

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3005499209
181

5

Mr. Ian Weatherston
Mallinckrodt Veterinary
421 East Hawley Street
Mundelein, IL 60060

Dear Mr. Weatherston:

Subject: Letter of Notification
ProTICall
EPA Registration Number 773-73
Your submission dated November 29, 1995

This amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable, provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

The change in product name from "Exspot for Dogs" to "Defend ProTICall" is acceptable. We assume that you intend to change the product name rather than add additional brand name although this is not clear in your application.

Although this product was previously sold over the counter in addition to veterinarians we assume now that your intend is to sell the product only through veterinary clinics.

We assume the language delineating 100% control of deer and American dog ticks and 90% control of brown dog ticks is supported by the data identified in the subject letter.

Please note that with the exception of the first and third change in your letter the other changes do not qualify as Notifications. The statement "Sold Only Through Veterinary Clinics" is more of a mandatory than advisory statement and does change the user group of the product since it was also previously over the counter.

CONCURRENCES

SYMBOL	773-73						
SURNAME	IAW						
DATE	1/25/95						

2 of 13

The performance claims, 100% and 90%, refers to the efficacy data and as such would qualify as an amendment rather than Notification.

Although additional brand names can be processed as notifications change in product name must be processed as an amendment action.

3. Submit three (3) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

4 9 13

continuum
G R O U P

Attachment 3B

INSIDE PANELS

DIRECTIONS FOR USE

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

Read entire label completely before using. **DO NOT USE ON CATS.** May be toxic if applied to or ingested by cats. Do not use this product in or on electrical equipment due to the possibility of shock hazard. Defend® ProTICall™ for Dogs may be used on puppies as young as 4 weeks of age.

HOW TO APPLY

Separate 1 cc ampule along perforations. Hold ampule in upright position. Point tip of tube cap up and away from user's face and body, then cut along dotted line. Invert ampule over dog. Part the hair of the dog. Squeeze the tube firmly to apply all of the solution to the dog's skin. Wrap container and put in trash.

Dosage for Dogs Weighing Less Than 33 Pounds

Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades.

Dosage for Dogs Weighing More Than 33 Pounds

Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades and apply 1 cc (one) of Defend ProTICall insecticide solution to the skin of the dog's back directly in front of the base of the tail.

For More Information, Call 1-800-TIC-FLEA

Lift Here for More Information

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. **DO NOT USE ON CATS.** Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure. Do not use on sick or debilitated dogs. Consult with a veterinarian before using on dogs with known organ dysfunction.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger or, if available, by

Attachment 3C

continuum
G R O U P

administration of syrup of ipecac. **DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.** If on Skin: Remove contaminated clothing and wash with plenty of soap and water. Call a physician if irritation persists. If in Eyes: Flush eyes with plenty of water. Call a physician if irritation persists. Adverse Reactions: Some animals may be sensitive to ingredients in this product. Reported reactions in dogs have included skin sensitivity. Increased itchiness, redness, rash, hair discoloration or hair loss at the application site may occur. Dogs may also show lethargy. Observe the dog following treatment, if sensitivity to Defend® ProTICall™ for Dogs occurs, discontinue use and bathe the dog. Seek Veterinary advice.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Storage: Store in cool, dry place. Protect from freezing. Pesticide Disposal: Securely wrap original container in several layers of newspaper and discard in trash. Container Disposal: Do not reuse empty container. Wrap container and put in trash.

Defend® ProTICall™ insecticide is an effective and easy to use product. Defend® ProTICall™ insecticide demonstrates 100% control of Deer Ticks and American Dog Ticks within 7 days of application. Defend® ProTICall™ insecticide demonstrates greater than 90% control of Brown Dog Ticks within 7 days of application. Defend® ProTICall™ insecticide demonstrates greater than 92% control of fleas within 3 days of application. As with all tick and flea control products, Defend ProTICall™ insecticide should be used as part of a control program aimed at reducing tick and flea populations in the dog's environment (bedding, carpets, kennel, yard). Consult your veterinarian or entomologist for program recommendations. Repeat applications may be made as necessary, but do not apply at intervals less than 7 days. **DO NOT USE ON CATS.**

Incidence of Ticks in the United States**Deer Ticks**

(Ixodes scapularis) Vector of LYME DISEASE

Brown Dog Ticks

(Rhipicephalus sanguineus)

American Dog Ticks

(Dermacentor variabilis)

6 7 13

George LaRocca

ProTICall

Page 15.

