

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 11, 2017

Mr. Micah T. Reynolds, Agent Intervet, Inc. (d/b/a Merck Animal Health) 2 Giralda Farms Madison, New Jersey 07940

Subject: Label Amendment – Label revisions to comply with spot-on mitigation language

Product Name: Activyl for Cats and Kittens

EPA Registration Number: 773-93 Application Date: July 20, 2016 Decision Number: 519775

Dear Mr. Reynolds:

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.

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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 Eric Bohnenblust by phone at(703) 347-0426, or via email at Bohnenblust.eric@epa.gov.

Richard Gebken, Product Manager 10 Invertebrate & Vertebrate Branch 2 Office of Pesticide Programs

Enclosure

ACTIVYL for Cats and Kittens

EPA Reg No: 773-93

DATED: January 3, 2017
Page 1 of 14

Amended version: 1.6 (2016 Pet Spot-On Registration Extension)

"Master Label": This master label includes text for different size packages and application rates specific to

pet's age and body weight.

## **CARTON - FRONT PANEL STATEMENTS**

## ACTIVYL for Cats and Kittens

(Note: "for Cats and Kittens" text in primary brand name, and other iterations in the alternate brand names that follow "Activyl" to be a minimum of 75% as large as the height of the largest letter in the brand name presentation.)

#### **Alternate Brand Names:**

ACTIVYL for Cats or Kittens ACTIVYL Spot-On for Cats and Kittens ACTIVYL Spot-On for Cats or Kittens

ACTIVYL for Cats

ACTIVYL Spot-On for Cats

ACCEPTED

01/11/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 773-93

Once-A-Month Topical Flea Treatment

Following to be placed in black box:

For Cats and Kittens 2 to 9 lb (0.9 to 4 kg) and 8 weeks of age or older ONLY (0.51 mL size only) For Cats over (greater than) (>) 9 lb (4 kg) and 8 weeks of age or older ONLY (1.03 mL size only)

#### **Active Ingredient:**

Indoxacarb:

## KEEP OUT OF REACH OF CHILDREN WARNING

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

#### **PROTOTYPE**



(note to reviewer: appropriate kitten or cat picture will be presented on the front panel depending on package)

LOGO - Merck Animal Health

EPA Reg. No. 773-93

EPA Est. No. 618-LA-1 Net Contents: X applicator(s), each 0.02 fl.oz. (0.51 mL) {Total X fl.oz (X mL)]

X applicator(s), each 0.03 fl.oz. (1.03 mL) {Total X fl.oz (X mL)]

<sup>()</sup> Bracket text allows for alternative presentations of the same claim.

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## PRIMARY CARTON - BACK PANEL STATEMENTS

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the package insert for complete Directions For Use.

#### RESTRICTIONS

▶ DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ▶ TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. ▶FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. ► USE ON CATS ONLY. ► DO NOT USE ON CATS (MALE OR FEMALE) INTENDED FOR BREEDING, PREGNANT OR NURSING. ► DO NOT USE ON OTHER ANIMALS. ▶ DO NOT USE MORE THAN ONCE A MONTH. ▶ DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ▶DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT.

#### FOR EXTERNAL USE ON CATS AND KITTENS ONLY.

For 0.51 mL package size: Do not use on cats or kittens under 8 weeks of age. Do not use on cats weighing less than 2

For 1.03 mL package size: Do not use on cats or kittens under 8 weeks of age. Do not use on cats weighing less than 9

(Note to reviewer: First Aid statements may be boxed and/or bulleted if label space allows or may be presented unboxed and unbulleted. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.)

FIRST AID			
If In Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>		
	Call a poison control center or doctor for treatment advice.		
If On Skin	<ul> <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>		
If Swallowed	<ul> <li>Call poison control center or doctor immediately for treatment advice.</li> <li>Have a person sip a glass of water if able to swallow.</li> </ul>		
	Do not induce vomiting unless told to by the poison control center or doctor.		
	Do not give anything to an unconscious person.		
HOT LINE NUMBER			
Have the product of	Have the product container or label with you when calling the poison control center or doctor		

or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.

SIDE EFFECTS: Monitor your cat after application. Accidental ingestion by the cat may cause intermittent excess salivation. Other immediate post-treatment observations may include licking the face, shaking the head and squinting. These effects should disappear within several minutes following exposure without requiring treatment. Please refer to the package insert for additional side effects information. If these or other side effects occur consult a veterinarian immediately.

## PRIMARY CARTON – SIDE PANEL STATEMENTS

## PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS** 

**WARNING.** Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on 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.

#### HAZARDS TO DOMESTIC ANIMALS

For external use on cats and kittens only. Do not use on kittens under 8 weeks of age OR weighing less than 2 lb/9lb (note to reviewer: weight used will be according to package size). Do not use on cats (male or female) intended for breeding, pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated cats. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides.

#### PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

<sup>()</sup> Bracket text allows for alternative presentations of the same claim.

## PRIMARY CARTON – SIDE PANEL STATEMENTS

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Store in a cool, dry place inaccessible to children and pets. **PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty,** do not reuse the container. Place in trash or offer for recycling if available. **If partly filled,** call your local solid waste agency for disposal instructions. Never place unused products down any indoor or outdoor drain.

Made in the USA.

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health. 2 Giralda Farms, Madison, NJ 07940 Copyright xxxx. All rights reserved. xxxxxxxx Rev. xx/xxxx

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

<sup>()</sup> Bracket text allows for alternative presentations of the same claim.

ACTIVYL for Cats and Kittens

EPA Reg No: 773-93

DATED: January 3, 2017
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Amended version: 1.6 (2016 Pet Spot-On Registration Extension)

## APPLICATOR LABELING STATEMENTS

## **ACTIVYL**

# KEEP OUT OF REACH OF CHILDREN WARNING READ ENTIRE LABEL BEFORE USE

0.02 fl. oz. (0.51 mL) 0.03 fl. oz. (1.03 mL)

EPA Reg. No. 773-93 EPA Est. No. 618-LA-1

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health.

Lot No:

<sup>()</sup> Bracket text allows for alternative presentations of the same claim.

ACTIVYL for Cats and Kittens

EPA Reg No: 773-93

Amended version: 1.6 (2016 Pet Spot-On Registration Extension)

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## FOIL POUCH LABELING STATEMENTS

To Open: Tear or cut across line with scissors ←-------

### DO NOT REMOVE APPLICATOR (TUBE) UNTIL READY TO USE

## ACTIVYL for Cats and Kittens

#### **Alternate Brand Names:**

ACTIVYL for Cats or Kittens ACTIVYL Spot-On for Cats and Kittens ACTIVYL Spot-On for Cats or Kittens ACTIVYL for Cats ACTIVYL Spot-On for Cats

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For Cats and Kittens 2 to 9 lb (0.9 to 4 kg) and 8 weeks of age or older ONLY (0.51 mL size only)
For Cats over (greater than) (>) 9 lb (4 kg) and 8 weeks of age or older ONLY (1.03 mL size only)

Indoxacarb: ...19.53%

## KEEP OUT OF REACH OF CHILDREN WARNING READ ENTIRE LABEL BEFORE USE

0.02 fl. oz. (0.51 mL) 0.03 fl. oz. (1.03 mL)

EPA Reg. No. 773-93 EPA Est. No. 618-LA-1

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health.

Lot No:

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ACTIVYL for Cats and Kittens

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(Due to carton size this additional information is referred to on the carton and includes complete directions for use with all carton box mandatory required statements found on the primary carton )

## For 0.51 mL and 1.03 mL package size

(note to reviewer: appropriate dose size will depending on package)

## PACKAGE INSERT STATEMENTS

## ACTIVYL for Cats and Kittens

#### **Alternate Brand Names:**

ACTIVYL for Cats or Kittens ACTIVYL Spot-On for Cats and Kittens ACTIVYL Spot-On for Cats or Kittens ACTIVYL for Cats ACTIVYL Spot-On for Cats

DATED: January 3, 2017

Once-A-Month Topical Flea Treatment

For Cats and Kittens 2 to 9 lb (0.9 to 4 kg) and 8 weeks of age or older ONLY

For Cats over (greater than) (>) 9 lb (4 kg) and 8 weeks of age or older ONLY

(0.51 mL size only)

(1.03 mL size only)

#### **Active Ingredient:**

Indoxacarb:

# KEEP OUT OF REACH OF CHILDREN WARNING

#### **DIRECTIONS FOR USE**

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

#### RESTRICTIONS

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ►TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. ►FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. ► USE ON CATS ONLY. ► DO NOT USE ON CATS (MALE OR FEMALE) INTENDED FOR BREEDING, PREGNANT OR NURSING. ► DO NOT USE ON OTHER ANIMALS. ► DO NOT USE MORE THAN ONCE A MONTH. ► DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ► DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT.

#### FOR EXTERNAL USE ON CATS AND KITTENS ONLY.

For 0.51 mL package size: Do not use on cats or kittens under 8 weeks of age. Do not use on cats weighing less than 2 lb.

For 1.03 mL package size: Do not use on cats or kittens under 8 weeks of age. Do not use on cats weighing less than 9 lb.

<sup>()</sup> Bracket text allows for alternative presentations of the same claim.

interactive version in (2010) of registration Extension)

## PACKAGE INSERT STATEMENTS - cont'd

(HOW TO APPLY) Open one foil pouch as directed and remove applicator (tube).







For cats and kittens 2 to 9lb (0.9 to 4 kg) ONLY (0.51 mL size only)



For cats (greater than) (>) 9 lb (4 kg) ONLY (1.03 mL size only)

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- **Step 1.** Hold applicator (tube) in upright position away from your face and snap tip open by bending it and folding it back on itself.
- **Step 2.** Part the hair and place applicator (tube) tip against the skin at the base of skull. Applying the product at the base of the skull will help prevent the cat from licking the product.
- **Step 3.** Squeeze applicator firmly applying entire contents directly to skin. Do not allow product to run off. Do not have contact with treated area (application site) until completely dry.

It is recommended to reapply every 30 days, but DO NOT apply more than 1 applicator (tube) per month. When application is complete, follow the Container Handling instructions under the Storage and Disposal section below.

(Note to reviewer: First Aid statements may be boxed and/or bulleted if label space allows or may be presented unboxed and unbulleted. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.)

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	FIRST AID	
	Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
If In Eyes	• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.	
	Call a poison control center or doctor for treatment advice.	
	Take off contaminated clothing.	
If On Skin	• Rinse skin immediately with plenty of water for 15-20 minutes.	
	Call a poison control center or doctor for treatment advice.	
	Call poison control center or doctor immediately for treatment advice.	
If Swallowed	Have a person sip a glass of water if able to swallow.	
	• Do not induce vomiting unless told to by the poison control center or doctor.	
	Do not give anything to an unconscious person.	
	HOT LINE NUMBER	

Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.

**SIDE EFFECTS**: Monitor your cat after application. Accidental ingestion by the cat may cause intermittent excess salivation. Other immediate post-treatment observations may include licking the face, shaking the head and squinting. In rare cases, application site reactions (e.g. scratching, redness, hair loss) may occur. These effects usually resolve without requiring treatment. Rare cases (fewer than 1 in 1,000) of neurological signs (e.g. incoordination, tremor, impaired balance, convulsions, dilated pupils, and impaired vision) and/or vomiting and very rare cases (fewer than 1 in 10,000) of decreased appetite, lethargy, hyperactivity, or vocalization may occur. These effects will generally resolve with supportive treatment. If these or other side effects occur consult a veterinarian immediately.

## PACKAGE INSERT STATEMENTS - cont'd

## PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

**WARNING.** Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on 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.

#### HAZARDS TO DOMESTIC ANIMALS

For external use on cats and kittens only. Do not use on kittens under 8 weeks of age. Do not use on cats weighing less than 2 lb/9lb (note to reviewer: weight used will be according to package size). Do not use on cats (male or female) intended for breeding, pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated cats. Accidental ingestion by the cat may cause intermittent excess salivation. Other immediate post-treatment observations may include licking the face, shaking the head and squinting. These effects should disappear within several minutes following exposure without requiring treatment. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides.

#### PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Store in a cool, dry place inaccessible to children and pets. **PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty,** do not reuse the container. Place in trash or offer for recycling if available. **If partly filled**, call your local solid waste agency for disposal instructions. Never place unused products down any indoor or outdoor drain.

EPA Reg. No. 773-93

EPA Est. No. 618-LA-1 Net Contents: X applicator(s), each 0.02 fl.oz. (0.51 mL) {Total X fl.oz (X mL)]

X applicator(s), each 0.03 fl.oz. (1.03 mL) {Total X fl.oz (X mL)]

Made in the USA.

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health.

2 Giralda Farms, Madison, NJ 07940

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(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

() Bracket text allows for alternative presentations of the same claim.

Amended version: 1.0 (2010 Fet Spot-On Registration Extension)

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## FRONT PANEL AND/OR SIDE PANEL CLAIMS -optional

- 1. Intended to be sold through veterinarians.
- 2. Intended to be dispensed (and) (or) sold through (by) licensed veterinarians and only to their clients for pets under a direct vet-client-patient relationship.
- 3. Product availability intended through licensed veterinarians.
- 4. Kills fleas (within 24 hours of application)
- 5. Kills (adult cat flea) (Ctenocephalides felis) and reduces egg production (as early as) two (2) days after treatment
- 6. Kills (adult cat flea) (Ctenocephalides felis) and reduces egg production for one (1) month
- 7. Inhibits (adult) flea emergence (and (interrupts) (inhibits) (flea) reproduction) (for (one) (1) month)
- 8. (Activyl® for Cats and Kittens) (Alternate or brand name) Reduces flea egg viability (and adult flea emergence)
- 9. (Activyl® for Cats and Kittens) (This product) (Alternate Brand Name) kills all flea stages (- egg, larvae, and adult)
- 10. Flea eggs and flea larvae in (the pet's) (your cat's) (the) surroundings are killed following contact with (a)(an) (Activyl® for Cats and Kittens) (alternate or brand name) treated pet.
- 11. Kills fleas that may transmit bartonellosis and transmit tapeworm.
- 12. If there is a high risk of re-infestation or if the pet has fleas, once monthly application is recommended. Do not apply more than once a month.
- 13. Kills fleas that may cause (flea allergy dermatitis)(FAD).
- 14. If there is a high risk of re-infestation or if the pet has fleas which may cause (flea allergy dermatitis) (FAD), once monthly application is recommended. Do not apply more than once a month.
- 15. (Activyl® for Cats and Kittens) (Alternate or brand name) kills fleas that may cause anemia.
- 16. (Activyl® for Cats and Kittens) (Alternate or brand name) kills fleas that may transmit tapeworms
- 17. The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats with (Activyl® for Cats and Kittens) (alternate or brand name) kills fleas that may cause FAD.
- 18. For the (prevention)(and)(treatment) of flea infestations on cats (and/or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) for (four)(4)(weeks)
- 19. For the (prevention)(and)(treatment) of flea infestations on cats (and/or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) for (one)(1)(month)
- 20. (Prevents) (and) (protects) against (re-)infestation of fleas for (four)(4)(weeks)
- 21. (Prevents) (and) (protects) against (re-)infestation of fleas for (one)(1)(month)
- 22. One treatment prevents flea infestations (on cats) (and/or) (kitten 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) for (four)(4)(weeks)
- 23. One treatment prevents flea infestations (on cats) (and/or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) for (one)(1)(month)

<sup>()</sup> Bracket text allows for alternative presentations of the same claim.

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- 24. Protects (your cat) (and/or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) from fleas for (four)(4)(weeks)
- 25. Protects (your cat) (and/or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) from fleas for (one)(1)(month)
- 26. Monthly treatment (recommended) for optimal (control)(and)(prevention) of fleas (on your)(cat)(and/or)(kitten). Do not apply more than once a month.
- 27. Monthly (control) (prevention)(and)(treatment) of fleas (on cats) (and/or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs)
- 28. Flea (control) (prevention)(and)(treatment) formulated for (cats)(and)(kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs)
- 29. (Controls)(Treatment against)(Protects against) (blood-feeding) (by) fleas following exposure to the product
- 30. Monthly treatments are recommended for optimal (control) (and) (prevention) of flea(s) (infestations). Do not apply more than once a month.
- 31. Water-resistant
- 32. Waterproof
- 33. (Activyl® for Cats and Kittens) (Alternate or brand name) (This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
- 34. (Activyl® for Cats and Kittens) (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
- 35. (Activyl® for Cats and Kittens) (Alternate or brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).

