



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2019

Timothy Dickens, Ph.D.
Thermacell Repellents, Inc.
c/o Scientific Coordination, Inc.
4629 Cherry Valley Dr.
Rockville, MD 20853

Subject: Label Amendment – Adding additional marketing statements
Product Name: ZECKEN ROLLEN TICK TUBES
EPA Registration Number: 71910-10
Application Date: May 9, 2018
Decision Number: 541110

Dear Dr. Dickens:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements 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 Agency 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich". The signature is written in a cursive style with some loops and flourishes.

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

ACCEPTED

01/29/2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 71910-10

Zecken Rollen Tick Tubes

[Alternate Brand names:

1. Thermacell Tick Control Tubes
2. Tick Control Tubes by Thermacell
3. Tick Control Tubes
4. Tick Stop, Tick Control Tubes]

{Appropriate marketing verbiage, and additional graphics and/or symbols from “Optional Marketing Statements” section may be added to the front panel}

Active Ingredient:

Permethrin 7.4%

Other Ingredients: 92.6%

Total 100.00%

Keep Out of Reach of Children

CAUTION

See [back] [side] [bottom] [panel] [and insert] for additional first aid and precautionary statements

Net Contents: [X¹] tick control tubes at 0.16 oz (4.5 grams) each

Total: [(X¹ x .16)] oz ([(X¹ x 4.5)] grams)

EPA Reg. No. 71910-10

EPA Est. No. 92674-BGR-01

Manufactured in Bulgaria

©Thermacell Repellents, Inc.

26 Crosby Drive

Bedford, MA 01730

Toll Free: 1-866-753-2837

Email: tickhelp@thermacell.com

{NOTES TO THE REVIEWER:

[] Denotes alternate/optional verbiage

{ } Denotes verbiage not printed on market labeling

= Number

Tubes may also be referred to as “tick tubes or “[Product name] Tubes”}

¹ [X = 1, 6, 12, 24, 96 tubes]

{Information found on [front] [back] [side] [bottom] panel [and insert]}

PRECAUTIONARY STATEMENTS First Aid

If Swallowed	<ul style="list-style-type: none">• 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 on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Immediately rinse skin with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information. [For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-866-753-3837, Monday through Friday, 8:30 AM to 4:30 PM EST. After 4:30 PM, call your poison control center.]	

{Note: The first aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Hazards to Humans and Domestic Animals

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

Physical or Chemical Hazards

Combustible. Do not use or store near excess heat or open flame.

{Information found on back, side panel and/or insert}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
[See leaflet inside box [carton] for usage directions.]

{Optional graphics to provide clarification to the user on how the product works}



[How Tick Control Tubes Work] [How it Works]

1. [Young] [Deer] Ticks feed on mice.
2. Tubes [are filled with] [contain] [cotton][material] treated with permethrin insecticide.
3. Mice collect the treated [material] [cotton] and use it to line their nests.
4. Ticks feeding on the mice are exposed to the [material treated with] permethrin insecticide and die. [Ticks feeding on the mice die]



[WHERE TO APPLY]

FOR OUTDOOR APPLICATION ONLY. [For the reduction of ticks associated with the mice that may serve as reservoirs for pathogens causing Lyme disease and babesiosis.] [Reduces ticks that feed on mice that may serve as reservoirs for organisms causing Lyme disease and babesiosis.] Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses. Tubes deposit a tick-killing substance on mice that breaks this cycle.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. Do not exceed the maximum distance of 10 yards between tubes in any direction. Limit treatment areas to those areas inhabited by mice and need not include mowed lawns or open grasslands. Position tubes so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: [Place tubes within 1 yard of the edge of mowed lawn] [Place tubes around the perimeter for the lawn in places with good coverage for mice such as in flower gardens, under bushes, [and] along fences and stonewalls, [and] [in wood piles and sheds] wherever mice may reside. For complete coverage, apply tubes to all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected.