Attachment 3D

continuum
G R O U P

BACK PANEL

(Defend logo)®
ProTICall™
KILLS & REPELS TICKS

Deer Ticks
(*Ixodes scapularis*) Vector of LYME DISEASE up to 4 Weeks
4X Magnification

Brown Dog Ticks
(*Rhipicephalus sanguineus*) up to 4 Weeks
1.6X Magnification

American Dog Ticks
(*Dermacentor variabilis*) for 2 to 3 Weeks
1.6X Magnification

NOTICE OF WARRANTY
MALLINCKRODT VETERINARY, INC. MAKES NO WARRANTY OF
MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE,
EXPRESS OR IMPLIED CONCERNING THIS PRODUCT OR ITS USES WHICH
EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN
ACCORD WITH THE STATEMENTS MADE ON THIS LABEL.

Mallinckrodt Veterinary, Inc.
421 East Hawley St.
Mundelein, IL 60060 USA
EPA Reg. No.: 773-73
EPA Est. No.: 6175-LA-1
Mfg. & Printed in U.S.A.
00000000

DEFEND is a registered trademark of Mallinckrodt Veterinary, Inc.
©1996 Mallinckrodt Veterinary, Inc.

Lot. No.

(UPC Code)

Attachment 4A



ProTICall

KILLS & REPELS TICKS

FOR USE ON DOGS AND PUPPIES



Deer Ticks
Ixodes scapularis
Vector of LYME DISEASE
up to 4 Weeks



Brown Dog Ticks
Rhipicephalus sanguineus up to 4 Weeks



American Dog Ticks
Dermacentor variabilis for 2 to 3 Weeks



KILLS & REPELS*

<p>Deer Ticks <i>Ixodes scapularis</i> Vector of LYME DISEASE up to 4 Weeks</p>	<p>Brown Dog Ticks <i>Rhipicephalus sanguineus</i> up to 4 Weeks</p>	<p>American Dog Ticks <i>Dermacentor variabilis</i> for 2 to 3 Weeks</p>
--	---	---

Also Kills & Repels Fleas & Mosquitoes up to 4 Weeks
Sold Only Through Veterinary Clinics

NOTICE OF WARRANTY
MALLINCKRODT VETERINARY, INC. MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR OTHERWISE, EXPRESSED OR IMPLIED CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORD WITH THE STATEMENTS MADE ON THIS LABEL.

DEFEND is a registered trademark of Mallinckrodt Veterinary.

EPA Reg. No.: 773-73
EPA Est. No.: 6175-1A-1
Mfg. & Printed in U.S.A.
Lot. No.

*U.S. Patent No. 4,020,181 + other patents pending
cis:trans ratio: Max 55% (±) cis and min. 45% (±) trans

Active Ingredients:	65%
Permethrin: (3-phenoxyphenyl) methyl (±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate**	35%
Inert Ingredients	Total 100% wt./wt.

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE INSIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents:
Six 1 cc Applicators

MALLINCKRODT VETERINARY

50442

16 X Mag. indication  **American Dog Ticks**
(Dermacentor variabilis) for 2 to 3 Weeks

16 X Mag. indication  **Brown Dog Ticks**
(Rhipicephalus sanguineus) up to 4 Weeks

4 X Mag. indication  **Deer Ticks**
(Ixodes scapularis) Vector of LYME DISEASE up to 4 Weeks



DIRECTIONS FOR USE:
It is a violation of Federal Law to use this product in a manner inconsistent with the label. Read entire label completely. **DO NOT USE ON CATS.** Must be applied to or ingested by cats. Do not use product in or on electrical equipment. Possibility of shock hazard. For Dogs may be used on puppies 4 weeks of age.

HOW TO APPLY:
Separate 1 cc ampule along top edge. Hold ampule in upright position with tube cap up and away from dog's head and body, then cut along dotted line. Invert ampule over dog's back. Part ampule over dog's back. Squeeze the tube firmly against the dog's skin to dispense the solution to the dog's skin. Wrap container and put in trash.



