

71711-16

11/28/2008

1/7



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 28 2008

Ms. Shannon Yanocha
Nichino America, Inc.
Linden Park, Suite 501
4550 New Linden Hill Road
Wilmington, DE 19808

Dear Ms. Yanocha:

The Agency is in receipt of the following Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10:

<u>Product</u>	<u>CSF</u>	<u>Label</u>
EPA Reg No 71711-16 <i>Buprofezin Technical</i>	Alternate, October 6, 2008	Proposed

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) submitted with the application is considered "acceptable" and has been placed in our records.

The label submitted with the application has been stamped "Notification" and placed in our records. Please note that a "Final Printed Label" must be submitted to the Product Management (PM) Team.

If you have any questions, please call me directly at 703-305-6249 or Maria I. Rodriguez of my staff at 703-305-6710.

Sincerely,
Theresa A. Howe for

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 71711-16	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Buprofezin Technical	PM# 18	
5. Name and Address of Applicant (Include ZIP Code) Nichino America, Inc. 4550 New Linden Hill Rd., Suite 501 Wilmington, DE 19808 <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. <u>NOTIFICATION</u> Product Name <u>NOV 28 2008</u>

Section - II

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

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

Final printed labeling for the Nichino America Inc. Buprofezin Technical label (EPA Reg. No. 71711-16), correcting the EPA Establishment Number. The correct establishment number is also reflected in the revised CSF, dated 10/6/08, via Notification.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. <u>20kg bag</u>	No. per container <u>5</u>	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <u>100kg drum</u>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Shannon Yanocha	Title Registration Specialist	Telephone No. (Include Area Code) 302-636-4001
2. Signature 		6. Date Application Received (Stamped)
3. Title Registration Specialist		
4. Typed Name Shannon Yanocha		
5. Date <u>10/4/08</u>		

D 401575
S 838374

71711-16

3/7

Nichino America, Inc.

Linden Park, Suite 501
4550 New Linden Hill Road
Wilmington, DE 19808
Tel: 302-636-9001 Fax: 302-636-9122

ALT
+ Label

Sent Via FEDEX

October 9, 2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

RE: Notification of Alternate Confidential Statement of Formula and Change in EPA Establishment Number Per PR Notice 98-10: Buprofezin Technical (EPA Reg. No. 71711-16)

To Whom It May Concern:


Nichino America, Inc. hereby submits a notification for an alternate source for the manufacture of Buprofezin Technical. The Confidential Statement of Formula has been revised to reflect the alternate source and the label has been revised to reflect the corresponding EPA Establishment number. The process for the technical is the same as on file with the EPA. The alternate source is registered for the same uses for which the formulated product is registered and it is similar to the current source. The label has also been updated to reflect the comprehensive list of crops previously approved for use by the Agency.

To support this action, included are the following:

- EPA Form 8570-1
- Two (2) copies of labeling, one highlighting changes (identified as bup16d 100908)
- Two (2) copies of the CSF with new producer, dated 10/6/08
- One (1) copy of the CSF on file, dated January 9, 2008
- PR Notice 98-10 Certification Statement

If you have any questions, you are welcome to call me at (302) 636-9001, extension 227 or email me at syanocha@nichino.net.

Sincerely,



Shannon Yanocha
Registration Specialist

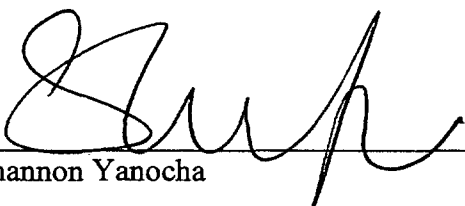
71711-16 4/7

CERTIFICATION STATEMENT

**NOTIFICATION OF REVISIONS TO THE LABEL AND
CONFIDENTIAL STATEMENT OF FORMULA
PER PR NOTICE 98-10**

**Nichino America, Inc. Buprofezin Technical
(EPA Reg. No. 71711-16)**

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.


Shannon Yanocha

Registration Specialist
Title

10/6/08
Date

NICHINO AMERICA, INC.

#Submitted
under
10/9/08.
MDR.

71711-16

5/7

Buprofezin Technical
BUP16d-100908
Page 1 of 3

BUPROFEZIN TECHNICAL

For Manufacturing or Formulating Use Only

Active Ingredient:

Buprofezin: 2-~~tert~~-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one 99.1%

Other Ingredients: 0.9 %

TOTAL **100.0%**

Contains 0.70 lbs. buprofezin per pound of product

EPA Reg. No. 71711-16

EPA Est. No. 67017- JPN- 005 ✓

NOTIFICATION

NOV 28 2008

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

If inhaled	<ul style="list-style-type: none">• Move person to fresh air• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to-mouth, if possible• Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call 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 the poison control center or doctor.• Do not give anything by mouth to an unconscious person.

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 1-800-348-5832 for emergency medical treatment information. In case of fire or spills, information may be obtained by calling 1-800-424-9300.

NOTE TO PHYSICIAN: There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. For product information use internet website www.nichino.net

Active Ingredient Made in Japan for
Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808
www.nichino.net

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals**CAUTION**

Harmful if swallowed. Wash thoroughly with soap and water after handling. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Harmful if inhaled. Avoid breathing spray mist. Remove contaminated clothing and wash before reuse.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

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

IMPORTANT-Read the entire Directions for Use and Disclaimer of Warranties before using this product.

DIRECTIONS FOR USE

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

Only for formulation into a insecticide, for:

- Verified w/ Richard Hebl*
- (1) Almonds, Pistachios; Bananas; Citrus (crop group 10); Cotton; Cucurbits (crop group 9); Fruiting Vegetables; Grapes; Leafy Vegetables (except brassica); Low-Growing Berries (subgroup 13-07G); Olives; Pome Fruit (crop group 11); Snap Beans, Stone Fruit (crop group 12);

Acerola, atemoya, avocado, biriba, black sapote, canistel, cherimoya, custard apple, feijoa, guava, ilama, jaboticaba, longan, lychee, mamey sapote, mango, papaya, passion fruit, pulasan, rambutan, sapodilla, soursop, Spanish lime star apple, starfruit, sugar apple, and wax jambu

Ornamentals (greenhouse and outdoor)

- (2) This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

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

STORAGE: Store in original container, unopened, in a cool, dry place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may 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 particles. Then dispose of empty container in a sanitary landfill, or by incineration, or, if allowed by State or local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

By using this product, user or buyer accepts the following conditions, warranty, disclaimer of warranties and limitations of liability.

CONDITIONS: The directions for use of this product are believed to be accurate and should be followed carefully. However, because of extreme weather and soil conditions, use methods and other factors beyond the control of Nichino America, Inc. (NAI), it is impossible for NAI to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. All such risks are assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, WHICH EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of NAI is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. NAI disclaims any liability whatsoever for incidental or consequential damages, including, but not limited to, liability arising out of breach of contract, express or implied warranty (including warranties of merchantability and fitness for a particular purpose), tort, negligence, strict liability or otherwise.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.

bup16d

100908

Via
NOTIFICATION
DZ