FOR TREATMENT OF [WOODLOTS] [WOODED] [AREAS] [PROPERTIES] Place tubes in a grid pattern with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding wooded areas. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

[Product] [Placement] [Tips] – {Optional Language}

- Place tubes within 10 yards of each other.
- Place tubes flat on the ground. Position tubes so that mice have access to both ends. Product works best if not covered by leaves or other material.
- Mice prefer dry nesting material. Place tubes in areas with good drainage away from marshy ground or areas that flood easily.

[WHEN TO APPLY]

Tubes may be applied anytime between April 1 and mid-September but should be applied at least twice a year. For best results apply [tubes] in April and July [just prior to the feeding activity periods for nymphal [ticks](May-June) and larval [ticks] (August-September). Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

{Optional Language}

The first application kills nymphal ticks that feed primarily in May and June; the 2nd application kills larval ticks that feed primarily in August and September.

The summer application is critical in order to stop the tick lifecycle. It kills larval ticks that turn into next spring's nymphal ticks.]

[HOW MANY TO APPLY]

[How Many Tick Tubes to Apply] [Treatment] [Coverage] [Area] Chart

{Coverage Matrix to explain to the consumer how many tubes they need for their yard}

Property Size	Treated Area [Mouse Habitat]	Tubes per application	[Tubes per year]
¼ Acre	[up to] [approximately] 5,500 sqft	6	12
½ Acre	[up to] [approximately] 11,000 sqft	12	24
1 Acre	[up to] [approximately] 22,000 sqft	24	48

[Property includes house, driveway, mowed lawn and treated area]

{*Optional Language*} [Helpful Tips on How Many to Apply]

- For a typical home on a quarter acre lot, six tubes will cover the mouse habitat [per application]; 12 tubes are required annually.
- Yards or wooded properties with above average amounts of shrubs, tall grass or woods may require additional tubes
- There is no need to treat the entire property, only those places inhabited by mice. [Don't treat mowed lawns or driveways.]
- Apply two times a year in spring and summer

Storage and Disposal

Do not contaminate water, food or feed by storage.

Pesticide Storage: Store at room temperature in an area inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

[100% Satisfaction Guaranteed. At [Company Name] [Product Name], we stand behind our products and our quality. If you are not completely satisfied with your [Product Name] purchase, you may return it to us for replacement or refund.]

[For refund or replacement,] please call customer care at 866-753-3837. To qualify, you must have a receipt and be within a year from the original purchase date to qualify.]

{Optional Marketing Statements}

{Where to use}

1. Use [treat] [around yards], [properties] [or] [wooded areas]
2. For treatment around yards, [gardens] and wooded properties.
3. Place in brush, woodpiles, rock walls and flower beds
4. Place tubes no more than 10 yards apart from each other.

{When to Use}

5. Apply [twice a year] [2x per year] [once in the spring and once in the summer].
6. Apply 2x a year [in spring and summer]

{Product Amounts}

7. [X²] [Product Name] [tubes] treat [approximately] [up to] [Y³] sq. ft. [Z⁴] acre
8. [X²] tubes treat [approximately] [up to] - [Y³] sq. ft. [of mouse habitat] [including] [brush-covered areas, woodlands, flower beds, woodpiles, rock walls] [per application]
9. *[How Many Tick Tubes to Apply] [Treatment] [Coverage] [Area] Chart
{Note to Reviewer: application rate remains the same, but number of tubes and coverage area can be adjusted based on package size}
{ Asterisk refers consumer to the Treatment Chart on the side of the box}*

{Efficacy}

10. A tick toxicant
11. Kills ticks [that may carry Lyme] [disease]
12. Aids in control of [deer ticks] [black-legged ticks] ticks [that may carry Lyme]
13. Aids in control of ticks [that may carry] [diseases] [such as] [Lyme disease, Anaplasmosis, [and] Babesiosis] [that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands].
14. As an aid in the control of ticks (that may carry Lyme disease) [that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands].
15. Kills ticks that feed on mice, reducing the overall tick population in an area

