

54382-3

03/21/2005

Copy to Mauraen Shewell, P.A. 3/9/5/17

Please read instructions on reverse before completing form

Form Approved. OMB No. 2070-0060



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 54382-3	2. EPA Product Manager Akiva Abramovitch	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Intervet Inc./Taktic Emulsifiable Concentrate Miticide/Insecticide	PM# 4	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millsboro, DE 19966 <input checked="" 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"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION

MAR 21 2005

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of minor changes to the disclaimer statement per PR Notice 98-10. This notification is submitted in response to California Notice to Registrants 2004-3 which requires changes to the "Disclaimer" section of the label (See attached draft label for proposed changes). 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 of 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 of PR Notice 98-10 and 40 CFR 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 type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/>
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph Paper glued Stenciled	<input type="checkbox"/> Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
2. Signature <i>Mary K. Hagler</i>		3. Title Senior Regulatory Affairs Specialist - Pharmaceuticals
4. Typed Name Mary K. Hagler		5. Date 08 March 05
Certification 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 statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)

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NOTIFICATION  
MAR 21 2005

# Taktic®

EMULSIFIABLE CONCENTRATE  
MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND  
LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLON IMPACTION)

ACTIVE INGREDIENT:	Percent by Weight:
Amitraz	12.5
INERT INGREDIENTS:	<u>87.5</u>
	TOTAL 100.0

This product contains Petroleum Distillate.

EPA Reg. No. 54382-3  
U.S. Patent Nos. 3,781,355 and 3,864,497

EPA Est. No. 264-CAN-001

USUARIO: Si usted no lee inglés, no use este producto  
hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this  
product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

## DANGER-PELIGRO

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY  
STATEMENTS

**NOTICE: This product contains a chemical known to the State of California  
to cause birth defects or other reproductive harm.**

INTERVET INC.  
Millsboro, DE 19966  
584300D

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)

**FIRST AID:**

<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give <b>any</b> liquid to the person.</li> <li>• Do not give anything to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<p>For incidents involving <b>HUMANS</b>, call <b>1-800-228-5635, ext 132</b>  For incidents involving <b>ANIMALS</b>, call <b>1-800-345-4735, ext 104</b>  Have the product container or label with you when calling a poison control center or doctor or going for treatment</p>	
<p><b>NOTE TO PHYSICIAN:</b> Amitraz, the active ingredient in this product, is a carbamate. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. Contains petroleum distillate – vomiting may cause aspiration pneumonia.</p>	

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans (and Domestic Animals)**

**DANGER**

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**Personal Protective Equipment (PPE)**

Applicators and other handlers must wear:

- Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- Chemical-resistant footwear plus socks.
- Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**User Safety Recommendations**

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

**PHYSICAL OR CHEMICAL HAZARDS**

Do not use or store near heat or open flame.

**STORAGE AND DISPOSAL**

**STORAGE:** Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

**DO NOT REUSE EMPTY CONTAINER.**

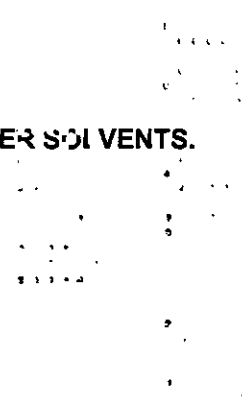
**CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE)**  
1-800-424-9300

**DIRECTIONS FOR USE**

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

**DO NOT USE ON HORSES or DOGS – CAN CAUSE DEATHS.**

**DO NOT OPEN CONTAINER UNTIL READY TO USE.**  
**USE TAKTIC®E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.**



## BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

### TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (*Amblyomma americanum*)

Gulf Coast Tick (*A. maculatum*)

Winter Tick (*Dermacentor albipictus*)

Brown Dog Tick (*Rhipicephalus sanguineus*)

American Dog Tick (*D. variabilis*)

Rocky Mountain Wood Tick (*D. andersoni*)

Spinose Ear Tick (*Otobius megnini*)

Black-legged Tick (*Ixodes scapularis*)

Tropical Bont Tick (*A. variegatum*)

Cayenne Tick (*A. cajennense*)

Cattle Tick (*Boophilus annulatus*)

Southern Cattle Tick (*B. microplus*)

Biting Louse (*Damalinia bovis*)

Sucking Lice (*Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*)

### MITES

Scab and Mange Mites (*Chorioptes bovis*, *Psoroptes ovis* and *Sarcoptes scabiei* var. *bovis*)

### Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

### Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scabies. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

## SWINE

**MANGE MITE AND LOUSE** (*Sarcoptes scabiei* var. *suis* and *Haematopinus suis*):

### IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

### Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowl, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amitraz-containing product.

### IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label. ~~when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use.~~ INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

© 2002 INTERVET INC.

584350C

MADE IN CANADA

NET CONTENTS: 760 ml (25.7 fl. oz.)



7/7

(302) 934-4340

08 March 2005

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the disclaimer statement for Taktic Emulsifiable Concentrate Miticide/Insecticide label (EPA Registration #: 54382-3; Intervet Inc., Company #: 54382). This notification is submitted in response to California Notice to Registrants 2004-3 which requires changes to the "Disclaimer" section of the label.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed text to be removed is indicated by strikethrough and is also highlighted. In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail ([mary.hagler@intervet.com](mailto:mary.hagler@intervet.com)) should you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Mary K. Hagler".

Mary K. Hagler, MS  
Senior Regulatory Affairs Specialist – Pharmaceuticals  
Intervet Inc.

Enclosure

The Intervet logo, consisting of the word "Intervet" in a stylized, lowercase font with a horizontal line through the middle of the letters.

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Lüne  
Intervet Inc.  
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P.O. Box 378  
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