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#### **ALTERNATE MARKETING TEXT - optional**

- 1. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (cats) (and) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs)
- 2. (Once) monthly (a month) application (treatment) (for) (cats) (and) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) to control fleas
- 3. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities) (i.e., flea allergy dermatitis). Do not apply more than once a month.
- 4. X applicators
- 5. X monthly doses (applications) (treatments)
- 6. Quick drying (non-greasy)
- 7. Long Lasting control of fleas for up to 1 month (30 days)
- 8. Long-lasting protection against fleas for up to 1 month (30 days)
- 9. Easy to apply (spot-on) (topical) (application) (treatment)
- 10. Convenient (to use)
- 11. Easy (Convenient) to apply
- 12. Easy (spot on) (to use) application
- 13. (Convenient) (Single) (Spot) application
- 14. No noticeable odor
- 15. No fragrance added
- 16. Formulated for cats (and) (kittens 8 weeks and older and weighing more than (2 lb (0.9 kg) and up to 9 lb (4.1kg))
- 17. Formulated for cats weighing more than 9 lb (4.1kg)
- 18. Monthly use breaks the flea life cycle
- 19. Questions (or) (comments) call (1-800-Tel. Number) (or) (Tel. No.)
- 20. For more information call (1-800- Tel. Number) (or) (Tel. No.)
- 21. For emergencies call (1-800- Tel. Number) (or) (Tel. No.)
- 22. If you have any questions, call Intervet Inc. Technical Services at (1-800- Tel. Number) (or)(Tel. No.)
- 23. (Manufacturer) (Satisfaction) Guaranteed or your money back.
- 24. Recommended monthly treatment for year round (control) (treatment) (prevention) against fleas. Do not apply more than once a month.

ACTIVYL for Cats and Kittens EPA Reg No: 773-93

Amended version: 1.6 (2016 Pet Spot-On Registration Extension)

Amended version. 1.0 (2010 f et Spot-On Registration Extension)

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## ALTERNATE MARKETING TEXT – optional- (cont'd)

- 25. (Control) (Treatment) (Prevention) for flea infestations
- 26. Protects (your) (cat) (and) (or) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs) for up to (1 month) (one month)(a month)
- 27. (Activyl® for Cats and Kittens) (Alternate or brand name)(This product) (It) may also be used to (control) (prevent) infestation on flea-free (cats) (and) (or) (kittens) 8 weeks (of age) or older and weighing more than (2 lbs) (9 lbs) taken into a flea-contaminated environment.
- 28. Indoxacarb is from the chemical class of oxadiazine insecticides
- 29. Indoxacarb is a Voltage-dependent sodium channel blocker
- 30. Reduction in flea egg production as early as (two) (2) days (after) (following) treatment
- 31. (Indoxacarb) Demonstrated excellent residual activity for (1 month) (4 weeks) against fleas (Ctenocephalides felis)
- 32. Indoxacarb (the active) (in alternate or brand name) (in this product) (in Activyl® for Cats and Kittens) blocks the channels that regulate the flow of sodium through the insect's nervous system.
- 33. Stops flea feeding, followed (closely) by paralysis and death after exposure to the product.
- 34. (Convenient) (Single) (Spot) application that provides (control) (treatment)(protection) (of) (from) existing flea (infestations)
- 35. Protects against reinfestation(s) (of) fleas (on) (your) (pet) (cat) (kittens 8 weeks of age or older and (weighing) (over) (2 lbs) (9 lbs)
- 36. Controls fleas on cats in a home environment
- 37. Product contained in child resistant packaging

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## **OPTIONAL NEXT DOSE STICKERS/ TREATMENT REMINDER (prototype)**

Use these handy stickers to help remember when your pet's next dose is due. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given, and on the same date for each of the remaining months.

#### Alternate text

It may be hard to remember when your cat('s) (and/or) (kitten's) next dose is due. The following has been developed as a tool to help you keep track of every dose. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given. Place another (sticker) (reminder) on the same date for the remaining months.

#### STICKER PROTOTYPE:

### Picture of cat may vary. Up to 12 sticker count consistent with package



## **CARD Prototype:**

PET'S NAME	
PRODUCT: (preprinted alternate brand name)	
DATE OF 1 <sup>st</sup> APPLICATION:	
DATE OF 2 <sup>nd</sup> APPLICATION:	
DATE OF 3 <sup>rd</sup> APPLICATION	