{Product Benefits}

16. Easy to use [apply]
17. [No set-up]; [No clean-up] [No prep] [No preparation] [No mess]
18. No Spray [application]
19. Apply in minutes.
20. Biodegradable

{Promotional Language}

21. [Value Pack] [Bonus Pack] [Mega Pack] [# of Tubes] [Treats approximately Y [sqft]
22. [Limited Time] [Bonus][Offer] [Special] [free][Extra] [Inside] [booklet]
23. 100% Satisfaction Guaranteed
24. [Guarantee] At Thermacell we stand behind our products and our quality. If you are not completely satisfied with your purchase, you may return it to us for replacement or refund.]
25. [For refund or replacement,] please call customer care at 866-753-3837. To qualify, you must have a receipt and be within a year from the original purchase date.

² [X = 1, 6, 12, 24, 96 tubes]

³ [Y = 916, 5,500, 11,000, 22,000, 88,000 sq. ft.]

⁴ [Z = ¼, ½, and 1 acre]

Optional Educational Booklet

{Product Welcome}

1. [Take back your outdoors with the no-spray, easy way to kill ticks.] [Welcome to the no-spray, easy way to kill ticks!] [Enjoy your outdoors more with a new way to kill ticks]
2. For more than 20 years people have counted on ThermoCell for effective protection against mosquitoes. Now, we're proud to introduce a solution that helps protect against another harmful pest: ticks.
3. Because ticks can carry Lyme and other serious diseases, they are not only annoying but dangerous. Each year there are over 300,000 cases of Lyme disease reported in North America and that number is rising.⁵
4. Tick Tubes provide an easy to apply, no-spray way to kill ticks [that may carry Lyme]. By working with nature, Tick Tubes kill young ticks early in their lifecycle before they can [harm] [infect] people and pets.
5. This booklet explains how the product works, along with when and where to use it. Please contact us with any questions, comments or suggestions at tickhelp@thermacell.com.
6. [Team ThermoCell] [ThermoCell] [Allegra Lowitt, General Manager]

Quick Start Guide

Treating the area around your yard [or property] with Tick Tubes is easy and can be done in a few minutes. No preparation or cleanup is needed.

- [Simply] Put tubes around your yard in places mice frequent such as flowerbeds, bushes, woodpiles, stone walls, and sheds.
- Place tubes no more than 10 yards apart.
- Apply [twice] [2x] a year in spring and summer.

Smart Landscaping [that may aid in tick control] {optional}

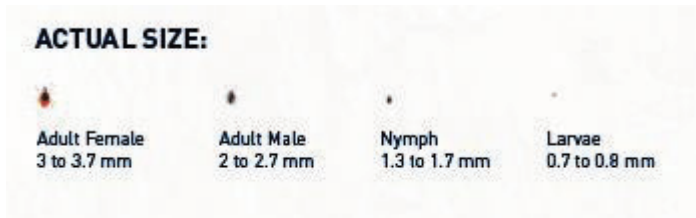
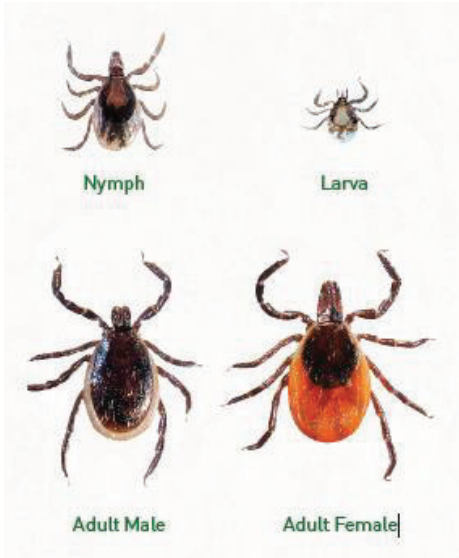
In addition to using Tick Tubes, you can make your yard less attractive to ticks through smart landscaping. Here are some simple landscaping techniques that can help reduce tick populations:

- Clear tall grasses and brush around homes and at the edge of lawns.
- Place a meter-wide barrier of wood chips or gravel between lawns and wooded areas and around patios and play equipment. This will restrict tick migration into recreational areas
- Mow the lawn frequently and keep leaves raked.
- Stack wood neatly and in a dry area (discourages rodents that ticks feed on).
- Keep playground equipment, decks, and patios away from yard edges and trees and place them in a sunny location, if possible.
- Remove any old furniture, mattresses, or trash from the yard that may give ticks a place to hide.
- Keep deer away from your yard. Fencing is the most effective method.

