



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 9, 2016

Brooke Hedrick
CSE Life Science Holdings, LLC
1204 Village Market Place, #273
Morrisville, NC 27560

Subject: Label Amendment – in response to an Agency letter to delete and/or revise several marketing claims
Product Name: Torc Duo for Dogs
EPA Registration Number: 91300-2
Application Date: January 28, 2016
Decision Number: 513204

Dear Ms. Hedrick:

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.

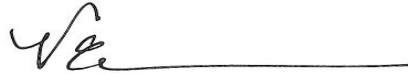
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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.

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

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Decision No. 513204

with FIFRA section 6. If you have any questions, please contact Gene Benbow by phone at 703-347-0235, or via email at Benbow.Gene@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'VE', followed by a horizontal line extending to the right.

Venus Eagle, Product Manager 01
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Stamped label

NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

[Front Panel]

TORC™ DUO FOR DOGS

A Liquid Topical Flea and Lice Product for Dogs
For Use ONLY on Dogs and Puppies 7 Weeks and Older Weighing [3 – 10 lbs.] [11 – 20 lbs.] [21 – 55 lbs.] [Over 55 lbs.]

ACTIVE INGREDIENTS:

Imidacloprid9.10%

Pyriproxyfen0.46%

OTHER INGREDIENTS:..... 90.44%

TOTAL: 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

[See [back] [side] [other] [panel] for FIRST AID and PRECAUTIONARY STATEMENTS]
Refer to Package Insert for Directions for Use, Storage and Disposal, and First Aid]

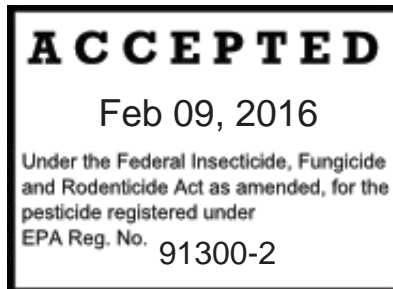
NET CONTENTS: X fl. oz.

[Picture of a dog in appropriate weight range on front panel to be included]

[For use ONLY on dogs 7 weeks and older and weighing 3 to 10 lbs.:]	[4] tube(s), each 0.014 fl. oz.
[For use ONLY on dogs 7 weeks and older and weighing 11 to 20 lbs.:]	[4] tube(s), each 0.034 fl. oz.
[For use ONLY on dogs 7 weeks and older and weighing 21 to 55 lbs.:]	[4] tube(s), each 0.084 fl. oz..
[For use ONLY on dogs 7 weeks and older and weighing Over 55 lbs.:]	[4] tube(s), each 0.135 fl. oz.

EPA REG. NO. 91300-2
EPA EST. NO. XXXXX-XX-X

[Manufactured for:]
[Distributed by:]
Promika, LLC
1204 Village Market Place, #273
Morrisville, NC 27560



[Icon size 1.5 cm x 1.5 cm, black on yellow background]

TORC™ DUO FOR DOGS

Topical Flea and Lice Product for Dogs

For Use ONLY on Dogs and Puppies 7 Weeks and Older Weighing [3 – 10 lbs.] [11 – 20 lbs.] [21 – 55 lbs.] [Over 55 lbs.]

READ THE ENTIRE LABEL BEFORE EACH USE

FIRST AID	
If Swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Do not give any liquid to the person.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If In Eyes:	<ul style="list-style-type: none">• 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 eye.• Call a poison control center or doctor for treatment advice.
If On Skin:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 - 20 minutes.• Call a poison control center or doctor for treatment or advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-844-685-9173.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than [3 lbs.] [11 lbs.] [21 lbs.] [55 lbs.]. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide products for Dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

Side Effects: Monitor your dog after application. Side effects, although very rare, may include signs of skin irritations 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 (such as lethargy) occur, consult your veterinarian or call 1-844-685-9173.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.



Icon size 1.5 cm x 1.5 cm

[Sample – Not for (Re)Sale]

[Manufactured for:]

[Distributed by:]

Promika, LLC

1204 Village Market Place, #273

Morrisville, NC 27560

[Made in the USA]

[Back Panel and/or Insert]

TORC™ DUO FOR DOGS

A Liquid Topical Flea and Lice Product for Dogs

For Use ONLY on Dogs and Puppies 7 Weeks and Older Weighing [3 – 10 lbs.] [11 – 20 lbs.] [21 – 55 lbs.]
[Over 55 lbs.]