Dosage for Dogs Weighing Less Than 33 Pounds: 1 cc



Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades.

For More Information, Call 1-800-TIC-FLEA

8 9 13



Defend[®] ProTICall

KILLS & REPELS TICKS

FOR USE ON DOGS AND PUPPIES




KILLS & REPELS*

Deer Ticks <i>Ixodes scapularis</i> Vector of LYME DISEASE up to 4 Weeks	Brown Dog Ticks <i>Rhipicephalus sanguineus</i> up to 4 Weeks	American Dog Ticks <i>Dermacentor variabilis</i> for 2 to 3 Weeks
---	---	---

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label completely before using. **DO NOT USE ON CATS.** May be toxic if applied to or ingested by cats. Do not use this product in or on electrical equipment due to the possibility of shock hazard. Defend[®] ProTICall[™] for Dogs may be used on puppies as young as 4 weeks of age.

HOW TO APPLY

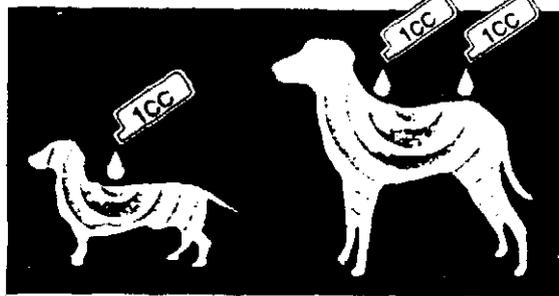
Separate 1 cc ampule along perforations. Hold ampule in upright position. Point tip of tube cap up and away from user's face and body, then cut along dotted line. Invert ampule over dog. Part the hair of the dog. Squeeze the tube firmly to apply all of the solution to the dog's skin. Wrap container and put in trash.

See Here for More Information



Dosage for Dogs Weighing Less Than 33 Pounds

Dosage for Dogs Weighing More Than 33 Pounds



Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades.

Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades and apply 1 cc (one) of Defend ProTICall insecticide solution to the skin of the dog's back directly in front of the base of the tail.

For More Information, Call 1-800-TIC-FLEA

Also Kills & Repels Fleas & Mosquitoes up to 4 Weeks
Sold Only Through Veterinary Clinics

Active Ingredients:

Permethrin: (3-phenoxyphenyl) methyl (±) cis, trans-3-(2,2-dichloroethyl)-2,2-dimethylcyclopropanecarboxylate**65%

Inert Ingredients35%

Total 100% wt/wt.

*U.S. Patent No. 4,020,181 + other patent pending
**cis:trans ratio: Max 55% (±) cis and min. 45% (±) trans

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE INSIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents:

1 cc Applicators

MAINTENANCE VETERINARY

50442

BEST COPY AVAILABLE

Attachment 4B

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. **DO NOT USE ON CATS.** Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure. Do not use on sick or debilitated dogs. Consult with a veterinarian before using on dogs with known organ dysfunction.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger or, if available, by administration of syrup of ipecac. **DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.**

If on Skin: Remove contaminated clothing and wash with plenty of soap and water. Call a physician if irritation persists.

If in Eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

Adverse Reactions: Some animals may be sensitive to ingredients in this product. Reported reactions in dogs have included skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site may occur. Dogs may also show lethargy. **Observe the dog following treatment,** if sensitivity to Defend[®] ProTICall[™] for Dogs occurs, discontinue use and bathe the dog. Seek Veterinary advice.

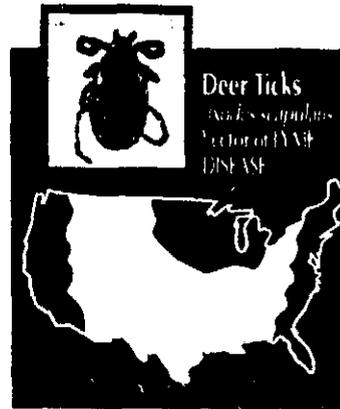
ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Storage:** Store in cool, dry place. Protect from freezing. **Product Disposal:** Securely wrap original container in several layers of newspaper and discard in trash. **Container Disposal:** Do not reuse empty container. Wrap container and put in trash.

