EPA Registration File
2596-181

DATA EXTRACTION REQUEST

Reg # 2596-81 Decision #

Description:

Material Sent:

X Electronic Label/Letter Dated 10/23/14 + CSF clean
(See PPLS for electronic file)

☐ Stamped Label Dated _____ (See jacket)

☐ Notification Dated _____ (See jacket)

☐ New CSF(s) Dated _____ (See jacket)

☐ Other: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Autumn Metzger

Division: RD - IRB

Phone: 305-5314

Date: 11/20/14

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
2596-181	10/23/2014

Term of Issuance:
Conditional

Name of Pesticide Product:
Hartz Reference #146

Name and Address of Registrant (include ZIP Code):

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. This registration is time-limited and expires two years from the date this product is first released for shipment.

   You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

Continue next page

Signature of Approving Official:

Venus Eagle

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:
10/23/2014

2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.

3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2015.

   Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager.

   The following is a list of information that must be included in the quarterly reports for each incident:

   EPA Registration Number
   Product name (brand name)
   Lot #
   Where purchased: internet, store, veterinarian
   Active Ingredient(s)
   Weight range for product

   Date on which incident occurred. (mm/dd/yyyy)
   State in which the incident occurred. (standard 2 letter abbreviation)
   Registrant case #

   Species: dog, cat, other (specify)
   Breed: (as reported by pet owner)
   Age: months or years
   Sex: M, F, or neutered
   Weight: pounds

   Primary Route of Exposure: dermal, oral, other animal, inhalation, other
   Body System: neurological, dermatological, GI, respiratory, ocular, other
   Major signs noted with separate column for each sign, using standard terminology
   Time to Onset: (hours, days)
   Treated by veterinarian: yes or no
   First time product used: yes or no
   Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
   Any known precondition
   EPA Severity Code: death, major, moderate, minor
   Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

   a. All incidents should be reported including all minor dermal and ocular irritation reports.

b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).

e. A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.

f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label (if applicable).

g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).

h. Table showing number of incidents for each cat breed, where provided.

i. Table showing number of incidents in cats for each clinical sign.

j. Table showing number of incidents in cats for each organ system.

5. Report aggregate incidents, but do not combine moderate and minor incidents.

6. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

7. You are required to comply with the DCIs identified below:

   a. Imidacloprid GDCI-129099-951, issued on 11/10/2010
   b. Pyriproxyfen GDCI- 129032-1299, issued on 2/21/2014

   If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
   http://www.epa.gov/oppsrrd1/contacts_prd.htm

8. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

9. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 2596-181."

10. Submit one copy of the final printed label for the record before you release the product for shipment.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/28/2014

If you have any questions, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division
(7505P)

Attachment – stamped label

[FRONT PANEL]
Hartz® Reference # 146

Alternate Brand Names

Hartz First Defense Max for Cats [*& or* Kittens]
Hartz First Defense Advanced PLUS for Cats [*& or* Kittens]
Hartz First Defense Advanced PRO for Cats [*& or* Kittens]
Hartz First Defense Evolution for Cats [*& or* Kittens]
Hartz First Defense Guardian for Cats [*& or* Kittens]
Hartz Generic Topical Treatment for Cats [*& or* Kittens]
Hartz Generic Flea Topical for Cats [*& or* Kittens]
Hartz Generic for Cats [*& or* Kittens]
Hartz First Defense ADVANCED for Cats [*& or* Kittens]
Hartz ADVANCE PRO Flea Treatment for Cats [*& or* Kittens]
Hartz UltraGuard Sentinel for Cats [*& or* Kittens]
Hartz UltraGuard Sentinel MAX for Cats [*& or* Kittens]
Hartz UltraGuard Sentinel PLUS for Cats [*& or* Kittens]
Hartz UltraGuard Sentinel PRO for Cats [*& or* Kittens]
Hartz UltraGuard Defender for Cats [*& or* Kittens]
Hartz UltraShield for Cats [*& or* Kittens]
Hartz ImidaShield II for Cats [*& or* Kittens]
Hartz ImidaShield II MAX for Cats [*& or* Kittens]
Hartz ImidaShield II PLUS for Cats [*& or* Kittens]
Hartz ImidaShield II PRO for Cats [*& or* Kittens]
Hartz ImidaShield for Cats [*& or* Kittens]
Hartz ImidaShield MAX for Cats [*& or* Kittens]
Hartz ImidaShield PLUS for Cats [*& or* Kittens]
Hartz ImidaShield PRO for Cats [*& or* Kittens]
Hartz ImidaGuard II for Cats [*& or* Kittens]
Hartz ImidaGuard II MAX for Cats [*& or* Kittens]
Hartz ImidaGuard II PLUS for Cats [*& or* Kittens]
Hartz ImidaGuard II PRO for Cats [*& or* Kittens]
Hartz ImidaGuard for Cats [*& or* Kittens]
Hartz ImidaGuard MAX for Cats [*& or* Kittens]
Hartz ImidaGuard PLUS for Cats [*& or* Kittens]
Hartz ImidaGuard PRO for Cats [*& or* Kittens]
Hartz ProCare for Cats [*& or* Kittens]
Hartz FirstCare for Cats [*& or* Kittens]

[Each of the above brands will be packaged in the weight classes designated below:]

For use ONLY on Cats 8 weeks and Older and Weighing 2 to 5 lbs.

or Weighing 5 to 9 lbs.
or Weighing Over 9 lbs.

[FRONT PANEL (cont.)]

ACCEPTED
10/23/2014
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2596-181

ACTIVE INGREDIENTS:

Imidacloprid 9.10%
Pyriproxyfen 0.46%
Other Ingredients. 90.44%
Total 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for precautionary statements and directions for use.

NET CONTENTS:

[*Large clear picture of a cat in appropriate weight range on front panel to be included*]

For use ONLY on Cats 8 weeks and Older and Weighing:	**Net Contents**
2 to 5 lbs.	0.031 fl. oz. (0.92 ml), Contains 4 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.056 fl. oz. (1.6 ml), Contains 4 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.108 fl. oz. (3.2 ml), Contains 4 tubes, each 0.027 fl. oz. (0.8 ml)

For use ONLY on Cats 8 weeks and Older and Weighing:	
2 to 5 lbs.	0.046 fl. oz. (1.38 ml), Contains 6 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.084 fl. oz. (2.4 ml), Contains 6 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.162 fl. oz. (4.8 ml), Contains 6 tubes, each 0.027 fl. oz. (0.8 ml)

[BACK PANEL]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies or consumer questions call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

IF ON SKIN OR CLOTHING: 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.

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. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than **[2 lbs.; 5 lbs.; 9 lbs.]** As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

[BACK PANEL (cont.)]

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.

READ ENTIRE LABEL BEFORE EACH USE

RESTRICTIONS

USE ONLY ON CATS OR KITTENS 8 WEEKS AND OLDER WEIGHING [2 to 5 lbs.; 5 to 9 lbs.; Over 9 lbs.]
DO NOT USE ON OTHER ANIMALS
DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS
DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT ON ANY CAT
DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.
DO NOT USE ON CATS WEIGHING LESS THAN 2 LBS. [this line only required on product labeled for use on cats weighing 2 to 5 lbs.]

Side Effects (Cats): Monitor your cat after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call, 1-800-275-1414.

[BACK PANEL (cont.)]
[DIRECTIONS FOR USE (cont.)]

[APPLICATION INSTRUCTIONS:]
[*Visuals Depicting How to Open Applicator Tube And Application To Animal*]

[OPTION 1:]
HOW TO APPLY

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. Part the hair on the neck at the base of the skull 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 pet's eyes, or allow your pet to ingest this product****. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the 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. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[OPTION 2:]
HOW TO APPLY

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 ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. Part the hair on the neck at the base of the skull 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 pet's eyes, or allow your pet to ingest this product****. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the 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. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[BACK PANEL (cont.)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable 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 1-800-274-1414 for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[INSTRUCTIONS FOR BLISTER PACK]

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.
4. Repeat steps 1 and 2 for each tube.

[OPTION 2:]

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

INDIVIDUAL TUBE TEXT

(Product name)

[The appropriate size and fill volume will be correctly used on each applicable cat's weight category]
ONLY FOR USE ON CATS AND KITTENS 8 WEEKS OR OLDER WEIGHING 2 to 5 lbs. - 0.0078 fl. oz. (0.23 ml)
or 5 to 9 lbs. - 0.014 fl. oz. (0.4 ml)
or 9 lbs. and Over - 0.027 fl. oz. (0.8 ml)

9.10% Imidacloprid
0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN
CAUTION
Read The Entire Label Before Use
EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1
(Lot no. is heat stamped in tube crimp – required on each)

OPTIONAL/ALTERNATE LABEL TEXT

For use on cats and kittens 8 weeks of age and older
(Insert Product Name) contains Imidacloprid, [and an/the] [insect growth regulator] [IGR] [Pyriproxyfen]
A single topical application remains effective for up to [4 weeks] [1 month]
Convenient, easy-to-apply topical solution
Convenient, easy-to-apply [and fragrance free] [monthly] [topical solution]
Once a month topical flea prevention and treatment for cats 8 weeks of age or older
(Insert Product Name) is indicated for the prevention and treatment of fleas on cats 8 weeks of age and older
For the prevention and treatment of flea infestations on cats

One treatment prevents further flea infestations for up to [4 weeks] [1 month] [30 days]
Kills fleas and continues to prevent infestations for up to [four weeks] [a month] [30 days]
Kills larval stages of fleas following contact with [a/an] [Product Name] treated cat
Stops existing flea infestations by killing adult fleas
Effectively breaks the flea life cycle
[Kills] [Controls] life stages
Comprehensive flea prevention and treatment
2-way flea protection ([kills] [controls]) adults and eggs
Treatment of cats with [Product Name] kills fleas and that may cause flea allergy dermatitis [FAD] [or flea bite hypersensitivity]
Flea adulticide and ovicide
Kills flea eggs
Controls flea problems
Provides flea protection
Controls existing fleas and flea eggs plus [and] [prevents] future flea infestations
[Brand Name] may be used year-round for flea [prevention] [protection]
Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation
Monthly use of [Product Name] on cats kills fleas that may cause ([flea allergy dermatitis] [flea bite hypersensitivity])
Controls existing flea infestations on your cat and prevents further infestations
Prevents fleas on treated cats from infesting (reinfesting)
Fragrance-free

Prevents (establishment of) new infestations after application
Prevents all flea stages (eggs) from developing
Kills fleas (and flea eggs) [for] [4 weeks] [1 month] [30 days]
Stays on and doesn't rub off for 1 month
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation (reinfestation)
Effective and convenient topical treatment
(With) patented applicator

Easy spot on topical applicator
Remains effective even after bathing or water immersion.
(Product Name) remains effective even after bathing or water immersion.