READ THE ENTIRE LABEL BEFORE EACH USE

Prevent and Treat Flea and Lice Infestations

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. To prevent harm to you and your dog, read the entire label and package insert before each use. Follow all directions and precautionary statements carefully. Use ONLY on Dogs 7 Weeks and Older and Weighing [3 - 10 lbs.] [11 - 20 lbs.] [21 - 55 lbs.] [Over 55 lbs.].

RESTRICTIONS:

- Use only on dogs 7 weeks and older weighing [3 – 10 lbs.] [11 – 20 lbs.] [21 – 55 lbs.] [Over 55 lbs.]
- Do not use on other animals.
- Do not exceed labeled dosage amount for dogs.
- Do not apply more than one (1) tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.

Do not treat more than [one] [1] dog per tube

HOW TO OPEN

[OPTION 1:]

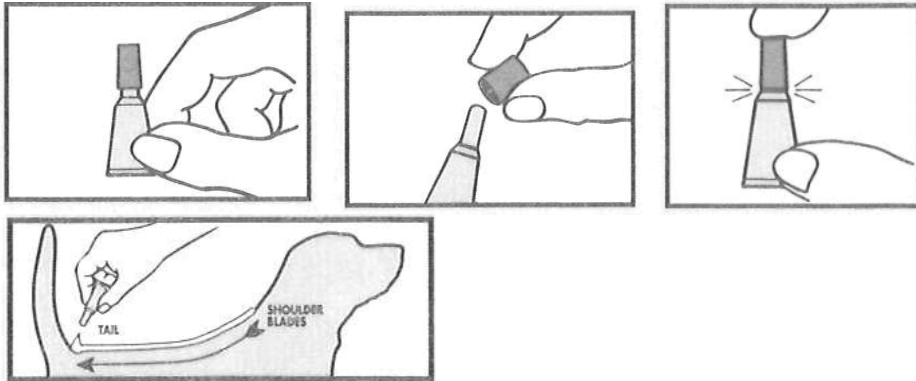
1. Being careful not to cut close to the blister cavities take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

APPLICATION INSTRUCTIONS:

[Visuals Depicting How to Open Applicator Tube and Application to Animal]



HOW TO APPLY

[OPTION 1: 3 to 10 lbs. or 11 to 20 lbs. packages]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your dog's eyes, or allow your dog to ingest this product. Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not re-treat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

[OPTION 2: 3 to 10 lbs. or 11 to 20 lbs. packages]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
3. Twist dispensing tip clockwise about half ($\frac{1}{2}$) turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your dog's eyes, or allow your dog to ingest this product. Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not re-treat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

[OPTION 3: 21 to 55 lbs. or over 55 lbs. packages]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply any excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Do not get this product in your dog's eyes, or allow your dog to ingest this product.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not re-treat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

[OPTION 4: 21 to 55 lbs. or over 55 lbs. packages]

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
3. Twist dispensing tip clockwise about half ($\frac{1}{2}$) turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply any excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Do not get this product in your dog's eyes, or allow your dog to ingest this product.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not re-treat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

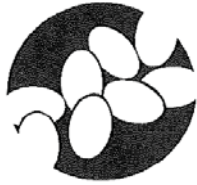
TORC™ DUO FOR DOGS kills fleas on dogs within 12 hours, which may reduce the incidence of flea allergy dermatitis (FAD) or flea bite hypersensitivity. This product prevents further flea infestation for four weeks by killing reinfesting fleas within 2 hours.

TORC™ DUO FOR DOGS kills fleas, flea eggs, and flea larvae and effectively controls all flea life-stages for quick and control of flea populations.

TORC™ DUO FOR DOGS is waterproof and is effective on your dog, even after shampoo treatment, swimming or exposure to rain or sunlight.

To prevent further flea infestation, use TORC™ DUO FOR DOGS monthly.
Use monthly to control and prevent fleas and lice.