**Incidence of Ticks
in the United States**



Deer Ticks
Ixodes scapularis
Vector of Lyme Disease



Brown Dog Ticks
Rhipicephalus sanguineus



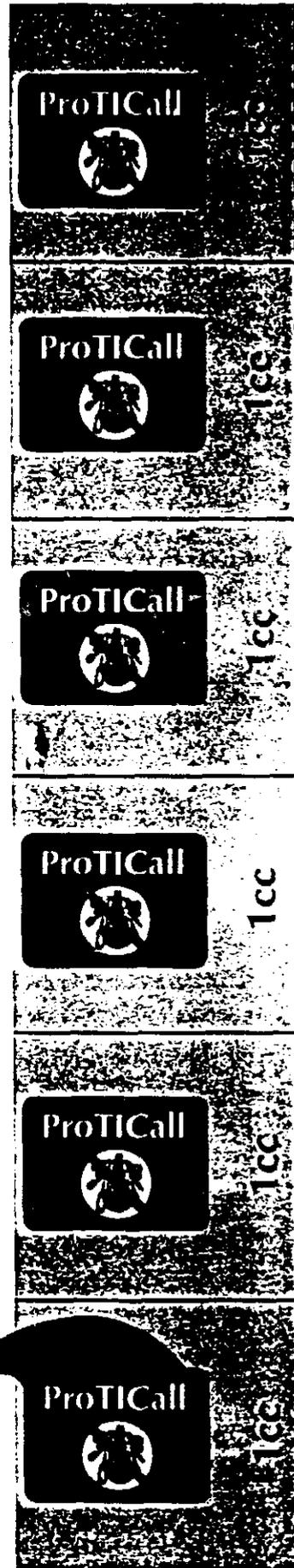
American Dog Ticks
Dermacentor variabilis

°		MONTH						
1	2	3	4	5	6	7	8	
6	7	8	9	10	11	12	13	
14	15	16	17	18	19	20	21	
22	23	24	25	26	27	28	29	
30	31							

Defend[®] ProTICall[™] insecticide is an effective and easy to use product. Defend[®] ProTICall[™] insecticide demonstrates 100% control of Deer Ticks and American Dog Ticks within 7 days of application. Defend[®] ProTICall[™] insecticide demonstrates greater than 90% control of Brown Dog Ticks within 7 days of application. Defend[®] ProTICall[™] insecticide demonstrates greater than 92% control of fleas within 3 days of application.

As with all tick and flea control products, Defend ProTICall[™] insecticide should be used as part of a control program aimed at reducing tick and flea populations in the dog's environment (bedding, carpets, kennel, yard).

Consult your veterinarian or entomologist for program recommendations. Repeat applications may be made as necessary, but do not apply at intervals less than 7 days. **DO NOT USE ON CATS.**



Attachment 5

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label completely before using. **DO NOT USE ON CATS.** May be toxic if applied to or ingested by cats. Do not use this product in or on electrical equipment due to the possibility of shock hazard. Defend® ProTICall™ for Dogs may be used on puppies as young as 4 weeks of age.

HOW TO APPLY

Separate 1 cc ampule along perforations. Hold ampule in upright position. Point tip of tube cap up and away from user's face and body, then cut along dotted line. Invert ampule over dog. Part the hair of the dog. Squeeze the tube firmly to apply all of the solution to the dog's skin. Wrap container and put in trash.



