

2382-190

3/14/2012

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**NOTIFICATION**

**MAR 14 2012**

Virbac Animal Health, Inc.  
c/o Jim Barron, Ph.D.  
1150 Connecticut Ave, NW  
Suite 1100  
Washington, DC 20036

Subject: **Notification:** Company change of Amitraz Technical product  
Amitraz Solid  
EPA Reg. No. 2382-190  
Your submission dated: February 17, 2012

Dear Dr. Barron:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 2-17-12 for the product EPA Reg No. 2382-190. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The Confidential Statement of Formula (CSF) and label submitted with the application have been stamped "Notification" and will be placed in our records.

It is also noted that the labeling for the First Aid and Precautionary Statements have been updated on this label as allowed in the Registration letter dated October 26, 2006 and is acceptable.

If you have any questions, please contact me @ 703-305-5314 or Metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Autumn Metzger", written over the word "Sincerely,".

Autumn Metzger  
Biologist  
Insecticide-Rodenticide Branch  
Office of Pesticide Programs



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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Virbac Animal Health; 2382-190	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Amitraz Solid	PM# 7	
5. Name and Address of Applicant (Include ZIP Code)  Virbac Animal Health 3200 Meacham Blvd. Ft. Worth, TX 76137  <input type="checkbox"/> 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 _____	

**NOTIFICATION**  
**MAR 14 2012**

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: TGA1 source change under PR-98-1; See cover letter.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container
				<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Fl Oz		5. Location of Label Directions <input type="checkbox"/> On Can <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other Shrink wrap label <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jim Barron	Title Regulatory Agent for Virbac Animal Health	Telephone No. (Include Area Code) 919 228-6479

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 BY: <i>Jim Barron</i>	3. Title Regulatory Agent for Virbac Animal Health
4. Typed Name: Jim Barron	5. Date: February 17, 2012



Exponent®

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facsimile 202-772-4979  
www.exponent.com

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February 17, 2012

John Hebert, PM Team 07  
Document Processing Desk  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Amitraz Solid; EPA Reg. No. 2382-190; Notification of Company Name change under PR-98-10; Amended Label and CSF.

Dear John:

Virbac Animal Health recently acquired the technical amitraz registration previously held by Ft. Dodge/ Pfizer Animal Health under EPA Reg. No. 80490-1. The EPA Reg. No. for the transferred Virbac product is 2382-190, as reflected in the attached Agency letter.

Virbac Animal Health is submitting, under PR-98-10, the attached Confidential Statement of Formula (CSF) and the attached Master Label for this product both reflecting the Company name change from Pfizer Animal Health to Virbac.

Note also that the attached label has been amended according to the Agency's 10/26/2006 letter to Pfizer Animal Health granting that registration.

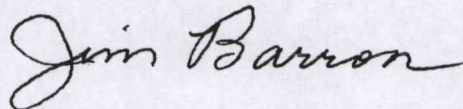
"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."



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facsimile 202-772-4979  
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If you have any questions or need additional information regarding this registration application, please do not hesitate to contact me at (919) 228-6479 or 919 534-6018. I am reachable also via email at [jbarron@exponent.com](mailto:jbarron@exponent.com).

Sincerely,



Jim Barron, Ph.D.  
Regulatory Agent for Virbac Animal Health

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# Amitraz Solid

For Manufacturing Use Only

**NOTIFICATION**  
**MAR 14 2012**

**ACTIVE INGREDIENT:**

Amitraz: N'(2,4-dimethylphenyl)-N-[[[(2,3-dimethylphenyl)imino]methyl]-  
N-methylmethanimidamide; (CAS # 33089-61-1).....98.00%

**OTHER INGREDIENTS:**.....2.00%

**TOTAL:**.....100.00%

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

**FIRST AID**

If swallowed:	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
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**HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-345-4735 for emergency medical treatment information.

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**CAUTION**

Harmful if swallowed. Wash hands thoroughly with soap and water after handling and before eating, ~~drinking~~, chewing gum, or using tobacco.

**Manufactured For:**  
Virbac Animal Health  
3200 Meacham Blvd  
Ft. Worth, TX 76137

**EPA Reg. No. 2382-190**  
**EPA Est. No.**

**Net Weight:**  
C C C C C C  
C C C C C C  
C C C C C C  
C C C C C C  
C C C C C C  
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**ENVIRONMENTAL HAZARDS**

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



### DIRECTIONS FOR USE

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

This pesticide may be used only for formulation into an insecticide for the following: (1) use on domestic animals (indoor residential use); (2) Use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s); and (3) Uses for experimental purposes that are in compliance with USEPA requirements.

### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store in original container, tightly closed and in a dry place.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

### LIMITED WARRANTY AND DISCLAIMER

Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond control of the seller, no guarantee, express or implied, is made as to the effects of such use or the results to be obtained if not used in accordance with printed directions and established safe practice. Buyer's exclusive remedy and seller's exclusive liability for any and all claims, losses, damages or injuries resulting from the use or handling of this product, whether or not based in contract, negligence, strict liability in tort or otherwise shall be limited, at the seller's option to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed.

Master Label Submitted under Notification 2-17-2012.