[OPTIONAL GRAPHICS/ICONS/PICTURES – COLOR MAY CHANGE]



[For Chemical Emergency, Spills, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night within USA and Canada: 1-800-424-9300 CCN712312 or +1 703-527-3887 (collect calls accepted)]

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. **Pesticide Disposal and Container Handling:** Nonrefillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Promika, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Promika, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Promika, LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Promika, LLC disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: 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, shall not exceed the purchase price paid or at Promika, LLC election, the replacement of product.]

[Label on Individual Tube]

TORC™ DUO FOR DOGS

[The appropriate size and fill volume will be correctly used on each applicable dog's weight category]

3 to 10 lbs. ≥ 7 wks
0.014 fl. oz.

11 to 20 lbs. ≥ 7 wks
0.034 fl. oz.

21 to 55 lbs. ≥ 7 wks
0.084 fl. oz.

Over 55 lbs. ≥ 7 wks
0.135 fl. oz.

9.10% Imidacloprid
0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read Entire Label Before Use

EPA Reg. No. 91300-NEW



[Lot No. is heat stamped in tube crimp – required on each]

NOTE TO REVIEWER: [(Brackets and parentheses indicated alternate language)]

OPTIONAL MARKETING CLAIMS [May appear on any panel/insert]

[Fleas]

- Kills fleas
- Month long flea protection
- Kills fleas within 12 hours of application
- Kills fleas for up to [4 weeks] [1 month]
- Kills fleas which may cause flea allergy dermatitis and flea bite anemia
- Effective against fleas that may cause flea allergy dermatitis and flea bite anemia
- Kills fleas that may cause transmission of tapeworms
- TORC™ DUO FOR DOGS is effective for the prevention and treatment of fleas on dogs
- Prevent further flea infestations for [4 weeks] [1 month]
- Protects against reinfesting fleas for [4 weeks] [1 month] [30 days]
- Kills fleas on dogs within 12 hours to prevent further infestations for [4 weeks] [1 month]
- Kills fleas before they lay eggs
- Kills all larval stages of fleas
- Targets all life stages of fleas

- [Prevents] [Stops] flea eggs and flea larvae from developing into biting adults
- Breaks the flea life cycle
- Triple flea protection: kills adults, larvae, and eggs
- Flea adulticide, larvicide, and ovicide
- Multi-stage flea control—egg, larvae, adult
- Controls existing fleas and flea eggs to prevent future flea infestations
- The Insect growth regulator (IGR) kills flea eggs and prevent reinfestation

[Lice]

- Kills biting and chewing lice
- Treat and prevent [(biting) (chewing)] lice infestations
- Stops existing [(biting) (chewing)] lice infestations
- Treats, prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice

[Combined]

- Kills fleas and lice
- Treat, eliminate and prevent flea and lice infestations
- Two-way protection against fleas and lice
- Month long flea and lice protection
- Provides protection for up [1 months] [30 days] [4 weeks] against fleas and lice

[Other]

- Only for use on dogs and puppies 7 weeks of age and older and weighing [3 – 10 lbs.] [11 – 20 lbs.] [21 – 55 lbs.] [Over 55 lbs.]
- TORC™ DUO FOR DOGS contains imidacloprid [, in conjunction with [an/the] [insect growth regulator] [IGR] [pyriproxyfen]]
- One topical application remains effective for [4 weeks] [a month]
- Convenient topical solution
- Easy-to-apply [monthly] [topical solution]
- Use monthly for best year round results
- A monthly topical application for dogs 7 weeks of age or older and weighing [3 – 10 lbs.] [11 – 20 lbs.] [21 – 55 lbs.] [Over 55 lbs.]
- Starts working through contact
- Remains effective after bathing and/or swimming
- Continues to kill fleas and ticks even if your dog gets wet
- Water resistant
- Waterproof
- Fragrance-free
- Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Advantage® II Dog
- Advantage® II is a registered trademark of Bayer Healthcare LLC Animal Health Division
- TORC™ DUO FOR DOGS is not manufactured, or distributed by Bayer Healthcare LLC Animal Health Division, seller of Advantage® II Dogs
- Apply monthly [every 30 days] [every 4 weeks]
- Convenient [applicator]
- Easy to use [applicator]
- Direct to your dog's skin
- Simple to [handle/apply]

