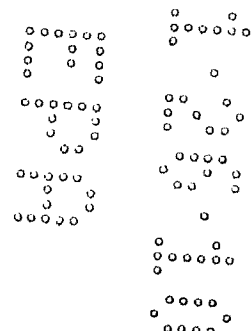
[EFFECTIVENESS GUARANTEED: COMBAT® [Insect Control Systems] stands behind this [insect killing system] [product] with a full [Satisfaction] Guarantee. Should you have any questions regarding COMBAT® [baits] [products], please call 1-800-426-6228.]

[For information,] [C]call the Combat® [Labs] [Information] Helpline at 1-800-426-6228 [for information]. -or- For questions or comments, please call the Combat® [Labs] [Information] Helpline at 1-800-426-6228 [for information].



[[The paperboard in this] [C]carton [contains] [is made from] _____% Recycled fiber [minimum _____% post consumer content]] [Please Recycle Empty Carton.]

{Note to Reviewer: Per PR-Notice 2007-4, this product will receive a batch code. The number will be laser-coded on each primary package of the product after the container is sealed.}



GENERAL INFORMATION

[THIS IS] [HOW] [THIS] [Combat] [*Alternate Brand Name*] WORKS:

1. Roaches enter the bait station and eat the bait.
2. Roaches return to their nest and die.
3. Other roaches eat them and die, creating a chain reaction.

-or-

1. Roaches enter the bait station and eat [feed on] the bait.
2. Roaches take the bait back to the nest.
3. Roaches share the bait, killing other roaches and destroying the nest.



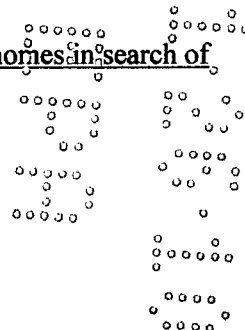
[Table below is optional.]

DATE PLACED (Month/Year)	LOCATION	REPLACEMENT DATE (After [3] [6] Months)

[This product is specifically designed for small and large roaches.]

[Small, ½" Cockroach Habits: Primarily live and breed in moist areas like kitchens and bathrooms.]

[Large, 1" to 1 ½" Cockroach. Habits: Primarily live and breed outdoors and enter homes in search of food. Bait station placement near potential points of entry is key.]



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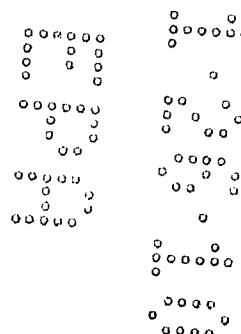
Master Label, JANUARY, 2010
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Combat Small Roach Bait F.03
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DIRECTIONS FOR USE

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

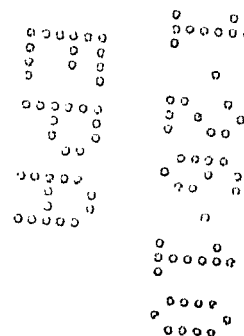
[APPLICATION INSTRUCTIONS]

1. [Remove wrapper.] [U]se all [2] [4] [6] [8] [12] [18] [24] [30] baits [at one time] [at the same time]. Break baits apart. Do not remove or puncture [the] label[s] on bait station[s]. [Now the baits are ready to use.]
2. Place baits wherever [you see or have seen [roaches] [signs of roaches]] [where roaches are found] [in the following places: under appliances and sinks, on floor along baseboards, near pet food storage and inside cabinets and drawers.]
Then place additional baits about 1½ feet away. [Put any remaining baits as shown in the diagram[s] to the [right] [[left] [above] [below.]] [Some of the most likely [locations for roaches] [roach hiding places] are shown in the diagram[s] to the [right] [left] [above] [below]. [Roaches find the bait faster when all bait stations [baits] are placed out.]
Do not use in beehives.
3. Place baits properly so that they are touching walls or corners. [Only use enclosed stickers [as needed] when placing baits on walls or upside down. It is not necessary to use stickers on all baits.] [Do not use sprays or foggers around bait stations.] [They can contaminate bait stations and reduce effectiveness.]
4. Replace all baits every [3] [6 months], or sooner if roaches return [because roaches have probably eaten all of the bait inside]. [Baits will need to be replaced since [because] [the] roaches have probably eaten all the bait inside.]



Claims for front or back

- Kills large and small roaches
 - Kills [for] up to 6 months
 - Kills roaches quickly
 - Kills [roaches] in hours
 - Quick kill formula
 - Kills roaches [where they [hide] [breed] [live]] [at the source]
 - Non-stop roach control for up to 6 months
 - [Satisfaction] [Quality] Guaranteed
 - Kills roaches you see and [even] those you don't
 - [Protects] [Defends] your home against roaches
 - Guaranteed to work or your money back
 - Child resistant bait stations
 - Continuous roach control for up to 6 months
 - Kills non-stop for up to 6 months
 - Kills roaches and keeps on killing for up to 6 months
 - Provides maximum roach control for up to 6 months
 - Works within hours and for up to 6 months
 - Starts [working] [killing] in hours, doesn't stop working for up to 6 months
 - Keeps killing for up to 6 months
 - Better bait formula [for improved control]**
 - Increased feeding [for improved control]**
 - Advanced [food] formula**
 - With foods roaches prefer
 - With [a blend of] [multiple] foods roaches eat
 - With multiple foods to kill roaches [and the nest]
 - Easy to use
 - Nothing to activate
 - No [mess] [or] [and no] objectionable odor
 - No [mess] [or] [and no] bad odor
 - Bonus Pack***
 - 50% More [Free]***
 - 100% More [Free]***
 - [50%] More Baits***
 - [100%] More Baits***
 - [6] [2] Bonus Baits With Purchase
 - More Baits – Better Value***
 - Value Pack – More Baits***
- *** vs. [standard size] [12] [count] [ct.] [package] [pkg.] [of this [Combat] product]



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Label, JANUARY, 2010
EPA Reg. No. 64240-33
Combat Small Roach Bait F.03
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BAIT STATION UNIT LABEL

COMBAT® Small Roach Bait F.03

Alternate Brand Names:

Combat Quick Kill Formula 1
Combat Plus^{Brand} Quick Kill Formula 1 Roach Baits
Combat Source Kill Max R1
Combat Defense System^{Brand} Source Kill Max R1

THIS SIDE DOWN OR AGAINST SURFACE

Note: Do not remove or puncture this label.

ACTIVE INGREDIENT: Fipronil[†] 0.03%

OTHER INGREDIENTS:..... 99.97%

[†] CAS No. 120068-37-3

DO NOT ALLOW CHILDREN OR PETS TO PLAY WITH THE BAIT STATIONS.

CAUTION:

Wash [hands] thoroughly with soap and water after handling bait stations.

DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is not available, place in trash. **If partially filled:** Call your local solid waste agency ~~for [toll free number] 1-800-CLEANUP~~ for disposal instructions. Never place unused product down any indoor or outdoor drain.

[For questions, comments or information about COMBAT, call toll free 1-800-426-6228.]

[Questions or Comments? Call 1-800-426-6228.]

EPA Reg. No. 64240-33 EPA Est. No. _____

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[19001 N. Scottsdale Rd.,] Scottsdale, AZ [ARIZONA] 85255

SEE OUTER [CARTON] [BAG] FOR [FULL] [COMPLETE] DIRECTIONS AND PRECAUTIONS

NET WT [0.035 oz (1g)] -or- [0.05 oz (1.4g)]