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (*or* Advantage® II)
Contains the (same) active ingredients used in Bayer Advantage® II (*or* Advantage® II) (products)
Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (*or* Advantage® II) (brand products)
[Product Name] is not manufactured by or distributed by Bayer. Advantage® II is a registered trademark of Bayer Healthcare LLC.

Only for cats and kittens 8 weeks of age or older
For cats and kittens 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose
First month, second month, third month, fourth month, fifth month, sixth month
Value pack
[1] [2] [3] [4] [5] [6] month supply
[4 *or* 6] monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(4 *or* 6) Pro-cision Flo® Applicator(s) (included)
(4 *or* 6) Pro-glide® Applicator(s) (included)
(Pro-cision Flo® Applicator)
(Pro-Glide® Applicator)
Featuring [Pro-cision Flo®] [Pro-Glide®] Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Convenient to use

After application, the treated area may appear wet for up to 24 hours
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____
Fourth Dose _____
Fifth Dose _____
Sixth Dose _____

Metzger, Autumn

CAT

From: DJones@hartz.com
Sent: Friday, October 10, 2014 3:07 PM
To: Metzger, Autumn
Subject: RE: EPA Master Labels for EPA File Symbols 2596-RIR and -RIG
Attachments: Hartz Reference #146 CAT EPA mstr lbl 2014 Oct 10a.pdf; Hartz Reference #148 CAT EPA mstr lbl 2014 Oct 10a.pdf

Hi Autumn,

Attached are today's version 2s of the cat drop labels with an Oct 10a in the file names.

The blister pack here is the same treatment with complete labeling on the outside when it is used.

Sunlight claims are deleted.

I moved the First Aid above Precautionary Statements on the back panel.

Thank you and enjoy the weekend.

Dave

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Date: 10/10/2014 01:51 PM
Subject: RE: EPA Master Labels for EPA File Symbols 2596-RIR and -RIG

Need to delete the sunlight claims (unless I missed those citations too but I don't remember seeing any sunlight data).

Also, same question about blister pack

And see Venus' comment on pg 3 (may be hard to read since in pencil). She wanted the First Aid box moved directly above the precautionary statement on the back panel.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, October 10, 2014 11:01 AM
To: Metzger, Autumn

Cc: SMcNear@hartz.com
Subject: EPA Master Labels for EPA File Symbols 2596-RIR and -RIG

Good morning,
Attached please find the cat topical labels modified as prescribed.
Thank you,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

Metzger, Autumn

From: Metzger, Autumn
Sent: Thursday, October 09, 2014 3:12 PM
To: 'DJones@hartz.com'
Subject: RE: EPA File Symbol 2596-RIG; Hartz Reference #148 CAT EPA mstr lbl 2014 Oct 9.doc
Attachments: 2596-RIG Hartz CAT spot on WITH AGENCY comments 10-9-2014.pdf

Here are the final comments. If you can get back by lunch tomorrow we'll be in good shape, thanks!

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Thursday, October 09, 2014 8:34 AM
To: Metzger, Autumn
Subject: EPA File Symbol 2596-RIG; Hartz Reference #148 CAT EPA mstr lbl 2014 Oct 9.doc

Good morning,
Here is the proposed revision of the cat topical master label.
Thank you again for all the time and help.
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

Metzger, Autumn

From: Metzger, Autumn
Sent: Tuesday, October 07, 2014 3:11 PM
To: 'DJones@hartz.com'
Subject: 2596-RIR and 2596-RIG CAT spot on products
Attachments: 2596-RIG and 2596-RIR label comments hand-written on -RIG 10-7-2014.pdf

Dave,

Here are the label comments for the cats. Most of the comments are similar to the dog comment but it may be quicker to go over briefly to make sure you can read my comments. I am available today before 3:30 or first thing tomorrow morning. I'd like to have these revised labels back by Thursday so the sooner the better.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

Metzger, Autumn

From: Metzger, Autumn
Sent: Tuesday, September 30, 2014 3:59 PM
To: DJones@hartz.com
Subject: 2596-RIR, 2596-RIG Product chemistry reviews
Attachments: 2596-RIR Product Chemistry Review 9-4-2014.pdf; 2596-RIG Product Chemistry Memo 9-2-2014.pdf

Hi Dave,

Please see attached the Product Chemistry reviews

For RIG, note that you need to add the "combustible" language.

We can now begin the label review. I'll start that this week and hopefully get you comments by Monday.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

BARCODE No.: 420152; **DECISION No.:** 486510 **FILE SYMBOL No.:** 2596-RIR;
PRODUCT NAME: Hatrz Reference #146; **PC Code(s):** 129099&129032; **Action Code:** R315;

DATE: **September 2, 2014**

SUBJECT: **Product Chemistry Review of Hartz Reference #146**

FROM: **Akiva Abramovitch, Ph.D.**
Technical Review Branch / RD (7505P)

THROUGH: **Shyam Mathur, Ph.D.**
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

SBm 9/4/14

TO: **Autumn Metzger/Venus Eagle, PM 1**
Insecticide-Rodenticide Branch/ RD (7505C)

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product containing Imidacloprid at 9.1% and Pyriproxyfen (Nylar) at 0.46%. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 492877-01 through 492877-03).

The CSF of the basic formulation dated August 28, 2014 (Replaces the December 1, 2013 CSF) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF dated 8/28/14.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Imidacloprid (9.1%) and Nylar/Pyriproxyfen (0.46%).

2. Has the registrant claimed substantial similarity to a registered product?

   [ ] Yes; [X] No; [ ] NA; if yes give the registration number of the cited product.

3. All the source materials for the active ingredients are derived from the registered sources: [X] Yes; [ ] No.

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: [X] Yes; [ ] No.

5. Confidential Statement of Formula(s):

[X] Basic CSF dated August 28, 2014 (Replaces the December 1, 2013 CSF)
Alternate CSFs- None

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

[] Yes, if not, explain below:
Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?
[] Yes; [ ] No; if not, explain below:

Metallic equivalent:	[ ] Yes	[X] NA;
Soluble arsenic:	[ ] Yes	[X] NA
Isomeric ratios:	[ ] Yes	[X] NA
Acid equivalent:	[ ] Yes	[X] NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%:	[ ] Yes	[X] No	[ ] NA
Methanol at > 4%:	[ ] Yes	[X] No	[ ] NA
Sodium nitrate/Sodium nitrite	[ ] Yes	[X] No	[ ] NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
[] Yes [X] No

Flash point 169 F.

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
[] Yes, [ ] No, [X] NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:
[] Yes [X] No

BARCODE No.: 420152; **DECISION No.**: 486510 **FILE SYMBOL No.**: 2596-RIR;
PRODUCT NAME: Hatrz Reference #146; **PC Code(s)**: 129099&129032; **Action Code**: R315;
7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	492877-02
830.1600	Description of materials used to produce the product		X		A	492877-02
830.1650	Description of formulation process		X		A	492877-02
830.1670	Discussion on the formation of impurities		X		A	492877-02
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	492877-02
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	492877-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress,
NA = Not Applicable; U = Upgradeable

8. Group **B:**

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Light yellow clear liquid with a solvent like odor	A	492877-01
830.6314	Oxidation/ Reduction	Components are not expected to React with oxidizing and reducing agents	W	492877-01
830.6315	Flammability	169 F	A	492877-01
830.6316	Explodability	Not explosive	A	492877-01
830.6317	Storage Stability	A study in progress	G	
830.6320	Corrosion	A study in progress	G	
830.7000	pH	6.70	A	492877-01
830.7300	Density (units)	9.772 lb/gal	A	492877-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA =Not applicable, I= In progress, U = Upgradeable.

CONCLUSION:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic formulation dated August 28, 2014 is acceptable.

2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.

3. The registrant satisfied the Group B data requirements with the exception of the Storage Stability and Corrosion data requirements. The pH was provided as requested by the Agency and reported at 6.70 on the revised CSF.

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM:

Date: 7/24/14

To: Venus Eagle, PM 1

From: Autumn Metzger, M.S. 7/24/14

Subject: PRODUCT PERFORMANCE REVIEW – citations of efficacy data

EPA Reg No/EPA File Symbols: 2596-RIG, **Decision** #486442 **DP Barcode:** 421696
EPA Reg No/EPA File Symbols: 2596-RIR, **Decision** #486510 **DP Barcode:** 421697

PRIA action code: R315

Formulation Type: Spot-ons for cats

Ingredients statement from the label with PC codes included:
Imidacloprid, 129099 (9.1%)
Pyriproxyfen, 129032 (0.44%)

Application rate(s) of product and each active ingredient:

Imidacloprid:	5 lb cat = 10.83 mg/kg	9 lb cat = 10.27 mg/kg
Pyriproxyfen:	5 lb cat = 2.2 mg/kg	9 lb cat = 2.2 mg/kg

Background: The registrant is applying for registration of spot on products with claims of killing/controlling fleas and flea eggs/larvae on cats

Summary of MRIDs:

MRID 43794101 – study on adult fleas and flea eggs on cats, supports general adult flea and flea egg claims on cats for 1 month

The following MRIDs were found unacceptable:

43794102 – Field study for cat fleas on cats. Study design not acceptable.
43679503 – Study on adult fleas on cats. Efficacy not acceptable.
43679504 – Study on adult fleas on cats. Efficacy not acceptable.
43679609 – Study performed on species other than cats.
43679610 – Study performed on species other than cats.
44256901 – Study performed on species other than cats.
44256902 – Study performed on species other than cats.
44256903 – Not a valid MRID number
45425101 – Study on adult fleas on dogs. Study design is not acceptable. Study does not support any claims.
45425102– Study on adult fleas on cat fur. Study design is not acceptable. Study does not support any claims.

Recommendations:
The MRID 43794101 supports a general kill/control claim against adult fleas and flea eggs for 1 month. This does not include Bayer's "kills fleas on cat for 12 hour claim" nor waterproof claims.

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

July 24, 2014

MEMORANDUM: HARTZ REFERENCE #148 COMPANION ANIMAL STUDY CITATIONS (#2)

Subject:	Name of Pesticide Product:	Hartz Reference #148
	EPA Reg. No. /File Symbol:	2596-RIG
	DP Barcode:	DP 421546
	Decision No.:	486442
	Action Code:	R315.2
	Submission:	#954965
	E-Sub.	-
	PC Code:	129099 (Imidacloprid: 9.1%) 129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
July-24-2014
Mbashi

To: Autumn Metzger/Venus Eagle RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORPORATION

FORMULATION FROM LABEL:

Active Ingredient(s):		by wt.
129099 Imidacloprid		9.10%
129032 Pyriproxyfen		0.46%
Other Ingredients:		90.44%
	TOTAL	100.00%

ACTION REQUESTED: "…this is the second try at citing companion animal safety studies. The first try did not cite accurate and passing previous studies. Please see if these citations will suffice… NOTE that they kept the 3 studies that did not suffice MRIDs 47089401-03. Please let me know if they are needed to supplement the other studies or if they can be/should be deleted from this data matrix. Attached: data matrix, old memo, proposed CSF, label.

