

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

NOTIFICATION

Mr. Aaron Johnson Elanco Animal Health 2500 Innovation Way Greenfield, IN 46410 MOTIFICATION

MAY 0 6 2013

Subject:

Notification of primary brand name change

EPA Registration Number: 72642-10

Decision: 476524

Dear Mr. Johnson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN)98-10 dated February 12, 2013, for the abovementioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions regarding this letter, please Samantha Hulkower at (703) 603-0683 or Hulkower.Samantha@epa.gov.

1/ Jan

Sincerely,

Product Manager 13 Insecticide Branch

Registration Division (7505P)

Enclosures: Copy of La

Copy of Label Stamped "Notification"

-	(·	(Print Form /	
SEPA	United State United State Environmental Protect Washington, DC	es ction Agency	Registratio Amendme Other	OPP Identifier Number	
	Applica	ntion for Pesticide - Sec	tion I		
1. Company/Product Numi 72642-10	per	2. EPA Product Man Mark Suarez	ager	3. Proposed Classification	
4. Company/Product (Nam Elanco Animal Health	e) / Cheristin for cats	PM# 13		X None Restricted	
Elanco Animal Health, 2500 Innovation Way,	A Division of Eli Lilly & Co. P.O. Box 708, Greenfield, IN 46	(b)(i), my product i to: EPA Reg. No	EPA Reg. No.		
		Product Name _ Section - II			
X Notification - Expla	sponse to Agency letter dated in below. onal page(s) if necessary. (For se	Agency lett "Me Too" /	Application.		
		Section - III			
1. Material This Product V	Vill Be Packaged In:				
Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No If "Yes" No. pai Unit Packaging wgt.		PI G	ntainer fetel festic iless aper ther (Specify)	
3. Location of Net Conten	ts Information 4. Size(s	Retail Container	5. Location of Label D On Label On Labeling	Directions accompanying product	
6. Manner in Which Label	is Affixed to Product Li	thograph Other sper glued tenciled			
Section - IV					
1. Contact Point Comple	te items directly below for identifi	cation of individual to be contacted,	if necessary, to proce	ss this application.)	
Name Aaron Johnson		Title Principal Consultant		lephone No: (iræicae Area Code) 17-276-4021	
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 Received (Ctamped)					
2. Signature	John	3. Title Principal Consultant, Regul	atory Affairs		
4. Typed Name		5. Date			

Febuary 12, 2013

Aaron Johnson



Elanco Animal Health

2500 Innovation Way Greenfield, IN 46140 317.276.2000

February 12, 2013

U.S. Environmental Protection Agency Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) Room S4900, One Potomac Yard 2777 Crystal Drive Arlington, VA 22202

Attn: Mr. Mark Suarez, Project Manager

Subject: Notification of primary brand name per PR Notice 98-10

Product: Spinetoram 11.2% Cat [EPA Reg. No. 72642-10]

Dear Mr. Suarez:

On behalf of Elanco Animal Health, I am submitting for your review this Notification to add the **primary brand name** to the subject product. This addition of the new brand name **Cheristin** ™ **for cats** is being done in compliance with the conditions outlined in PRN 98-10.

In addition to this letter, the Notification is comprised of:

- A fully executed Application for Pesticide Registration (EPA form 8570-1)
- Certification statement (included with the 8570-1 form)
- One copy of the stamped approved label dated January 17, 2013
- A copy of the draft label with the changes clearly marked
- A copy of the label containing the new primary brand name

Additionally, Elanco would like to notify EPA of two additional changes to the label. First, the product registration numbers have been changed from 72642-RN to 72642-10, as directed by the approval notice dated January 17, 2013. Second, a marketing statement has been removed from the labeling which stated "kills adult fleas before they lay eggs," as this was requested by EPA to be removed from the list of optional marketing claims. The statements have been identified in the highlighted version of the old label, and new label reflects the removal of this statement.

If you have any questions or comments, please feel free to contact me at your earliest convenience. If I cannot be reached, please contact Cory Herr, Director of U.S. Regulatory Innovation, at (317). 651-2776 or at herr_cory_t@elanco.com.

Sincerely,

Aaron Johnson, DVM, MS Principal Regulatory Consultant

Elanco Animal Health Office: 317-276-4021 Fax: 317-277-4167

Email: ajohnson@elanco.com



Elanco Animal Health

2500 Innovation Way Greenfield, IN 46140 317.276.2000

RE: Notification of Primary Brand Change [EPA Registration # 72642-10]

Explanation Continued:

"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 section 12 and 14 of FIFRA."

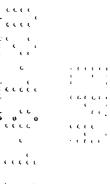
Signature

_ '

Date 12 Feb 20 13

Aaron E. Johnson, DVM, MS Elanco Animal Health Principal Consultant, Regulatory Affairs (317) 276-0421 (317) 277-4167 (fax) ajohnson@elanco.com

Aaron E. Johnson (



Cheristin™ for cats Master Label Page 1 of 25

Marketing claims: see lists at the end of the draft labels. Alternative language in (parentheses) NOTIFICATION MAY 0 6 2013

CARTON LABEL

FRONT PANEL

Cheristin[™] for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

TOTAL

100.0%...

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

BACK PANEL

DIRECTIONS FOR USE

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

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- 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.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for Elanco Animal Health A Division of Eli Lilly and Company Indianapolis, IN 46285

EPA Reg. No. 72642-10 EPA Est. No.



PACKAGE INSERT LABEL

Cheristin[™] for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0]	11.2%
OTHER INGREDIENTS	88.8%
TOTAL	

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens dess than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- 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.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

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

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

- 1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
- 2. Remove one applicator tube from the blister package.
- 3. Hold applicator tube in an upright position.
- 4. Press cap down until it clicks (indicating the tube has been punctured). Hold up ight and remove cap. Check to be sure there is an opening at the tip of tube.
- 5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between the shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)

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6. Discard empty applicator tube in the trash.

Picture/drawing of opening the tube.

Picture/drawing of parting the hair on neck at base of head.

Picture/drawing of applying the product.

Monthly application is recommended to prevent and treat flea infestations. Cheristin[™] for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

<u>If empty</u>: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

<u>If partly filled:</u> Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, and disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OF OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

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Manufactured for Elanco Animal Health A Division of Eli Lilly and Company Indianapolis, IN 46285

EPA Reg. No. 72642-10 EPA Est. No.

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Applicator Labeling

Cheristin[™] for cats Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-10

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Cheristin[™] for cats

Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-10

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Cheristin[™] for cats only to cats and kittens 8 weeks of age and older.

Visit $\underline{www.CheristinForCats.com}$ to sign up and receive an email reminder from your cat when it is time to receive CheristinTM for cats.

Graphic of calendar

Month 1 (Graphic)

Month 2 (Graphic)

Month 3 (Graphic)

Month 4 (Graphic)

Month 5 (Graphic)

Month 6 (Graphic)

Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [Ctenocephalides felis] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) sizs(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Cheristin[™] for cats, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8.

Page **12** of **25**

weeks of age (and older) only

- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

Cheristin[™] for cats Sub-Label #1 Residential Page 13 of 25

Marketing claims: see lists at the end of the draft labels. Alternative language in (parentheses)

CARTON LABEL

FRONT PANEL

Cheristin[™] for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

Page 14 of 25

BACK PANEL

DIRECTIONS FOR USE

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

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin[™] for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973

FIRST AID

IF IN EYES:

- 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.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for

Elanco Animal Health A Division of Eli Lilly and Company Indianapolis, IN 46285

EPA Reg. No. 72642-10 EPA Est. No.

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PACKAGE INSERT LABEL

Cheristin[™] for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 &	. 187166-15-0]	11.2%
OTHER INGREDIENTS		88.8%
	TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterina lian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

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Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

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

Read the entire label, directions for use and frequency of application each time before using the product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

- 1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
- 2. Remove one applicator tube from the blister package.
- 3. Hold applicator tube in an upright position.
- 4. Press cap down until it clicks (indicating the tube has been punctured). Hold uprignition remove cap. Check to be sure there is an opening at the tip of tube.
- 5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
- 6. Discard empty applicator tube in the trash.

Picture/drawing of opening the tube.

Picture/drawing of parting the hair on neck at base of head.

Picture/drawing of applying the product.

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Monthly application is recommended to prevent and treat flea infestations. Cheristin[™] for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

<u>If empty</u>: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

<u>If partly filled:</u> Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for Elanco Animal Health A Division of Eli Lilly and Company Indianapolis, IN 46285

EPA Reg. No. 72642-10 EPA Est. No.

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Applicator Labeling

Cheristin™ for cats Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-10

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Page 20 of 25

Blister Labeling

Cheristin™ for cats

Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-10

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Page 21 of 25

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Cheristin[™] for cats only to cats and kittens 8 weeks of age and older.

Visit <u>www.CheristinForCats.com</u> to sign up and receive an email reminder from your cat when it is time to receive Cheristin[™] for cats.

Graphic of calendar

Month 1 (Graphic)

Month 2 (Graphic)

Month 3 (Graphic)

Month 4 (Graphic)

Month 5 (Graphic)

Month 6 (Graphic)

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Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [Ctenocephalides felis] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit Rickettsia felis and Rickettsia typhi, Francisella tularensis
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Cheristin™ for cats, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8 weeks of age (and older) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control

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and prevention of fleasSatisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

Cheristin[™] for cats Sub-label #2 Commercial Page 24 of 25

(label to be placed near discharge control valve, this statement can be removed from printed label)

Cheristin[™] for cats

spinetoram

ACTIVE INGREDIENT

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID

IF IN EYES:

- 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.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor:
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

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DIRECTIONS FOR USE:

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

General use pesticide. For use only for the further manufacture or repacking of a registered pesticide product for companion animals.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in original package only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Never pour unused product down the drain or on the ground.

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into manufacturing process or appropriate waste collection system. Fill the container about 10% full with water, and if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into a waste collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Manufactured for Elanco Animal Health A Division of Eli Lilly and Company Indianapolis, IN 46285

EPA Reg. No. 72642-10 EPA Est. No. 70996-CAN-002

NET CONTENTS:_	
(may be completed	l by manual entry)