1 ml (cc) for More Information

Dosage for Dogs Weighing Less Than 33 Pounds

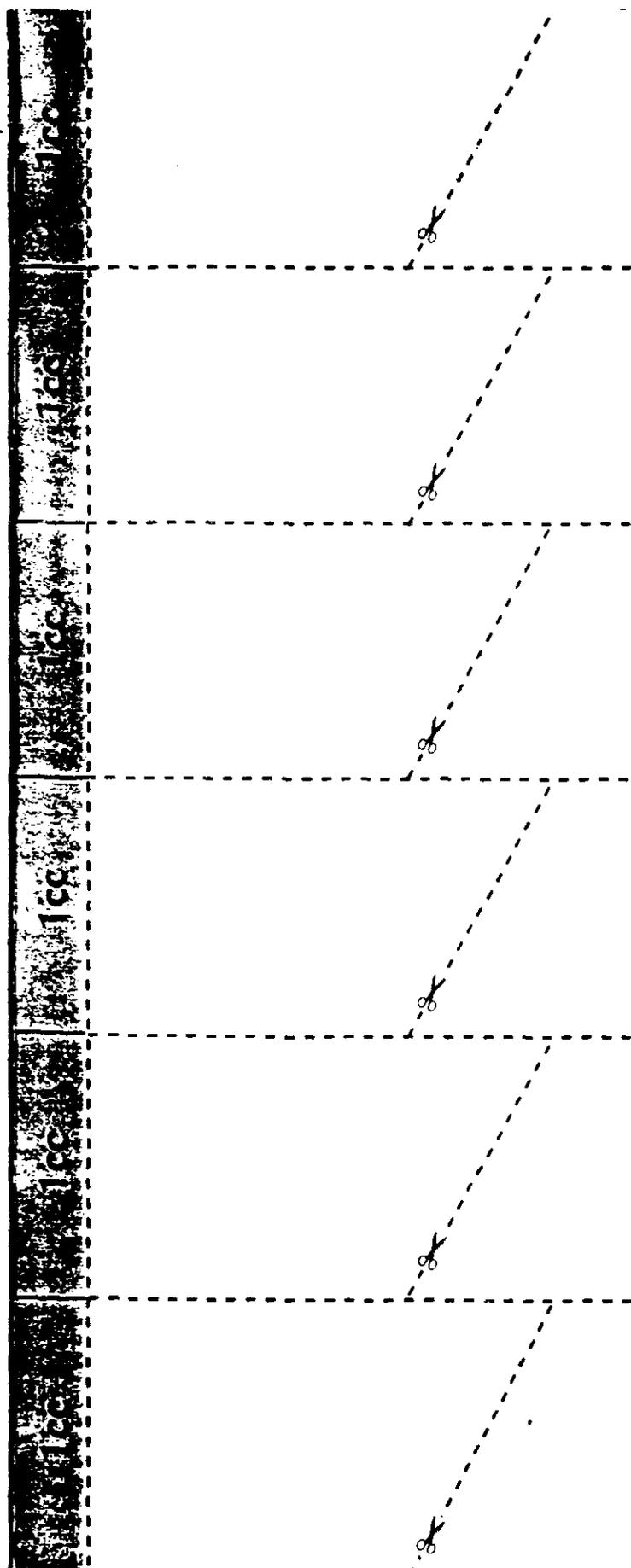
Dosage for Dogs Weighing More Than 33 Pounds



Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades.

Apply 1 (one) cc of Defend ProTICall insecticide solution to the skin of the dog's back between the shoulder blades and apply 1 cc (one) of Defend ProTICall insecticide solution to the skin of the dog's back directly in front of the base of the tail.

For More Information, Call 1-800-TIC-FLEA



Attachment 5

Defend[®]

ProTICall

KILLS & REPELS TICKS

FOR USE ON DOGS AND PUPPIES







KILLS & REPELS*

<p>Deer Ticks <i>(Ixodes scapularis)</i> Vector of LYME DISEASE up to 4 Weeks</p>	<p>Brown Dog Ticks <i>(Rhipicephalus sanguineus)</i> up to 4 Weeks</p>	<p>American Dog Ticks <i>(Dermacentor variabilis)</i> for 2 to 3 Weeks</p>
--	---	---

Also Kills & Repels Fleas & Mosquitoes up to 4 Weeks
Sold Only Through Veterinary Clinics

Active Ingredients:
 Permethrin: (3-phenoxyphenyl) methyl (±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate**65%
 Inert Ingredients.....35%
Total 100% wt./wt.

*U.S. Patent No. 4,020,181 + other patent pending
 **cis:trans ratio: Max 55% (±) cis and min. 45% (±) trans

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE BUNDLES PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents:
Six 1 cc Applicators

MALLINCKRODT VETERINARY

50442

BEST COPY AVAILABLE