BACKGROUND: The material received by TRB includes an updated (07/11/2014) data matrix with the following companion animal study citations: MRIDs 47089401, 47089402 and 47089403 (previously addressed in a TRB memorandum dated June 5, 2014) and (additional) MRIDs 43679501, 43679502, 44157302, 45097001, 47089404, 47089405, 47089406 and 47924801. The proposed label indicates use only on cats 8 weeks of age and older with three dose-weight ranges: 0.0078 fl. oz. or 0.23 mL for cats weighing 2 to 5 lbs; 0.014 fl. oz. or 0.4 mL for 5 to 9 lbs; and 0.027 fl. oz. or 0.8 mL for over 9 lbs.

COMMENTS AND RECOMMENDATIONS:

1. From the acute toxicity studies for 2596-RIG (refer to TXR 5015021, TRB memorandum dated June 27, 2014 for 2596-RIG) the density of this formulation is 1.143 g/mL, so a dose of 0.23 mL on a 2 lb (0.907 kg) cat would be 0.29 g formulation/kg, or 0.026 g (26 mg) imidacloprid/kg. A dose of 0.4 mL on a 5 lb (2.268 kg) cat would be 0.202 g formulation/kg or 0.018 g (18 mg) imidacloprid/kg, and 0.8 mL on a 9 lb (4.08 kg) cat would be 0.224 g formulation/kg or 0.020 g (20 mg) imidacloprid/kg. For pyriproxyfen (which has very low toxicity to mammalian species), 0.23 mL formulation on a 2 lb cat would be a dose of 1.33 mg pyriproxyfen/kg, 0.4 mL on a 5 lb cat would be 0.93 mg pyriproxyfen/kg, and 0.8 mL on a 9 lb cat would be 1.03 mg pyriproxyfen/kg.

2. The studies in MRID 43679501 and 43679502 were reviewed by HED (TXR 0011821; memorandum from Myron S. Ottley dated March 5, 1996) with the following comments:

   [For 43679501]: *a total of 4 males and 5 females in 3 groups (1-2/sex/group) were dermally exposed to Imidacloprid, 10% Spot-On formulation. Dose levels were 50 mg/kg/day x 1 day, and 50/mg/kg/day x 3 days. Controls received placebo (Formulation less active ingredient) at 50/mg/kg/day x 3 days. Animals then were observed for 14 days.*

   No major treatment related dermal, clinical signs, body weight effects or clinical chemistry changes were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that cats can tolerate 50 mg/kg without significant adverse reactions.

   This acute dermal study is classified as Acceptable when combined with another study (see below). The number of animals/group is too small and not in keeping with general study practice. However, when data are combined with the companion study in the cat (MRID 43679502), the information is considered useful. This satisfies the requirements for a domestic animal study in the cat.

   [For 43679502]: *18 cats of various and mixed breed (3 or 4 males, 2 or 3 females per group of which 1 or 2 males/group and 1 or 2 females/group were 11 - 12 weeks old) were dermally exposed to Imidacloprid, 10% Spot-On at seven-day intervals for a total of eight treatments. Dose levels were 10 or 50 mg/kg. Controls received placebo (formulation less active ingredient) at 50/mg/kg.*

   No major treatment related dermal, clinical signs, body weight effects or clinical chemistry/hematology were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult cats can tolerate up to 50 mg/kg of the active ingredient without significant reactions.

This repeated dose dermal study satisfies the requirement for a Domestic Animal Safety study for topical use in adult cats and is classified as Acceptable.

It was the conclusion of the original reviewer that these two studies indicate adult cats can tolerate up to 50 mg/kg of the active ingredient, so they would (applying a 5X safety factor) support a dosage rate of 10 mg imidacloprid/kg. These studies then do not support the proposed maximum dosage rates for 2596-RIG (0.23 mL on a 2 lb cat = 26 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20 mg imidacloprid/kg).

3. The study in MRID 44157302 [Shmidl, J.; Arther, R. (1996) General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number: 74747: TR-96F-006: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 45 p. Relates to L0000102.] was reviewed by HED (TXR 0012322, memorandum from Virginia Dobozy dated September 24, 1997). The following is from the executive summary:

   In a domestic animal safety study (MRID # 44157302), six 8 week-old kittens/sex were treated with Advantage™ (9.1% imidacloprid) at 5X the recommended use rate (2.0 ml) at weekly intervals for eight treatments. Six kittens/sex were treated with the vehicle control at the recommended use rate (0.4 ml) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 8 week-old kittens can tolerate a dose of 5X the recommended use rate.

   The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.

   The initial body weights of the twelve 5X kittens are reported on page 8 of MRID 44157302; the 4 lowest weight males (0.73, 0.73, 0.83 and 0.84 kg) and 4 lowest weight females (0.82, 0.82, 0.85, 0.85 kg) had a mean weight of 0.81 kg . Since each was treated with 2.0 mL of a formulation containing 9.1% imidacloprid, they were each exposed to 207 mg imidacloprid which, divided by 0.81 kg, results in a mean of 256 mg/kg (207 mg ÷ 0.81 kg). **This study supports a dose rate of 256 mg/kg ÷ 5 = 51.1 mg/kg, which is greater than (and supports) the proposed maximum dosage rates for 2596-RIG (0.23 mL on a 2 lb cat = 26 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20 mg imidacloprid/kg).**

4. The study in MRID 45097001 [Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, Adult Cats: Lab Project Number: 75122. Unpublished study prepared by Bayer Corporation. 139 p. {OPPTS 870.7200}] was reviewed by TRB (TXR 5001582, memorandum from M. Hashim dated September 22, 2000). The following is excerpted from the executive summary:

In a companion animal safety study (MRID 45097001), Advantage Plus® 9 and 18 for cats (Active Ingredients: 9.1% Imidacloprid w/w; 0.9% Pyriproyfen w/w) was topically applied at dose volumes of 2.0 ml for cats weighing less than or equal to 9 lbs, and 4.0 mL for cats weighing greater than 9 lbs (5 times the recommended doses) to groups of 6 male and 6 female cats, 7 months to one year of age. Controls were dosed with the vehicle at volumes of 2.0 mL for cats weighing less than or equal to 9 lbs and 4.0 ml for cats weighing greater than 9 lbs (5.6 times the volume of vehicle in the recommended doses). Animals were treated on (study) days 0, 7, 14, and 21.

Treatment related clinical signs included transient salivation which ceased within 2 hours of treatment on day 0 (4 of 12 test animals and 1 of 12 vehicle control animals reported from licking the test material), and a rough hair coat appearance at the treatment site on all animals of both groups following treatment on days 14 and 21. None of the cats were observed salivating following the last 3 treatments. One animal from the test group had pruritis at one hour on day 21. There was vomiting by two cats in the test group on days 19 and 25, which did not occur in periods following the test (substance) applications. Vomiting may be associated with licking the test substance. This does not appear to be exposure related... There were no other treatment related effects on hematology, coagulation or clinical chemistry parameters. There were no treatment related effects on body weight or food consumption, and there were no signs of irritation at the application sites...

Any clinical signs on the study showed no consistent toxicological response. This study is classified as ***Acceptable /Guideline*** *for a companion animal safety study (OPPTS 870.7200) in cats.*

Individual body weights (in kg) are reported on p. 30 of MRID 45097001. Day -1 weights for the six group A (5X) females were 2.6, 2.7, 2.8, 3.1, 2.4, and 2.8 kg; weights for the six group A (5X) males were 4.1, 5.0, 4.9, 4.0, 3.9 and 3.8 lbs. From information on p. 33 all group A cats except for the two heaviest weight males received 2.0 mL test material on day 0; the two heaviest weight males each received 4.0 mL. On a bodyweight basis, individual dosage rates for the 6 females were 0.77, 0.74, 0.71, 0.65, 0.83 and 0.71 mL/kg; for the 6 males rates were 0.49, 0.80, 0.82, 0.50, 0.51 and 0.53 mL/kg. Taking the mean from the 4 highest values (0.83, 0.77, 0.74, 0.71 mL/kg) for the females and 4 highest values (0.82, 0.80, 0.53, 0.51 mL/kg) for males gives 0.71 mL/kg. The test material had (from p. 135 of MRID 45097001) a specific gravity of 1.097 and contained 9.1% imidacloprid, so the mean dosage in terms of this active was 71.3 mg imidacloprid/kg; dividing this value by 5 gives 14.3 mg imidacloprid/kg.

The study in MRID 45097001 then does not support the proposed maximum dosage rates for 2596-RIG (0.23 mL on a 2 lb cat = 26 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20 mg imidacloprid/kg).

5. The material in MRID 47089404 [Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.46 (W/W)% Pyriproxyfen Spot-on with 4.6% Water Blank Formulation at Three Times the Use Rate Volume in the Target Species, 8-Week Old Kittens.. Project Number: 75191/1, 150/937. Unpublished study prepared by Mobay Corp. and Bayer Corp. 8 p.] consists of an amendment (correcting the completion date on the title page from June 8, 2001 to June 27, 2001) to the study in MRID 47089401. This does not change the supplementary classification of MRID 47089401.

6. The study in MRID 47089405 [Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.46% (W/W) % Pyriproxyfen Spot-on with 4.6% (W/W) Water Blank Formulation at Three Times the Use Rate Volume in the Target Species, 8-Week Old Kittens.. Project Number: 75191, 150/937. Unpublished study prepared by Mobay Corp. and Bayer Corp. 135 p.] was reviewed by TRB (TXR 50079330, memorandum dated September 6, 2007 from B. Backus). The following is excerpted from the executive summary:

   In a companion animal safety study (MRID 47089405), there were two groups, each containing 7 male and 7 female kittens (from 7 weeks 5 days to 8 weeks old at first dosing; day -1 bodyweights: males: 1.48-2.14 lbs; females: 1.36-1.92 lbs; source: Liberty Research Inc., Waverly, NY). Kittens in Group A were treated with the proposed formulation without the actives (but with 4.6% added water) at 3X the label exposure rate for solvents (3 x [0.4 – 0.04] mL = ~1.1 mL; this does not correct for the added water) while kittens in Group B received no treatment and served as controls...

   On the days of dosing (Days 0, 7, 14 and 21) each kitten was observed five times, once prior to dosage and then at hourly intervals for four hours after application... There were no mortalities, as all kittens survived to the termination of the study on Day 35...

   This study is classified as ***Supplementary*** *as a companion animal safety study (OPPTS 870.7200) in 8 week-old kittens, in part because it did not involve actual testing of the proposed formulation with actives. This study was apparently conducted (at least in part) to establish the existence of a 3X safety factor with respect to the normal use application exposure levels of the solvent(s) of the proposed Imidacloprid-Pyriproxyfen formulation and the level at which toxicity occurs. As one of the 14 Group A kittens showed signs of toxicity (including unsteadiness and tremors) on Days 1-3 similar to those observed in kittens exposed to 5.6X or 5X levels of the solvent(s) in other studies (MRIDs 47089401 and 47089403) a 3X margin of safety was not established.*

   Since the study was classified as supplementary and there was no actual testing of the proposed formulation with actives, it cannot be used to support the registration of 2596-RIG.