Deer Tick Information {optional}

DEER TICK INFORMATION

Blacklegged ticks (aka Deer ticks) can carry dangerous diseases such as Lyme disease, Babesiosis, and Anaplasmosis. Nymphs and adult females [can] transmit diseases [to humans] [to people and pets].



Most people get Lyme disease from nymphal ticks because they are difficult to spot and feed during May, June and July [when people are spending time outside] [when people are enjoying outdoor activities]. A nymphal tick is the size of a poppy seed.

THE TICK LIFECYCLE {Optional Language}

- Deer Ticks have a complex 2-year lifecycle with four stages: egg, larva, nymph, [and] adult
- [Young] [larval and nymphal] ticks feed primarily on mice, [but also feed on rodents, deer and humans.] [but also feed on humans, birds and other rodents]. [Adult ticks feed primarily on deer and humans.]
- [Eggs laid in the spring hatch in the summer as larvae. These ticks need a blood meal and feed primarily on mice. The larvae molt over winter and emerge in May as nymphs. Nymphs feed in May, June and July primarily on mice but also on rodents and humans. Nymphs then molt into adults which becomes active in October and feed primarily on deer but also on people and pets. In the spring the adult female tick lays up to 3000 eggs and the cycle starts over again.]
- By turning mice from tick hosts into tick killers, [product name] [Tick Tubes kill ticks decreasing the tick population and reducing the chance that ticks pass harmful diseases to you or your family. [By turning mice from tick hosts into tick killers, Tick Tubes end the tick lifecycle, reducing the tick population and decreasing the chance that ticks pass harmful diseases to you or your family.]

FREQUENTLYASKED QUESTIONS {Optional Language}

How do I know that the tubes are working?

After only a few days or weeks, you will notice that mice have begun removing the cotton from the Tick Tubes. Replace empty tubes with new ones.

Can I move the Tick Tubes once they have been placed around the yard?

If the specially treated material is sticking out from the ends of one of the tubes, it is best to leave the tubes where they are. A mouse or several of them have already crawled into the tube and are removing the material for their nests. [The specially treated material is already on the fur of the mice, and their transformation from tick host to tick killer has begun.]

What should I do if the specially treated material has not been removed from a tube?

If it's been a few weeks, place the Tick Tube in another part of the yard. It's important to place Tick Tubes in places where mice frequent, usually in places with good coverage where they feel safe from predators.

What if my neighbors do not treat their property? Are Tick Tubes still useful?

Yes. Ticks don't move more than a few feet, so they can't move from your neighbor's yard to yours on their own power. However, they could get into your treated yard on the back of a larger animal –for example a dog, cat or deer. So in the ideal world, your neighbors would also treat their yard with Tick Tubes because the larger the treated area, the greater the protection. That said, the most important thing is to continually treat your own yard.

What is in the specially treated material inside the Tick Tubes that kills ticks?

The material is treated with permethrin, an ingredient [insecticide] that kills ticks.

(Tube Label)

Zecken Rollen Tick Tube

Active Ingredient:

Permethrin: 7.4%

Other Ingredients 92.6%

Total 100.0%

Keep Out of Reach of Children

CAUTION

See outer carton for complete directions and precautions

Net Contents: 0.16 oz (4.5 g)

EPA Reg. No. 71910-10

EPA Est. No. 92674-BGR-01

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[26 Crosby Drive] Bedford, MA 01730-1402

Batch number: