

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

January 12, 2012

Ms. Nancy Huebl Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173

Subject: Label Notification(s) of Alternate Brand Name per PRN 98-10

Dear Ms. Huebl:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 98-10 dated November 15, 2011 to add an alternate brand name for the following product(s):

RF2175 CCSO-K

EPA Reg. No. 2724-814

Alternate Brand Name(s): Kirkland Signature Flea & Tick Control for Cats

The Registration Division (RD) has conducted a review of this request to add Alternate Brand Name(s) and finds that the label change(s) requested falls within the scope of PRN-98-10 and has been found to be acceptable.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>nonrefillable</u> containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780.

Sincerely,

Richard J. Gebken Product Manager

Insecticide Branch

Registration Division (7505P)

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Please read instructions on r	everse before comp	g form.		Fq	pproved. OMB No. 2	070-0060. Approval expires 2-28-93		
<b>⊕</b> EPA	on Agency 160	X	Registration Amendment Other	OPP Identifier Number				
		Applica	ation for Pesticide - Sec	tion I				
Company/Product Number     Wellmark International/272	24-814	3. Proposed Classification						
l. Company/Product (Name) Wellmark International/F	any/Product (Name) ark International/RF2175 CCSO-K			PM# 10				
5. Name and Address of Appli	cant / Registrant (Include	ZIP Code)	6. Expedited Revie	ew. In ac	ccordance with FIFRA	Section 3(C)(3)		
Wellmark International				(b)(i), my product is similar or identical in composition and labeling to:				
1501 East Woodfield Road, Suite 200W			EPA Reg. No. NOTIFICATION					
Schaumburg, Illinois 601	73							
Chack if this is	a nous address		Product Name	J	AN 1 2 2012			
Check if this is	a new address		Continue II	Alica, 17670.30				
			Section - II					
Amendment - Explain bel	ow.			al printed lab	els in response to ted			
Resubmission in respons	e to Agency letter dated			Too" Applic				
X Notification - Explain below.			Other - Explain below.					
Explanation: Use addition	nal page(s) if necessary.	(For section Lands	rection II )					
labeling or the confidential s EPA. I further understand t	statement of formula of hat if this notification is	this product. I un not consistent wi	O and EPA regulations at 40 C derstand that it is a violation of th the terms of PR Notice 98- der sections 12 and 14 of FIF	of 18 U.S.C 10 and 40	. Sec. 1001 to willfully	make any false statement to		
			Section - III					
I. Material This Product Will	be Packaged In:							
Child-Resistant Packaging	Unit Packaging		Water Soluble Packagin		2. Type of Container			
Yes	X Yes		Yes Metal					
X No	No		X No		X Plastic Glass			
* Certification must be submitted	If "Yes Unit No. per Packaging wgt. container 0.06 fl oz 6		If "Yes Unit No. per Packaging wgt. container		X Paper Other (Spec	bify)		
3. Location of Net Contents In		4. Size(s) Retail	Container	5 Loca	ation of Label Directions			
					On Label			
X Label X Container Six 0.06 fl oz tu		On Label Accompa			nying Product			
6. Manner in Which Label is A	ffixed to Product	Lithog Paper Stenci	glued	Other Prin	ted cardboard carton			
		Ciclion	Section - IV					
Contact Point (Complete	items directly below for	ridentification of i	ndividual to be contacted, if ne	ecessary to	process this applicat	ion.)		
Name	201011 101		Title	,	-	ne No. (Include Area Code)		
						0-5376		
	any knowingly false or mi		tion achments thereto are true, accur s my be punishable by fine or imp			6. Date Application Received  (Stamped)		
			3. Title Senior Registration Specialist			(((()		
4. Typed Name 5.			5. Date 15-Nov-11					

Wellma. .. International

1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 847 330 5300 www.wellmarkinternational.com

# Wellmark

November 15, 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: R. Gebken, PM10

SUBJECT: PER PRN 98-10 NOTIFICATION OF ALTERNATE BRAND NAME

FOR RF2175 CCSO-K/EPA REG. NO. 2724-814

Dear Mr. Gebken:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised labeling for the above product. The label cover sheet details the change. The alternate brand name is: Kirkland Signature Flea & Tick Control for Cats.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,

WELLMARK INTERNATIONAL

Mancy Huebl

Sr. Registration Specialist nhuebl@central.com

enclosure

cc:

C. Elmi/H. Friedli

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[] Optional Copy

# RF2175 CCSO-K

Alternate brand name: Kirkland Signature Flea & Tick Control for Cats

[Text for "Cat" in the product name must be at least 75% of the size of the largest letter in the Brand Name]

Front Panel - For Use Only on Cats and Kittens 12 weeks of age or older and [5 lbs. and over] [over 2.6 lbs and under 5 lbs] Small size only, Do not apply to kittens weighing less than 2.6 lbs.

[Flea & Deer Tick] [Treatment] [and] [Control]

(General/Protection claims)

1 ml [cc] [0.34 fl oz] for cats [kittens] over 2.6 lbs and under 5 lbs.; 1.8 ml [cc] [0.61 fl oz] for cats/kittens 5 lbs. and over

Do not use more than one vial per cat

For use only on cats/kittens [weighing] [over 2.6 lbs and under 5 lbs.][5 lbs. and over]

Only For use on cats/kittens weighing [5 lbs and over][over 2.6 lbs and under 5 lbs]

Flea & Deer Tick [Protective] for cats [& kittens]

[Flea & deer tick] treatment for cats [& kittens]

[Special formula for cats/kittens][Superior flea prevention and treatment specially formulated for use only on [all] cats and kittens [12 weeks of age and older]

Spot On [Topical][Non-systemic] treatment for pets [cats]

Flea, Deer Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens

5 in 1 Control [Protection][Treatment] (Fleas, Flea Eggs, Flea Larvae Deer Ticks, and Mosquitoes)

[1 month][monthly][flea, deer tick, & flea egg][ protection

Monthly treatment for [fleas, flea eggs, & deer ticks]

Flea [and deer tick][and mosquito] control for your cat/kitten

A smart approach to flea control

Improved flea, deer tick, and mosquito control

Keeps fleas, deer ticks, and mosquitoes under control

[Advanced] Spot On [Plus] Insect Control [Treatment and Prevention]

A flea control program

Controls flea, deer tick, and mosquito problems

Pet-assured [secure] flea, deer tick, and mosquito protection

Provide your cat/kitten with flea, deer tick, and mosquito protection, right from the start

Provides protection

Direct on-animal protection from fleas, deer ticks, and mosquitoes

Provides relief [protection] from fleas, deer ticks, and mosquitoes

Once-a-month [topical][Spot On] protection from fleas, and deer ticks,

Long lasting, flea, deer tick, and mosquito protection

(Kills/Repels/Controls claims)

[Actively] Kills [Controls] [adult] fleas, deer ticks, [larvae], and flea eggs for [up to][4 weeks][1 month][per application]

[Actively] Kills [fleas][deer ticks][flea eggs][larvae][&][and][mosquitoes][by contact]Kills [and/or Repels] mosquitoes [for up to 18 days][by contact]

Controls fleas, deer ticks, and mosquitoes & prevents flea reinfestations [in your home]

[Kills deer ticks] (for up to 1 month [4 weeks]) [per application]

Protects your pet [cat][kitten] from fleas, deer ticks, and mosquitoes (which may transmit heartworm disease)

Effectively controls fleas, deer ticks, and mosquitoes

Kills [Controls] deer ticks that may transmit [][Lyme disease][and Cytauzoonosis] for up to [1 month][4 weeks]

Protect your [cat/kitten] pet from [against] deer ticks that may transmit Lyme disease

Kills [and repels] mosquitoes [that may transmit heartworm disease]

Prevents mosquitoes from feeding on cats

Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation

Preventative treatment for fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation

Control highly irritating flea, deer tick, and mosquito [insect] bites

(More general claims)

When it comes to fleas and deer ticks, there's no room for compromise [Brand] protecting pets for over 35 years

(Flea egg/life cycle claims)

Kills [Controls] flea eggs for up to [30 days][1 month][4 weeks][per application]

Kills flea eggs, the source of home flea infestations and pet re-infestations, for up to [30 days][1 month][4 weeks]

Advanced [topical][flea egg treatment] that's easy and convenient to use

[Kills][Prevents][Keeps] flea eggs from hatching for up to [30 days][1 month][4 weeks]

Prevents flea eggs from developing into biting adults for up to [30 days][1 month][4 weeks][per application] An effective flea topical [A Spot On] product that kills adult fleas and halts the development of flea eggs

[immature stages in the flea life cycle]

Kills [flea] eggs before they hatch into biting adults

Prevents re-infestation for up to [1 month][30 days][4 weeks]

Kills hatching [developing] flea eggs

Interrupts normal flea development [Stops the flea life cycle]

Interrupts the flea life cycle

Breaks the flea life cycle for up to [1 month][4 weeks][30 days]

Controls[Kills][Lasts][Works][Protects] flea infestations for up to [1 month][4 weeks]

One-two punch controls fleas and flea eggs

Controls existing fleas and flea eggs, plus [and][prevents] future flea infestations

Plus kills flea eggs and larvae to prevent future infestations

(Application claims)

[#] pack [# days'] [#] doses [1/2/3/4/5/6] months supply

One tube gives [1 month][4 weeks] of protection

[Pre-measured][Convenient][and][&][No mess][easy][simple] to [use][handle][apply] disposable applicator [tube]

Convenient [and effective], once-a-month [liquid][topical][Spot On] solution

Practical solution

Simple choice [flea & deer tick control]

A [One] simple application provides your cat/kitten with protection for up to [1 month]

Apply to one spot for head to tail (total body) flea protection [control]

Apply to 1 spot - spreads over the cat's [entire] body [from head to tail] through natural skin oils

Spreads naturally with cat's skin oils

[Plus] Contains a natural coat conditioner

[Once][One] Monthly Application

Easy to use [once] monthly application [liquid] prevents [and controls] fleas [& deer ticks]

Reapply [Repeat] [once] monthly

Repeat [treatment] every month

Monthly Control [Relief][treatment]

...3

(Applicator claims)

Unique Applicator [tube] Shape [Design][helps prevents misuse on dogs][helps prevents misapplication on

Unique shape [only for cats & kittens 5 lbs and over][only for cats & kittens under 5 lbs]

Pet Specifix® Applicator Accu-Tip Dispenser

[New][X] Pro-cision Flo™ Applicators [tubes]

[New][Exclusive][Pinpoint][Applicator] for [pinpoint][exact][direct][easy][direct to skin] application

Patent pending

For pinpoint accuracy

Direct to your cat's skin

Easily penetrates hair

The [Pro-cision Flo<sup>™</sup>][exclusive][[new] applicator [tube][easily penetrates hair][fur][coat] for

[improved][direct] application [directly to your cat's skin]

Easy to apply [identify][use] applicator [tube]

The right choice [applicator][tube] for the right cat/kitten

Make [Select] the right choice [applicator][tube][shape]

Choice [selection] is simple

Easy choice

Simple choice delivery system

Easy to use applicator [tube] [provides direct on-animal protection]

Longer Applicator [tube][tip] for easy application [to long-haired cats]

Longer tube [applicator][tip] is ideal for long-haired pets [cats/kittens]

Helps Prevent [misapplication on dogs] misuse on dogs with unique [specially designed] applicator [tube]

EZ-squeeze [Easy squeeze] tube [applicator][shape]

(Product Claims)

Odorless

Clean fresh scent

Effective Control [Relief][Prevention]

Fast [Quick] acting [Relief]

Starts working by contact

Dual-action for immediate and long-lasting effects

Quick acting, long lasting [treatment]

Long lasting and easy to use [apply]

[Flea prevention] Helps stop itching and scratching [from flea bites]

### (IGR claims)

From ZODIAC®, the originator of Insect Growth Regulator [IGR] technology

[Plus][Contains][With] PRECOR® [vIGRen®], the first insect growth regulator for flea control

Contains [Features] an Insect Growth Regulator (IGR) to inhibit the development of flea eggs

Flea control for cats with [PRECOR®][vIGRen®] Insect Growth Regulator (IGR)

[(S)-Methoprene] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle at the egg

[(S)-Methoprene] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas

[inhibits the development of flea eggs into adult fleas]

Controlling flea reproduction is the first step in controlling flea populations on your pet and in your home [(S)-Methoprene] Insect Growth Regulator (IGR) prevents flea reinfestation on your pet and in your home Flea treatment and preventative with an [insecticide] adulticide and Insect Growth Regulator (IGR)

(Brand claims)
We (Brand) put(s) your pet(s) first
Brand...putting (your pet) pets first
Right choice = best defense
Perfect choice
Brand - caring & committed
Brand makes the choice simple
[Satisfaction guaranteed][Money-back guarantee]

## (Formula claims)

Etofenprox provides a novel [smart] approach to flea, deer tick, and mosquito control Advanced Formula [for cats & kittens]

Features [Contains] an [insecticide] adulticide to kill [and/or][control] adult fleas [deer ticks, and mosquitoes]

# (Prevention claims)

Preventing fleas and deer ticks from infesting your pet is much easier than treating an existing problem Flea prevention has never been easier

An excellent preventative, offering protection against fleas

Prevents flea, deer tick, and mosquito infestations

Prevents flea recurrence

Control flea infestations by preventing them

Flea prevention is the best flea control strategy

Quick and sure flea, deer tick, and mosquito prevention

A quick and sure way to avert a flea problem is to [prevent it] use a preventative

It is far easier to prevent fleas than to control them

Flea control involves [requires] preventative measures [for your pet][and][for your home]

[][Year-round][Flea Treatment][Preventative]

Use a flea preventative year-round (to prevent painful bites, itching and scratching, discomfort

### (FRONT PANEL)

# **ACTIVE INGREDIENTS:**

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(S)-Methoprene (CAS # 65733-16-6)	3.6%
Etofenprox (CAS # 80844-07-1)	40.0%
OTHER INGREDIENTS:	56.4%
Total	100.0%

### KEEP OUT OF REACH OF CHILDREN

See back panel for ingredients and additional Precautionary Statements

EPA Reg. No. 2724-814

EPA Est. No.

Net Contents: (Number): 0.034 fl oz (1.0 cc) Applicator [tube] (Cats/Kittens over 2.6 lbs and under 5 lbs)/

0.061 fl oz (1.8 cc) Applicator [tube] (Cats/Kittens 5 lbs and over)

#### **READ ENTIRE LABEL BEFORE USE**

USE ONLY ON CATS OR KITTENS 12 WEEKS OF AGE AND OLDER AND [OVER 2.6 LBS AND UNDER 5 LBS][5LBS AND OVER]. DO NOT APPLY TO CATS WEIGHING LESS THAN [5 LBS][2.6 LBS]

# DO NOT ALLOW CHILDREN TO APPLY PRODUCT.

[Specially formulated for cats [& kittens]][For use on cats only][Do not use on other animals]

#### INTRODUCTION:

[Brand] Flea & Tick Control for Cats is a topically applied long-lasting product specifically formulated for cats to prevent and control flea infestations. This product contains Etofenprox, which kills biting adult fleas, deer ticks and mosquitoes your cat may acquire from its surroundings. This product provides relief from flea infestations for up to 1 month by killing adult fleas on your cat or kitten and flea eggs in your home.

[RF2175 CCSO-K is a topically applied [long-lasting] product specifically formulated for cats and kittens with [containing] [it also contains] an insect growth regulator (IGR)[S-Methoprene][to prevent and control flea infestations][to kill fleas before they hatch][which prevents flea eggs from maturing into biting adults]. It [This product] also contains the highly effective flea, deer tick, and mosquito killing agent [Etofenprox][Brand Name], which kills biting adult fleas, deer ticks, and mosquitoes your cat may acquire from its surroundings. A single application of RF2175 CCSO-K will provide egg hatch inhibition for up to 30 days [1 month][4 weeks]. Each package contains enough product for xx monthly applications (xx days of protection [control]). RF2175 CCSO-K provides relief from flea infestations for up to 1 month [4 weeks] by killing adult fleas on your cat or kitten and flea eggs in your home. Adult fleas can live on your cat/kitten while producing vast numbers of eggs, which drop off your cat/kitten and develop in the surrounding environment. Normal insecticides will not kill the flea eggs, but RF2175 CCSO-K [is designed to] kill(s) adult fleas and flea eggs, breaking the flea life cycle and providing your cat relief from flea bites at the same time.]

[After application, your cat's natural skin oils [disperse] carry RF2175 CCSO-K over your cat's body for protection against biting adult fleas and the development of flea eggs. [(product) may stain leather and suede fabrics for (24)(24 to 48) hours after application.] Once adult fleas are evident on your cat, there is likely an infestation of flea eggs and flea larvae in your home. To completely kill the existing flea population, you may need to treat your home and your cat/kitten's bedding (home sprays, foggers), as well as your yard (yard spray/outdoor fogger) with traditional flea products approved for use on cats/kittens, around the home, or in your yard. RF2175 CCSO-K can be used in conjunction with other [Brand] premise products. As with all flea products, [they are] [RF2175 CCSO-K is] most effective when used as part of a total program aimed at reducing all stages of fleas in the cat's environment. [BRAND] products [They] are designed to complement each other in an integrated program for flea, deer tick, and mosquito management. To assure proper treatment, we recommend use of [Brand] products as directed to treat all pets in the household, as well as the indoor and outdoor home environments.]

**DIRECTIONS FOR USE**: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **USE RESTRICTIONS:**

This product works by application directly to the cat's skin, not to the hair. When applying, manually push aside cat's hair to allow direct application to the skin. Do not use more than one tube/vial/cartridge per cat and do not apply more than once every month. Do not get this product in your cat's eyes or mouth. Do not allow your cat to ingest this product.

#### USE ONLY ON CATS AND KITTENS 12 WEEKS OF AGE AND OLDER.

[1 ml [cc] [0.034 fl oz] dose for use on cats and kittens over 2.6 lbs and under 5 lbs.

1.8 ml [cc] [0.061 fl oz] dose for use on cats and kittens 5 lbs. and over (Same size applicators with different fill amounts)]

# [APPLICATION METHOD]

First Monthly Application:

1. [Bend at perforation and tear off 1<sup>st</sup> month's applicator.]

2. Hold [applicator] upright [and bend area of plastic at perforation, tear off and discard.] [Hold applicator upright] and snap tip back, away from face and body.

3. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin.

4. Do not spread this product by hand over the cat. Do not bathe the cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.

5. [Repeat application once monthly.][Do not treat more than once per month.]

Month \_\_\_\_\_ Day\_\_\_\_ Year\_

6. Discard empty applicator as described in STORAGE and DISPOSAL

Monthly treatments are required for optimal control and prevention of fleas.

Adding a Dose Reminder section to appear as follows on the back panel:

The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats/kittens with this product rapidly kills fleas and may reduce the incidence of this condition.

Second Monthly Application	n: Month	Day	Year		
Third Monthly Application:	Month	Day	Year		
Fourth Monthly Application	: Month	Day	Year	]	
Optional marketing text for	subregistrant				
TREATMENT SCHEDULE Dosage: 1 applicator every					
Pet's Name	First Treatment	Date	Second Trea (30 Days		Third Treatment Date (30 Days From 2nd)
NOTES:					
REMINDER: I purchased	[Brand Name]	fro	om	1	

**STORAGE AND DISPOSAL:** Pesticide Storage: Store applicators together in a cool area away from children and animals. **Container Disposal:** If empty: Do not reuse empty applicator [tube]. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**HAZARDS TO HUMANS**: Wash your hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation

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old or on kittens weighing less than 2.6 lbs. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your cat/kitten with mild soap and rinse with large amounts of water. If signs continue, please call 1-888-987-4110 or consult a veterinarian immediately. Due to the bitter taste of the product, oral exposure could result in salivation. Be careful not to get any product in the cat's mouth during application. For multiple cat households, prevent the cats from grooming each other until the product has dried. If the problem continues or other clinical signs are noted, please call 1-888-987-4110.

FIRST AID	
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.</li> <li>Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
	duct container or label with you when calling a poison control center or doctor or going for treatment.
You may also	contact 1-888-987-4110 for emergency medical treatment information.

**Side Effects**: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or Wellmark at 1-888-987-4110. (This box will appear in lower right hand corner of back panel)

# WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-888-987-4110 [or contact your veterinarian if your pet is experiencing an adverse event].

To learn more about treating current infestations and preventing future outbreaks, please, visit our website: [URL]

[For more information, call our experts at 1-888-987-4110 (weekdays, 9am - 5 pm EST)]

To learn more, visit [URL]

For product use information, call [phone number] or visit our Web site: [URL]

Wellmark International 1501 East Woodfield Road 200W Schaumburg, IL 60173 Made in USA

TEXT FOR LIQUID TUBE / CARTRIDGE / VIAL Product name Etofenprox 40%, (S)-Methoprene 3.6%, Other Ingredients 56.4% KEEP OUT OF REACH OF CHILDREN READ DIRECTIONS BEFORE USING EPA Reg. No. 2724-814 Net Contents

For Use Only on Cats/Kittens 12 weeks of age or older and [5 lbs. and over] [over 2.6 lbs and under 5 lbs]