7. The material in MRID 47089406 [Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.45% Pyriproxyfen Spot-on with 5.0% Water Blank Formulation in

the Target Species, 8-Week Old Kittens. Project Number: 75190/1, 150/828. Unpublished study prepared by Mobay Corp. and Midwest Research Institute and Charles River Laboratories, Inc. 8 p.]. This is an amendment to the study in MRID 47089405 and does not affect its supplementary classification.

8. The study in MRID 47924801 [Madsen, T. (2009) Evaluation of the General Safety of M880. Project Number: 152/141, S07648, 33714. Unpublished study prepared by Sinclair Research Center, Inc. 193 p.] was reviewed by TRB (TXR 5012077, memorandum dated April 15, 2010 from B. Backus). The following is excerpted from the executive summary:

In a companion animal safety study (MRID 47924801), 5 groups, each containing 6 males and 6 females, of domestic shorthair kittens (54-57 days old on Day 0; Day -1 body weights: males: 0.691-1.012 kg; females: 0.555-0.935 kg; source: Liberty Research, Inc., Waverly, NY), were topically treated (on Day 0) with (Group 1): mineral oil at a total dose of 1.15 mL; (Group 2): 3X vehicle substance at a total dose of 0.63 mL; (Group 3): 5X vehicle substance at a total dose of 1.05 mL; (Group 4): 3X test substance at a total dose of 0.69 mL; and (Group 5): 5X dose test substance at a total dose of 1.15 mL...

The groups and test materials they received (with amounts applied) are shown in the table below:

Group	***Test Material Applied***	***Volume of each application***	***Cumulative amount applied on Day 0; also on Day 14***
1	*Mineral oil*	*1st app = 0.35 mL; 2nd & 3rd = 0.4 mL*	*1.15 mL*
2	*Vehicle of proposed formulation (no active ingredients) at 3X*	*3 applications @ 0.21 mL*	*0.63 mL*
3	*Vehicle of proposed formulation (no active ingredients) at 5X*	*3 applications @ 0.35 mL*	*1.05 mL*
4	*Proposed formulation (with active ingredients) at 3X*	*3 applications @ 0.23 mL*	*0.69 mL*
5	*Proposed formulation (with active ingredients) at 5x*	*1st app = 0.35 mL; 2nd & 3rd = 0.4 mL*	*1.15 mL*

All animals survived to the end of the study...

It is concluded that the margin of safety in kittens administered topical application of the product formulation is at least 3X. Possible effects observed at 5X included lethargy in one male kitten following the second set of applications, and decreased body weight gains in both males and females in the period from day -1 to day 20. As noted in the current 870.7200 Guidelines: "Consideration will be given to products with less than a 5X margin of safety, depending on the severity of clinical signs of toxicity (e.g. transient, non-life-threatening signs)."

This companion animal safety study in male and female domestic shorthair kittens is ***Acceptable/Guideline*** *and* ***does satisfy*** *the guideline requirement for a companion animal safety study (OPPTS 870.7200) in 54-57 day (8 week) kittens.*
Individual body weights for MRID 47924801 are reported on page 89 for males and page 90 for females. Individual day -1 bodyweights for group 5 (5X) males were 1.012, 0.881, 0.777, 0.857, 0.889 and 0.762 kg, and for group 5 (5X) females were 0.935, 0.786, 0.613, 0.746, 0.762 and 0.792 kg. The mean weight ± S.D. for the four least-weight males and four least-weight females is 0.773 ± 0.081 kg (1.704 ± 0.178 lbs). The test formulation density is reported (p. 18 of MRID 47924801) as 1.095. The minimum pyriproxyfen dosage for the 5X group on Day 0 is reported (p. 18 of MRID 47924801) as 5.848 mg/kg, and the minimum imidacloprid dosage is 110.744 mg/kg; since these values would be associated with the maximum weight kitten (1.012 kg) the [assayed?] percentages of actives can be calculated: formulation dosage was 1.15 mL x 1.095 g/mL = 1.259 g was applied to each kitten; 1.259 g ÷ 1.012 kg = 1.244 g/kg = 1244 mg/kg. The percentage of imidacloprid in the formulation was then 110.744 ÷ 1244.32 x 100% = 8.9% and the percentage of pyriproxyfen was 5.848 ÷ 1244.32 x 100% = 0.47% [According to the Certificate of Analysis on p. 68 of MRID 47924801 the percentage of imidacloprid was 9.1% and the percentage of pyriproxyfen was 0.46%].

Assuming the percentage of imidacloprid was 9.1% then the mean formulation dosage for the four least-weight males and four least-weight females was 1.259 g ÷ 0.773 kg = 1.629 g/kg, and the mean dosage of imidacloprid was 1.629 g/kg x 0.091 = 0.148 g/kg = 148 mg/kg. Dividing this by 5 gives 29.6 mg imidacloprid/kg for a 1X dose. The mean dosage of pyriproxyfen for these same kittens was 1.629 g/kg x 0.0047 = 7.66 mg/kg, and dividing this value by 5 gives 1.53 mg pyriproxyfen/kg for a 1X dose.

The study in MRID 47924801 then supports the proposed maximum dosage rates for 2596-RIG (0.23 mL on a 2 lb cat = 26 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20 mg imidacloprid/kg). For pyriproxyfen (which has very low toxicity to mammalian species), 0.23 mL formulation on a 2 lb cat would be a dose of 1.33 mg pyriproxyfen/kg, 0.4 mL on a 5 lb cat would be 0.93 mg pyriproxyfen/kg, and 0.8 mL on a 9 lb cat would be 1.03 mg pyriproxyfen/kg, all below the supported 1X value of 1.53 mg pyriproxyfen/kg.

9. TRB concludes that the citations to MRIDs 44157302 and/or 47924801 satisfy the companion animal safety data requirements (including minimum age of 8 weeks and the proposed maximum dosage rates of 0.23 mL on a 2 lb cat = 26 mg imidacloprid/kg; 0.4 mL on a 5 lb cat = 18 mg imidacloprid/kg; 0.8 mL on a 9 lb cat = 20 mg imidacloprid/kg) to support the registration of 2596-RIG.

Metzger, Autumn

From: DJones@hartz.com
Sent: Friday, July 11, 2014 10:30 AM
To: Metzger, Autumn
Cc: SMcNear@hartz.com
Subject: Re: 2596-RIR and 2596-RIG cat spot ons; updated 2596-RIR matrix
Attachments: 2596-RIR Data matrix 2014 Jul 11 signed scan.pdf; Data matrix CASS sum tbl 2014 Jul 11.pdf

Good morning,
I have attached a revised data matrix for 2596-RIR, Hartz Ref. #146 now dated July 11, 2014. On the bottom of page 3, the last 2 lines are new and the entirety of page 4 is new. To aid in the review I have attached a scan of the DER summaries for all the domestic/companion animal studies.

If I can improve this submission in any other way, please let me know. The 2596-RIG updated matrix will be following shortly.
I had asked about the PRIA due date in my May e-mail. Can you please share that information for this submission when you have a chance.
Thank you,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Date: 07/09/2014 03:54 PM
Subject: 2596-RIR and 2596-RIG cat spot ons

Mr Jones,

Please find the acute tox and companion animal safety memos for both attached. The CA studies did not pass. You will be receiving a 75 day letter soon (via email).

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314
[attachment "2596-RIR Acute Tox memo 6-27-2014.pdf" deleted by David L. Jones/ML1] [attachment "2596-RIR companion animal safety memo 6-5-2014.pdf" deleted by David L. Jones/ML1] [attachment "2596-RIG Companion animal safety memo 6-5-2014.pdf"

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 7/11/2014	EPA Reg No./File Symbol 2596-RIR	Page 1 of 4
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identification and Composition	Submitted	The Hartz Mountain Corporation	own	
830.1600	Description of Materials Used to Produce the Product	Submitted	The Hartz Mountain Corporation	own	
830.1620	Description of the Production Process	Submitted	The Hartz Mountain Corporation	own	
830.1650	Description of the Formulation Process	Submitted	The Hartz Mountain Corporation	own	
830.1670	Discussion of Formation of Impurities	Submitted	The Hartz Mountain Corporation	own	
830.7100	Viscosity	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.1750	Certified Limits	Submitted	The Hartz Mountain Corporation	own	
830.1800	Enforcement Analytical Method	Submitted	The Hartz Mountain Corporation	own	
830.6302	Color	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6303	Physical State	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6304	Odor	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6315	Flammability	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6316	Explodability	Waiver Request	The Hartz Mountain Corporation	own	
830.6317	Storage Stability	To be submitted	The Hartz Mountain Corporation	own	In process

Signature	Name and Title	Date
David Jones	David Jones/Manager Regulatory Affairs	07/11/2014

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DATA MATRIX

Date 7/11/2014	EPA Reg No./File Symbol 2596-RIR	Page 2 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6320	Corrosion Characteristics	To be submitted	The Hartz Mountain Corporation	own	In process
830.6321	Dielectric Breakdown Voltage	Waiver request	The Hartz Mountain Corporation	own	
830.7000	pH	Waiver request	The Hartz Mountain Corporation	own	
830.7300	Density/Relative Density/Bulk Density	Submitted	The Hartz Mountain Corporation	own	Self-Certification
870.1100	Acute Oral Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1200	Acute Dermal Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1300	Acute Inhalation Toxicity	Waiver request	The Hartz Mountain Corporation	own	
870.2400	Acute Eye Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2500	Acute Dermal Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2600	Skin Sensitization	Submitted	The Hartz Mountain Corporation	own	
870.7200	Companion Animal Safety Study	47089401	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089402	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089403	Bayer Healthcare	PAY	
Not specified	Pesticide Use-Product Performance (Efficacy)	43679503	Bayer Healthcare	OLD	

Signature	Name and Title	Date
	David Jones/Manager Regulatory Affairs	07/11/2014

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 7/11/2014	EPA Reg No./File Symbol 2596-RIR	Page 3 of 4
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679504	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679609	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679610	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794101	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794102	Bayer Healthcare	OLD	
95-9	Pesticide Use-Product Performance (Efficacy)	44256901	Bayer Healthcare	OLD	
95-9	Pesticide Use-Product Performance (Efficacy)	44256902	Bayer Healthcare	OLD	
95-9	Pesticide Use-Product Performance (Efficacy)	44256903	Bayer Healthcare	OLD	
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425101	Bayer Healthcare	PAY	
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425102	Bayer Healthcare	PL	
810.3300	Pesticide Use-Product Performance (Efficacy)	47109101	Bayer Healthcare	PAY	
810.3300	Pesticide Use-Product Performance (Efficacy)	47298201	Bayer Healthcare	PAY	
810.3300	Pesticide Use-Product Performance (Efficacy)	48240118	Bayer Healthcare	PAY	
86-1	Domestic Animal Safety	43679501	Bayer Healthcare	OLD	
86-1	Domestic Animal Safety	43679502	Bayer Healthcare	OLD	

Signature	Name and Title	Date
	David Jones/Manager Regulatory Affairs	07/11/2014

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DATA MATRIX

Date 7/11/2014	EPA Reg No./File Symbol 2596-RIR	Page 4 of 4
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
86-1	Domestic Animal Safety	44157302	Bayer Healthcare	OLD	
870.7200	Companion Animal Safety	45097001	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47089404	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47089405	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47089406	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety	47924801	Bayer Healthcare	PAY	

Signature	Name and Title	Date
	David Jones/Manager Regulatory Affairs	07/11/2014

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PROPOSED CAT DATA MATRIX CASS AND EFFICACY CITATIONS
July 11, 2014

MRID	Title	Guideline No.	Study Type	DER conclusion	Subm Date	DT Site	DT Pest	Misc.
43679501	Shmidl, J.; Arther, R. (1995) Acute Toxicity Evaluation for Dermal Treatment of Cats with Imidacloprid (Bay t 7391) Spot-On: Lab Project Number: TR-94D-010: 74579. Unpublished study prepared by Miles Inc. Animal Health DeSoto Research Facility. 19 p.	86-1	Domestic Animal Safety	This acute dermal study is classified as Acceptable when combined with another study (see below). ... However, when data are combined with the companion study in the cat (MRID 43679502), the information is considered useful. This satisfies the requirements for a domestic animal study in the cat.	6/7/1995	Laboratory Mammals	NA	11556-116; 11556-118
43679502	Shmidl, J.; Arther, R. (1995) General Safety Evaluation for Topical Use of Imidacloprid (Bay t 7391) Spot-On On Cats: Lab Project Number: TR-95F-006: 74591. Unpublished study prepared by Bayer Corp. DeSoto Research Facility. 41 p.	86-1	Domestic Animal Safety Study	See 43679501 above. When both cited, meets cat CASS data requirement.	6/7/1995	Laboratory Mammals	NA	11556-116; 11556-118
44157302	Shmidl, J.; Arther, R. (1996) General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Kittens Eight Weeks of Age: Lab Project Number: 74747: TR-96F-006: 10332. Unpublished study prepared by Bayer Corp., DeSoto Research Facility. 45 p. Relates to L0000102.	86-1	Domestic Animal Safety Study	The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.	11/12/1996	8 wk old kittens	NA	9.1% Imid.
45097001	Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, Adult Cats: Lab Project Number: 75122. Unpublished study prepared by Bayer Corporation. 139 p. {OPPTS 870.7200}	870.7200	Domestic Animal Safety Study	Toxicologically similar to MRID 47924801 which was deemed acceptable, see that entry elsewhere in this table	4/12/2000	Cats	NA	
47089401	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75120, 150/851. Unpublished study prepared by Mobay Corp. and Bayer Corp. and Charles River Laboratories, Inc. 162 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089402	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot-on Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75120/1, 150/851. Unpublished study prepared by Mobay Corp. and Bayer Corp. and Charles River Laboratories, Inc. 8 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089403	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.45% Pyriproxyfen Spot-on with 5.0% Water Blank Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75190, 150/828. Unpublished study prepared by Mobay Corp. and Midwest Research Institute and Charles River Laboratories, Inc. 167 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129

PROPOSED CAT DATA MATRIX CASS AND EFFICACY CITATIONS
July 11, 2014

MRID	Title	Guideline No.	Study Type	DER conclusion	Subm Date	DT Site	DT Pest	Misc.
47089404	Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.46 (W/W)% Pyriproxyfen Spot-on with 4.6% Water Blank Formulation at Three Times the Use Rate Volume in the Target Species, 8-Week Old Kittens.. Project Number: 75191/1, 150/937. Unpublished study prepared by Mobay Corp. and Bayer Corp. 8 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089405	Abraham, A. (2000) Evaluation of the General Safety of 9.1% Imidacloprid with 0.46% (W/W) % Pyriproxyfen Spot-on with 4.6% (W/W) Water Blank Formulation at Three Times the Use Rate Volume in the Target Species, 8-Week Old Kittens.. Project Number: 75191, 150/937. Unpublished study prepared by Mobay Corp. and Bayer Corp. 135 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47089406	Abraham, A. (2001) Evaluation of the General Safety of 9.1% Imidacloprid with 0.45% Pyriproxyfen Spot-on with 5.0% Water Blank Formulation in the Target Species, 8-Week Old Kittens. Project Number: 75190/1, 150/828. Unpublished study prepared by Mobay Corp. and Midwest Research Institute and Charles River Laboratories, Inc. 8 p.	870.7200	CASS		3/9/2007	8 week old kittens	NA	Support for 11556-126 and 11556-129
47924801	Madsen, T. (2009) Evaluation of the General Safety of M880. Project Number: 152/141, S07648, 33714. Unpublished study prepared by Sinclair Research Center, Inc. 193 p.	870.7200	CASS	This companion animal safety study in male and female domestic shorthair kittens is acceptable/guideline and does satisfy the guideline requirement for a companion animal safety study (OPPTS 870.7200) in 54 - 57 day (8 week) kittens.	12/3/2009	8 wk old kittens	NA	11556-150

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

7/10/2014

David Jones
Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094

Subject: Data Deficiency

Product Names:	Hartz Reference #146 and Hartz Reference # 148
EPA File Symbols:	2596-RIR and 2596-RIG
OPP Decision Numbers:	486442 and 486510
Application Dates:	1/18/2014
EPA Receipt Dates:	12/23/2013
PRIA Due Date:	10/28/2014

Dear Mr. Jones:

The application referred to above has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process. Therefore, the application is considered deficient. **Labeling/other information as specified below must be submitted to the Agency within 15 days of the date of this letter, before the processing of the application can be continued.**

If, after 75 days, you do not adequately respond, or you subsequently fail to complete the application within the time scheduled for completion noted above, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new application.

Upon receipt of the revised information, the Agency may require additional time to process your application, and you will be requested to consider a new PRIA due date, allowing the Agency to complete the review process.

The deficiency identified in the Agency's review at this time are:

1. Companion Animal Safety – the cited MRIDs (47089401 -47089403) are classified as supplementary as companion animal safety studies (guideline numbers OPPTS 870.7200) as they did not demonstrate an adequate 5x margin of safety. They have never supported any registration of any products.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

For reference purposes, the timelines are as follows:

July 25, 2014: New companion animal safety studies or citations

September 23, 2014: If you have not responded, or you subsequently failed to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn.

Please respond to this letter by **7/25/2014** by contacting Autumn Metzger, metzger.autumn@epa.gov (703-305-5314) or Venus Eagle, eagle.venus@epa.gov (703-308-8045) with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Meredith F. Laws
Chief, Insecticide-Rodenticide Branch
Registration Division

Enclosure:

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

June 5, 2014

MEMORANDUM: HARTZ REFERENCE #146 COMPANION ANIMAL STUDY CITATIONS

Subject:	Name of Pesticide Product:	Hartz Reference #146
	EPA Reg. No. /File Symbol:	2596-RIR
	DP Barcode:	DP 420154
	Decision No.:	486510
	Action Code:	R315.2
	Submission:	#945490
	E-Sub.	-
	PC Code:	129099 (Imidacloprid: 9.1%) 129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
June-5-2014

Ubashi

To: Autumn Metzger/Venus Eagle RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORPORATION

FORMULATION FROM LABEL:

Active Ingredient(s):		by wt.
129099 Imidacloprid		9.10%
129032 Pyriproxyfen		0.46%
Other Ingredients:		90.44%
	TOTAL	100.00%

ACTION REQUESTED: "IDENTICAL SUBMISSION FOR 2596-RIG. BOTH ARE CITING SAME BAYER MRIDS… Please review the CITED MRIDS from Bayer to see if they will cover this new cat spot on…"

BACKGROUND: The material received by TRB includes citations to MRIDs 47089401, 47089402 and 47089403, a data matrix (dated 04/28/2014) which specifically cites these 3 studies (and only these 3 studies) to satisfy the 870.7200 guideline data requirement, a CSF (dated December 1, 2013) for a basic formulation, and a proposed label (indicating use only on cats 8 weeks of age and older with three dose-weight ranges: 0.031 fl. oz. or 0.92 mL for cats weighing 2 to 5 lbs; 0.056 fl. oz. or 1.6 mL for 5 to 9 lbs; and 0.108 fl. oz. or 3.2 mL for over 9 lbs).

COMMENTS AND RECOMMENDATIONS:

1. The cited studies have been previously reviewed by TRB (TXR 5007933, memorandum dated September 6, 2007 for EPA File Symbol 11556-REA).

2. From TXR 5007933 one study (conducted on kittens ranging in age from 7 weeks and 5 days to 8 weeks) consisted of MRID 47089401 with additional information in MRID 47089402. This study was classified as supplementary as a companion animal safety study (OPPTS 870.7200) as it did not demonstrate a 5X margin of safety.

3. From TXR 5007933 the study (conducted on kittens ranging in age from 7 weeks and 6 days to 8 weeks) in MRID 47089403 was also classified as supplementary as a companion animal safety study (OPPTS 870.7200). It did not include testing of the proposed formulation with active ingredients, and it did not demonstrate an adequate 5X margin of safety between the application rate exposure level to the solvent(s) of the proposed product and that which could result in adverse effects in the kittens.

4. Since the studies in MRID 47089401 (with additional material in 47089402) and MRID 47089403 are classified as supplementary, they cannot be used to support the registration of Hartz Reference #146 (EPA File Symbol 2596-RIR), and they cannot be used to support the proposed dose levels and weight ranges.

5. It is noted that EPA File Symbol 11556-REA has never been registered, and the studies in MRIDs 47089401 (additional material in 47089402) and 47089403 have never supported the registration of any product(s).

Metzger, Autumn

From: Metzger, Autumn
Sent: Wednesday, July 09, 2014 3:53 PM
To: 'DJones@hartz.com'
Subject: 2596-RIR and 2596-RIG cat spot ons
Attachments: 2596-RIR Acute Tox memo 6-27-2014.pdf; 2596-RIR companion animal safety memo 6-5-2014.pdf; 2596-RIG Companion animal safety memo 6-5-2014.pdf; 2596-RIG Acute tox review imidacloprid pyriproxyfen spot 6-27-2014.pdf

Mr Jones,

Please find the acute tox and companion animal safety memos for both attached. The CA studies did not pass. You will be receiving a 75 day letter soon (via email).

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good morning,
Thank you for bringing this to my attention. I have attached scans of Statements of Data Confidentiality Claims, signed and paginated to fit into the volume. If I need to modify them, please advise, but it is the same format as previously submitted with conventional data volumes. Always interested in improving my submissions so thank you for any recommendations.
Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

P.S. - I have prepared pages for Hartz Ref. 147 and 148 to insert when needed. They were filed simultaneously. Thanks again.

From: "McVearry, Emily" <McVearry.Emily@epa.gov>
To: "djones@hartz.com" <djones@hartz.com>,
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>
Date: 01/10/2014 08:46 AM
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good morning, Mr. Jones:

This email is to address an issue found in the submitted studies associated with your Amended registration of products Hartz Reference # 145/ Hartz Reference #146:

MRID 492875-09: Volume 9- Supplemental Information

- You must include one of the two acceptable statements of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See page 8 and 13 of the Notice.

MRID 492877-09: Volume 9- Supplemental Information

- You must include one of the two acceptable statements of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See page 8 and 13 of the Notice.

Please verify and send the corrections either by e-mail or through our secure fax line as soon as possible. If you have any questions, please do not hesitate to contact me.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

June 27, 2014

MEMORANDUM: HARTZ REFERENCE #146 (2596-RIR): ACUTE TOXICITY STUDIES

Subject:	Name of Pesticide Product:	Hartz Reference #146
	EPA Reg. No. /File Symbol:	2596-RIR
	DP Barcode:	DP 420153
	Decision No.:	486510
	Action Code:	R315.2
	Submission:	#945490
	E-Sub.	-
	PC Code:	129099 (Imidacloprid: 9.1%) 129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
June-27-2014
M Hasler

To: Autumn Metzger/Venus Eagle RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORPORATION

FORMULATION FROM LABEL:

Active Ingredient(s):		by wt.
129099 Imidacloprid		9.10%
129032 Pyriproxyfen		0.46%
Other Ingredients:		90.44%
	TOTAL	100.00%

ACTION REQUESTED: "…Please review the following MRIDs for the newly submitted cat spot on. Please note that the MRIDs submitted for 2596-RIG are VERY similar but not identical

and the formulations are identical (I think). Please look at them both together to see if there is anything strange about them and why they would submit them this way."

BACKGROUND: The material received by TRB includes a proposed label (dated December 23, 2013), a data matrix (dated 04/28/2014; indicating the acute oral LD_{50}, dermal LD_{50}, primary eye irritation, primary dermal irritation and dermal sensitization studies have been submitted and that there is a waiver request for the inhalation LC_{50} study), a basic CSF (dated December 1, 2013), acute oral LD_{50} (MRID 49287704), dermal LD_{50} (49287705), eye irritation (49287706), skin irritation (49287707), and dermal sensitization (49287708) studies as well as a waiver request (49287709) for the inhalation study.

COMMENTS AND RECOMMENDATIONS:

1. The 5 acute toxicity studies (MRIDs 492877-04 through -08) have been reviewed by TRB and have all been classified as acceptable. Hartz Reference #146 (EPA File Symbol 2596-RIR) is in Toxicity Category III for oral toxicity and eye irritation, Toxicity Category IV for dermal toxicity and skin irritation, and is not a dermal sensitizer.

2. Based on the product use pattern (application of a limited amount directly to cat/kitten skin), TRB concludes that an inhalation study waiver is appropriate with assignment to Toxicity Category IV by this exposure route.

3. The acute toxicity data requirements for the registration of EPA File Symbol 2596-RIR have been satisfied.

4. The following is the acute toxicity profile for Hartz Reference #146 (EPA File Symbol 2596-RIR):

Oral LD_{50} (rat)	Toxicity Category III	Acceptable	MRID 49287704
Dermal LD_{50} (rat)	Toxicity Category IV	Acceptable	MRID 49287705
Inhalation LC_{50}	(Toxicity Category IV)	Waived	
Eye Irritation	Toxicity Category III	Acceptable	MRID 49287706
Dermal Irritation	Toxicity Category IV	Acceptable	MRID 49287707
Skin Sensitization	Non-sensitizer	Acceptable	MRID 49287708

5. Based on the acute toxicity profile, the following is the precautionary and first aid labeling for EPA File Symbol 2596-RIR, as obtained from the Label Review System:

PRODUCT ID #: **002596-00181**

PRODUCT NAME: **HARTZ REFERENCE #146**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

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, using tobacco or using the toilet. Avoid contact with eyes or clothing. [Wear protective eyewear.]* Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

*[Protective eyewear may be specified, if appropriate].

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-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.

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.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

6. Examination of the CSFs of 2596-RIR and 2596-RIG indicates they have the same declaration of active ingredients; however, there is a difference in the inerts/solvents. Although the two formulations have the same acute toxicity profile, 2596-RIG appears to be slightly more toxic by the oral route (LD_{50} = 1650 mg/kg, as compared to 2311 mg/kg for 2596-RIR; in addition, the signs of toxicity following oral dosing at equivalent doses were more pronounced for 2596-RIG). However, 2596-RIG has slightly less eye and skin irritation potential than 2596-RIR (eye irritation: 2596-RIG, corneal opacity clearing by 48 hours and all scores zero at 72 hours, MMTS = 12.3 at 24 hours; 2596-RIR: corneal opacity in 3/3 eyes through 72 hours, with clearing by day 4 and all scores zero by day 7; MMTS = 34.7 and mean score = 22.3 at 24 hours; dermal irritation: 2596-RIG: all scores zero at all times, PDII [Primary Dermal Irritation Index] = 0.00; 2596-RIR: all scores for erythema and edema = 1 at 30-60 minutes, all scores at 14, 48 and 72 hours = 0; PDII = 0.5).

Reviewer: Byron T. Backus, Ph.D.
Date: June 27, 2014
Risk Manager (EPA): 01

The following is the Acute Toxicity Data Evaluation Record (DER) for five acute toxicity studies (MRIDs 492877-04 through -08) and inhalation waiver request (MRID 49287709) submitted for EPA File Symbol 2596-RIR.

1. DP BARCODE: 420153				
2. PC CODES: 129099 (Imidacloprid), 129032 (Pyriproxyfen)				
3. CURRENT DATE: June 27, 2014				
4. TEST MATERIAL: Dermal Treatment TS# 13821; Formula: TS# 13821; Imidacloprid: 9.1%; Nylar [Pyriproxyfen]: 0.46%; other ingredients: 90.44%; described as a light amber liquid; density: 1.144 g/mL (consistent [within 3%] with CSF)				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity (UDP) / rat / Product Safety Labs, Dayton, NJ / Lab Study No. 37571 / November 18, 2013 / OCSPP 870.1100; OECD 425	49287704	Doses: 1040 mg/kg (1 rat); 1650 mg/kg (3 rats); 2600 mg/kg (2 rats). Test material given undiluted. Both rats dosed at 2600 mg/kg died within 1 day of dosing; all others survived. **Oral LD_{50}= 2311 mg/kg** (sigma =0.2). Signs (recovery by day 2): 1040 mg/kg: hypoactivity, irregular respiration & reduced fecal volume; 1650 mg/kg: same as 1040 plus hunched posture. At 2600 prone posture and irregular respiration. All survivors gained wt day 0 to 7 (19-46 g) and day 7 to 14 (2-14 g). Survivors: no gross abnormalities at necropsy. Decedents: extremely distended stomach, moderately distended intestines, mottled liver.	III	A
Acute dermal toxicity / rat / Product Safety Labs, Dayton, NJ / Lab Study No. 37638 / December 2, 2013 / OCSPP 870.1200; OECD 402	49287705	5000 mg undiluted test material/kg applied to 5M & 5F rats, with 24-hr dermal exposure. No mortality or signs of systemic toxicity. **Dermal LD_{50}>5000 mg/kg.** One F had dermal irritation clearing by day 3. All gained weight days 0-7 (M: 9-19 g; F: 3-20 g) and 7-14 (M: 15-35 g; F: 6-18 g). No abnormalities observed at necropsy.	IV	A

Acute inhalation toxicity (waiver request) / OCSPP 870.1300; OECD 403	49287709	Maximum amount of product/dose = 4 mL; low volatility [also use pattern]. Waiver is appropriate.	(IV)	W
Primary eye irritation / rabbit / Product Safety Labs, Dayton, NJ / Lab Study No. 37639 / December 3, 2013 / OCSPP 870.2400; OECD 405	49287706	0.1 mL instilled in right eye of each of 3 rabbits. Corneal opacity in 3/3 through 72 hrs, with clearing by day 4. Iritis observed in 2, with clearing by day 7. Positive conjunctival effects in all 3 through 48 hours. All scores zero on day 7. MMTS = 34.7 at 1 hr.	III	A
Primary dermal irritation / rabbit / Product Safety Labs, Dayton, NJ / Lab Study No. 37640 / December 2, 2013 / OCSPP 870.2500; OECD 404	49287707	Each of 3 rabbits received 4-hr dermal semi-occlusive exposure to 0.5 mL undiluted test material. At 30-60 minutes all scored 1 for erythema and 1 for edema. At 24, 48 & 72 hrs all scores were zero. PDII = 0.50.	IV	A
Dermal sensitization / guinea pig / Product Safety Labs, Dayton, NJ / Lab Study No. 37641 / December 12, 2013 / OCSPP 870.2600; OECD 406	49287708	Buehler Method: 20F guinea pigs received 3 weekly 6-hr induction treatments to 0.4 mL undiluted test material on their left sides. On day 27 they (and a group of 10F previously unexposed controls) were exposed (6 hrs) on right side to 0.4 mL undiluted test material. Following challenge all 20 induced and 10 control animals had scores of zero at 24 & 48 hrs. Positive control (α-hexylcinnamaldehyde) gave appropriate response.	Not a sen-siti-zer	A

n.d. = not determined; Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap

Metzger, Autumn

From: DJones@hartz.com
Sent: Friday, May 09, 2014 2:43 PM
To: Metzger, Autumn
Subject: RE: 2596-RIG and 2596-RIR, 10 day defiency letter: Response from The Hartz Mountain Corporation, updated data matrices

Good afternoon again,
I wanted to let you know I am working on these data matrices and labels. Thank you for the direction. I want to be sure I am supporting all the label claims marketing wants and is prepared to pay the submitter for citing. Also I need to ask you how to submit dog label changes (-RIN and -RIE) I need to insert a page for the larger weight class dogs. When I do that I would like to incorporate the hazard, first aid and other tox reviewer mandated changes to do it all at once. I am working on that. If you have any suggestions on how to best approach that for EPA and Hartz I am open to your thoughts and direction.
I will out Monday, mainly doctors offices, but back Tuesday. I am targeting getting those all back by next Friday.
Thank you for all you have done for us. Hope you enjoy your weekend.
Sincerely,
Dave

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Date: 05/08/2014 12:03 PM
Subject: RE: 2596-RIG and 2596-RIR, 10 day defiency letter: Response from The Hartz Mountain Corporation, updated data matrices

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For your dog products, specifically you need to add the following MRIDS:

44256901

Also, there are no waterproof, or shampoo MRIDs for this product, so if you have those types of claims on the dog labels you will need to remove them or cite for them as well.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Monday, April 28, 2014 3:20 PM
To: Metzger, Autumn
Cc: SMcNear@hartz.com
Subject: Re: 2596-RIG and 2596-RIR, 10 day defiency letter: Response from The Hartz Mountain Corporation, updated data matrices

Good afternoon,
We appreciate the opportunity to submit modified data matrices for the subject applications. Upon further research and discussions, additional MRIDs have been referenced. These added MRIDs were previously submitted by Bayer Healthcare.
Regarding your request to include additional details in regard to the citation on the matrix, I was unable to add them easily. Instead I have attached a summary of the PDMS elements for these MRIDs as a separate attachment. We have strong reason to believe one and all of these efficacy citations have been previously accepted by the agency in support of

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094	2596-RIR
	Product Name Hartz Reference #146
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 12/01/2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid
Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☑ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Imidacloprid	[redacted]	[redacted]
Pyriproxyfen		

Signature	Name and Title	Date
	David Jones/Mgr. Reg. Affairs	05/09/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Metzger, Autumn

From:	DJones@hartz.com
Sent:	Monday, April 28, 2014 3:20 PM
To:	Metzger, Autumn
Cc:	SMcNear@hartz.com
Subject:	Re: 2596-RIG and 2596-RIR, 10 day defiency letter: Response from The Hartz Mountain Corporation, updated data matrices
Attachments:	Data Matrix Hartz Ref 146 2014 Apr 28 signed.pdf; Data Matrix Hartz Ref 148 2014 Apr 28 signed.pdf; MRID sum data matrix Ref 146 and 148 2014 Apr 28.pdf

Good afternoon,
We appreciate the opportunity to submit modified data matrices for the subject applications. Upon further research and discussions, additional MRIDs have been referenced. These added MRIDs were previously submitted by Bayer Healthcare.
Regarding your request to include additional details in regard to the citation on the matrix, I was unable to add them easily. Instead I have attached a summary of the PDMS elements for these MRIDs as a separate attachment. We have strong reason to believe one and all of these efficacy citations have been previously accepted by the agency in support of a currently marketed pesticidal product.
Should you have any questions or if I may provide any further assistance in this review, please contact me.
Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "Djones@hartz.com" <Djones@hartz.com>,
Date: 04/15/2014 07:59 AM
Subject: 2596-RIG and 2596-RIR, 10 day defiency letter

Dear Mr. Jones,

Please see attached.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314
[attachment "2596-RIG and 2596-RIR SIGNED 10 -day defienciency letter from Lois.pdf" deleted by David L. Jones/ML1] [attachment "2596-RIG and 2596-RIR SIGNED efficacy screen not acceptable 3-26-2014.pdf" deleted by David L. Jones/ML1]

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 4/28/2014	EPA Reg No./File Symbol 2596-RIR	Page 1 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identification and Composition	Submitted	The Hartz Mountain Corporation	own	
830.1600	Description of Materials Used to Produce the Product	Submitted	The Hartz Mountain Corporation	own	
830.1620	Description of the Production Process	Submitted	The Hartz Mountain Corporation	own	
830.1650	Description of the Formulation Process	Submitted	The Hartz Mountain Corporation	own	
830.1670	Discussion of Formation of Impurities	Submitted	The Hartz Mountain Corporation	own	
830.7100	Viscosity	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.1750	Certified Limits	Submitted	The Hartz Mountain Corporation	own	
830.1800	Enforcement Analytical Method	Submitted	The Hartz Mountain Corporation	own	
830.6302	Color	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6303	Physical State	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6304	Odor	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6315	Flammability	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6316	Explodability	Waiver Request	The Hartz Mountain Corporation	own	
830.6317	Storage Stability	To be submitted	The Hartz Mountain Corporation	own	In process

Signature	Name and Title	Date
	David Jones/Manager Regulatory Affairs	04/28/2014

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date 4/28/2014	EPA Reg No./File Symbol 2596-RIR	Page 2 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6320	Corrosion Characteristics	To be submitted	The Hartz Mountain Corporation	own	In process
830.6321	Dielectric Breakdown Voltage	Waiver request	The Hartz Mountain Corporation	own	
830.7000	pH	Waiver request	The Hartz Mountain Corporation	own	
830.7300	Density/Relative Density/Bulk Density	Submitted	The Hartz Mountain Corporation	own	Self-Certification
870.1100	Acute Oral Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1200	Acute Dermal Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1300	Acute Inhalation Toxicity	Waiver request	The Hartz Mountain Corporation	own	
870.2400	Acute Eye Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2500	Acute Dermal Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2600	Skin Sensitization	Submitted	The Hartz Mountain Corporation	own	
870.7200	Companion Animal Safety Study	47089401	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089402	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	47089403	Bayer Healthcare	PAY	
Not specified	Pesticide Use-Product Performance (Efficacy)	43679503	Bayer Healthcare	OLD	

Signature	Name and Title	Date
David Jones	David Jones/Manager Regulatory Affairs	04/28/2014

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 4/28/2014	EPA Reg No./File Symbol 2596-RIR	Page 3 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #146 cat	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679504	Bayer Healthcare	OLD	nothing new
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679609 ✓	Bayer Healthcare	OLD	adult fleas on dogs (was bridged)
Not Specified	Pesticide Use-Product Performance (Efficacy)	43679610 ✓	Bayer Healthcare	OLD	adult fleas on dogs (was bridged
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794101 ?	Bayer Healthcare ever reviewed?	OLD	fleas/flea eggs on cat
Not Specified	Pesticide Use-Product Performance (Efficacy)	43794102	Bayer Healthcare	OLD	cat fleas on cats
95-9	Pesticide Use-Product Performance (Efficacy)	44256901 ✓	Bayer Healthcare perfused on dogs	OLD	12 hr speed grey fleas
95-9	Pesticide Use-Product Performance (Efficacy)	44256902 ✓	Bayer Healthcare	OLD	lamadale on dogs on dogs
95-9	Pesticide Use-Product Performance (Efficacy)	44256903 ✓	Bayer Healthcare	OLD	shampoo on
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425101	Bayer Healthcare don't support anything	PAY	
Not Specified	Pesticide Use-Product Performance (Efficacy)	45425102	Bayer Healthcare	PL	
	no Lic = 47190401				
			47109101		
			47298201		
			no water		

Signature David Jones	Name and Title David Jones/Manager Regulatory Affairs	Date 04/28/2014

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

MRID	Title	Guideline No.	Study Type	Subm Date	DT Site	DT Pest	Misc.
43679503	Cunningham, J. (1995) Efficacy Evaluation of Bay t 7391 (Imadacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats: Lab Project Number: MIC 194: 74571. Unpublished study prepared by Agresearch Consultants, Inc. 32 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Cats	Fleas	11556-116; 11556-118
43679504	Cruthers, L. (1995) Efficacy Evaluation of Bay t 7391 (Imadacloprid) 10% Solution Applied Dermally for Control of Fleas on Cats: Lab Project Number: PD-7391-95F-004: 74581. Unpublished study prepared by Professional Laboratory and Research Services, Inc. (PLRS). 46 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Cats	Fleas	11556-116; 11556-118
43679609	Cunningham, J. (1995) Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs: Lab Project Number: 74572. Unpublished study prepared by AgResearch Consultants, Inc. 35 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Dogs	Fleas	11556-116; 11556-118
43679610	Cunningham, J.; Everett, R. (1994) Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs: Lab Project Number: 74541: MID 194. Unpublished study prepared by AgResearch Consultants, Inc. 15 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/7/1995	Dogs	Fleas	11556-116; 11556-118
43794101	Hopkins, T.; Kerwick, C.; Woodley, I. (1995) Efficacy Evaluation of BAY t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Adult Fleas and Flea Eggs on Cats: Lab Project Number: BH036/95: 74634: 95REPORT/AUSTRALI.DOC. Unpublished study prepared by Bayer Australia Ltd. 33 p.	None	Pesticide Use - Product Performance (Efficacy)	9/22/1995	Cat/Pets	Fleas	11556-116; 11556-118
43794102	Leibisch, A. (1995) Controlled Field Trials on the Efficacy and Tolerance of a Spot-On Formulation of Imidacloprid (BAY NTN 33893) 10% for Control of the Cat Flea (C. felis) in Domestic Cats: Lab Project Number: HVS 95-01: 74635: 95REPORT/74635.DOC. Unpublished study prepared by Institute of Parasitology, Hannover Vet School. 7 p.	None	Pesticide Use - Product Performance (Efficacy)	9/22/1995	Cat/Pets	Fleas	DER says data supports amend to 11556-116 and -118
44256901	Cruthers, L. (1997) Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (final Report): Lab Project Number: 74800: PLRS 9665: 150.341. Unpublished study prepared by Professional Laboratory & Research Services, Inc. 51 p.	95-9	Pesticide Use - Product Performance (Efficacy)	4/17/1997	Dogs	Fleas	DER says data supports amend to 11556-116 and -118
44256902	Hopkins, T.; Woodley, I.; Gyr, P. (1997) Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs: (Revised Report): Lab Project Number: 74828: 97REPORT/ARTHER/HOPKINS.DOC. Unpublished study prepared by Bahrs Hill Research Station. 14 p.	95-9	Pesticide Use - Product Performance (Efficacy)	4/17/1997	Dogs	Fleas	DER says data supports amend to 11556-116 and -118
44256903	Cunningham, J. (1997) Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs: Lab Project Number: BD#296: 150.353: BD 296. Unpublished study prepared by AgResearch Consultants, Inc. 27 p.	95-9	Pesticide Use - Product Performance (Efficacy)	4/17/1997	Dogs	Fleas	PDMS lists 11556-116 and 11556-118
45425101	Mehlhorn, H.; Mencke, N.; Hansen, O. (1999) Effects of Imidacloprid on Adult and Larval Stages of the Flea Ctenocephalides felis after In Vivo and In Vitro Application: a Light-and Electron-microscopy Study: Lab Project Number: 75292. Unpublished study prepared by Heinrich-Heine University of Dusseldorf. 17 p.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/6/2001	Indoor dwelling	Fleas	
45425102	Rust, M.; Mencke, N.; Hinkle, N. et al. (2001) The Influence of Imidacloprid on Adult Cat Flea Feeding. Suppl. Compend. Contin. Educ. Pract. Vet 23(4):18-21.	Not Specified	Pesticide Use - Product Performance (Efficacy)	6/6/2001	Indoor dwelling	Fleas	Public literature

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

APR 1 5 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Numbers: 486442, 486510
EPA File Symbols: 2596-RIG, 2596-RIR
Petition Number: n/a
Product Names: Hartz Reference #148, Hartz Reference # 146
EPA Receipt Date: 1/18/2014
EPA Company Number: 2596
Company Name: Hartz Mountain Corporation

David Jones
400 Plaza Drive
Secaucus, New Jersey 07094

Dear Mr. Jones:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

Specifically, the citations provided to address the efficacy data do not support the registration of the subject products.

After screening the efficacy data cited for your pending products it was determined that the study designs are not acceptable or they lack required efficacy standards. Therefore, the efficacy studies cited cannot be used to support your pending new products.

Since these cited studies cannot be used, please cite another product/data set that you feel is similar to your new products or submit the new product specific efficacy data.

In order for the review of your products to continue, you will need to correct your application to address the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Autumn Metzger at metzger.autumn@epa.gov or 703-305-5314.

Sincerely,

Lois Rossi

Lois Rossi
Division Director
Office of Pesticide Programs

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM:

Date: 3/26/14

Subject: PRODUCT PERFORMANCE TECHNICAL REVIEW SCREEN

Reviewer: Autumn Metzger, M.S. 3/26/14

EPA Reg No/EPA File Symbols: 2596-RIG, **Decision** #486442
EPA Reg No/EPA File Symbols: 2596-RIR, **Decision** #486510

Formulation Type: Spot-ons

Ingredients statement from the label with PC codes included:
Imidacloprid, 129099 (9.1%)
Pyriproxyfen 129032 (0.44%)

Application rate(s) of product and each active ingredient:

Imidacloprid	5 lb cat = 10.83 mg/kg	9 lb cat = 10.27 mg/kg
Pyriproxyfen	5 lb cat = 2.2 mg/kg	9 lb cat = 2.2 mg/kg

Background: The above products are applying for registration to kill/control fleas and flea eggs/larvae on cats

Summary of deficiencies:

MRID 43679504 – study for fleas on cats

Does not support any claims due to lack of efficacy.

MRID 45425101 – study on adult & larval fleas

Study design not acceptable to support any pests. Does not support any claims

MRID 45425102 – study on adult fleas

Study design not acceptable to support any pests. Does not support any claims

MRID 43679503 – study on adult fleas

Study design not acceptable as too few test species used in each group. In addition, efficacy was only found at acceptable levels up to day 14 in the 7.5mg/kg dosing.)

Recommendations:
The MRIDs listed above do not support any pests nor claims.

61

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-30-13

Experts In-Processing Signature: B. B. Date 1-7-14 Fee Paid: Yes ✓

Division management contacted on issues No____ Yes ____ Date ____

EPA Reg. Number: 2596-RIR	EPA Receipt Date: 12-30-13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
			X			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	no			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, reduced risk rationale**			X
10	**Required Data and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

*Submitted Studies PASSED PRN 11-3 review
*Inerts not approved - see Inert Status Form
*contacted registrant on 01/10/14 to inform them of inert issues and issues with the submitted studies.
*Both studies that were submitted were missing signatures on Confidentiality Sheet.
* 1/10/14, registrant submitted corrections for submitted studies
* Inert issues were not resolved
* 1/14/14, registrant informed me they needed more time with the corrections. I instructed registrant to forward all future correspondence to PM.
* Jacket failed

SM

MRID: 492877

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUSUS, NJ 07094

RE: Application for Registration dated: 30-Dec-2013
Date Fee Payment: 23-Dec-2013
Product Name: Hartz Reference # 146
EPA Registration Number: 2596-RIR
Decision Number: D-486510

Dear Registrant:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f)(4)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected.

Specifically, the following items were missing or improperly formatted:

Inert Issues
Inert issues were not resolved.

MRID 492877-09: Volume 9- Supplemental Information
You must include one of the two acceptable statements of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See page 8 and 13 of the Notice.

In addition, registrant was contacted on 01/10/2014 to inform them of deficiencies with application and accompanying submitted studies. The registrant emailed corrections for the accompanying studies, but they needed more time to correct the inert issues.

Furthermore, pursuant to FIFRA Section 33(b)(2)(G) the Agency must retain 25% of the registration service fee. Any future submissions to the Agency will be considered a new application and subject to the full registration service fee and another initial contents screen of all necessary fees, forms, data, and draft labeling.

If you have questions, please contact Steve Schaible (703-308-9362; schaible.stephen@epa.gov).

Sincerely,

XXXXXXXX, Director
Office of Pesticide Programs

DRAFT

McVearry, Emily

From: McVearry, Emily
Sent: Wednesday, January 15, 2014 8:40 AM
To: 'DJones@hartz.com'
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good Morning, Mr. Jones:

Please forward any future correspondence to the appropriate product manager, and be sure to include Stephen Schaible (schiable.stephen@epa.gov) to that correspondence as well.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: McVearry, Emily
Sent: Friday, January 10, 2014 10:09 AM
To: 'DJones@hartz.com'
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good morning,

Thank you for sending your corrections. They look great! I will insert the corrections to ensure the studies pass the preliminary screen.

Best regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, January 10, 2014 9:29 AM
To: McVearry, Emily

Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: McVearry, Emily
Sent: Friday, January 10, 2014 7:19 AM
To: 'djones@hartz.com'
Cc: Ashe, Anthony
Subject: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good Morning, Mr. Jones:

This e-mail is to address an inert issue with your application for registration of products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# : 2596-RIN/ 2596-RIR):

Please review the attached document "Inert Clearance Status Form" for more detail.

Please verify and send the corrections either by e-mail or through our secure fax line. I will need the corrections by Wednesday, January 15th at 11am EST. If you have any questions, please do not hesitate to contact me.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

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

January 7, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-486510
EPA File Symbol or Registration Number: 2596-RIR
Product Name: HARTZ REFERENCE # 146
EPA Receipt Date: 30-Dec-2013
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315
NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;ACTION ASSOCIATED WITH ANOTHER PRIA ACTION

The fee for this secondary action is $5,048 (for more information please see http://www.epa.gov/pesticides/fees/new-products-table.pdf). The Agency has received payment in the amount of $8,400. A refund in the amount of $3,353 will be sent to you when this action is completed. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{9454901~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 1

Receipt No.	S- 945490
EPA File Symbol/Reg. No.	2596-RIR
Pin-Punch Date:	12/30/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R315

Granted: R315, 2

Amount Due: $ 5048

Parent/Child Decisions:

2596-RIN

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Steve Schaible Date: 1/2/14

Remarks: shares PC, acute tox w/ RIN
cites some EAS, efficacy studies as - RIG

Receipt for Section 3

S: 945490 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

Print Letter

Enter More Information

Tracking

Company: 2596 THE HARTZ MOUNTAIN CORPORATION

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2596-RIR Product Name: HARTZ REFERENCE # 146

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 23-Dec-2013 OPP Rec'vd Date: 30-Dec-2013

Front End Date: 30-Dec-2013 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: New Ingredient:

Receipt Description:

NEW PRODUCT REGISTRATION

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Receipt Content

Study

CSF

View/Edit

Hartz

THE HARTZ MC .AIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

No. 326831

DATE: 19-DEC-13 VENDOR NAME: US ENVIRONMENTAL PROTEC VENDOR NO: 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
Code R315	02-DEC-13	1000086087 P- Pest Reg PSF	0.00	8,400.00
			0.00	8,400.00

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT. Thank You!

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK ICON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK.

Hartz
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS NJ, 07094

Bank of America
64-1278
611 GA

No. 326831

CHECK DATE	CHECK NUMBER	CHECK AMOUNT
19-DEC-13	326831	******8,400.00

PAY Eight Thousand Four Hundred Dollars And 00 Cents**********

TO THE ORDER OF
US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE REGISTRATION SERVICE FEE
PO BOX 979031
ST LOUIS, MO 63197-9000

By DRL

By

*Commercial/financial information may be entitled to confidential
t t t*

⑈326831⑈ [redacted]

LIST OF DATA SUBMITTERS SENT OFFER-TO-PAY LETTERS

Application for Hartz Reference #146

Spot On Data for Products with:

Imidacloprid (Case #7605) 0.91%
Pyriproxyfen (Case #7424) 0.46%

Selective Citation Method – Only one data owner

EPA Company No. 11556
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
ATTN: DR. BRUCE MARTIN
PO BOX 390
SHAWNEE MISSION, KS 66201

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-	2. EPA Product Manager V. Eagle	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) HARTZ Reference #146	PM# 1	
5. Name and Address of Applicant *(Include ZIP Code)* The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 [ ] *Check if this is a new address*	6. ~~Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:~~ ~~EPA Reg. No.~~ ~~Product Name~~	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

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

New product registration. Formula and acute toxicity data identical to Hartz Reference 145 submitted simultaneously.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[X] Yes [ ] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. 2 to 9 g; No. per container 1 to 10	If "Yes" Package wgt; No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1 to 10 tubes	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [X] Other Printed

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
David Jones	Mgr. Regulatory Affairs	201.271.4800

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title Manager Regulatory Affairs
4. Typed Name David Jones	5. Date Dec. 23, 2013

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Hartz

49287700

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

December 23, 2013

FedEx Delivery

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

Re: New Pesticide Product Application, Hartz Reference #146

Dear Sir/Madam,

Enclosed please find a pesticide registration application package for Hartz Reference #146. Included after the Transmittal Document are the usual and customary support materials. Hartz would like to point out that the toxicology reports are identical for the Hartz Reference #s 145 and 146 to help the Agency avoid duplicate reviews.

Enclosed is a check payable to the US Environmental Protection Agency in the amount of $8400. This is to cover the PRIA Code R315.

Direct contact by phone or e-mail is welcomed if I can assist in the processing of information presented in this package.

Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
(201) 271-4800, ext. 7414
djones@hartz.com

Encl.

TRANSMITTAL DOCUMENT

Submitter:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Company Contact: _____

Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

Regulatory Action in Support of Which This Package is Submitted:

EPA Reg. No. 2596-___; HARTZ Reference #146; PRIA Code R315; $8400

New product application. Acute toxicology data and chemistry data are included in package. Data matrix: Selective Citations.

Submission Date:

12/23/2013

List of Submitted Documents:

Cover letter

Application Form

Confidential Statement of Formula (2 copies)

Formulator's Exemption Statement

Certification with Respect to Data with list

Data Matrix

Data Matrix, confidential public copy

TRANSMITTAL DOCUMENT

Proposed Label Text (Five copies)

PRIA Fee, Check No. for $8400.00

49287701 Volume 1 – Product Chemistry with Self-Certification

49287702 Volume 2 – Product Chemistry, Confidential Sections

49287703 Volume 3 – Product Chemistry Enforcement Analytical Method

49287704 Volume 4 – Acute Oral Toxicity

49287705 Volume 5 – Acute Dermal Toxicity

49287706 Volume 6 – Primary Eye Irritation

49287707 Volume 7 – Primary Skin Irritation

49287708 Volume 8 – Dermal Sensitization Study

49287709 Volume 9 – Data Waiver Requests

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201) 271-4800	EPA Registration Number/File Symbol 2596-
Active Ingredient(s) and/or representative test compound(s) Imidacloprid and Pyriproxyfen	Date Dec. 23, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor Use	Product Name Hartz Reference #146

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
	Dec. 23, 2013	David Jones/Mgr. Regulatory Affairs

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Pages 80-81-*Confidential Statements of Formula may be entitled to confidential treatment*