

71711-8

11-28-2008

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 28 2008

Ms. Marie A. Maks
Nichino America, Inc.
Linden Park, Suite 501
4550 New Linden Hill Road
Wilmington, DE 19808

Dear Ms. Maks:

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 71711-6 <i>ET-751 Technical</i>	Alternate, August 7, 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 María I. Rodríguez of my staff at 703-305-6710.

Sincerely,

A handwritten signature in cursive script that reads "Theresa A. Stone for".

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

<p>United States Environmental Protection Agency Washington, DC 20460</p>		Registration	OPP Identifier Number
		Amendment	
	<input checked="" type="checkbox"/>	Other	

Application for Pesticide - Section I

1. Company/Product Number 71711-6	2. EPA Product Manager Joanne Miller	3. Proposed Classification
4. Company/Product (Name) ET-751 Technical	PM# 23	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include Zip Code) Nichino America Inc. 4550 New Linden Hill Road 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. NOTIFICATION Product Name NOV 28 2008	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input 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: NOTIFICATION; Submit revised CSF with change in establishment name and number on label and CSF
Attachments: 2 copies of the label and CSF, "Certification Statement", "Formulator's Exemption Statement", letter M.A. Maks to Notification, dated August 5, 2008

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. container 50 kg	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Package wgt container	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
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*** Certification must be submitted**

3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container	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 type="checkbox"/> Lithograph <input type="checkbox"/> Other ___ adhesive backed label ___ <input checked="" 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 Marie A. Maks	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (302) 636-3001 Ext. 203
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Certification		6. Date Application Received (Stamped)
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.	2. Signature 	
4. Typed Name Marie A. Maks	3. Title Senior Manager, Regulatory Affairs	
5. Date 		

Certification Statement

**NOTIFICATION OF ESTABLISHMENT CHANGE
PER PR NOTICE 98-10**

**Nichino America, Inc. Pyraflufen-Ethyl Technical
(EPA Reg. No. 71711-6)**

“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 the 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.”

Marie A. Maks

Marie A. Maks

Senior Manager Reg Aff

Title

August 5, 2008

Date

CSF (ALT)
+ Label

Sent Via FEDEX

August 7, 2008

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

RE: Submission of a Notification Per PR Notice 98-10 Product Chemistry
Section III. A. With Change in Establishment for Technical
Nichino America, Inc. ET-751 Technical
(EPA Reg No. 71711-6)

To Whom It May Concern:

Nichino America, Inc. requests the EPA to review the application for a new establishment number for the manufacture of ET Technical as a notification. 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 new establishment number reflects another toll-manufacturer for the technical that is owned Nihon Nohyaku Co., Ltd. The process for the technical is the same as on file with the EPA. The only change to the "CSF" was the change in the producer.

Attached are the following:

- Two (2) copies of labeling, identified as ET 6c 080508; one copy has change in establishment highlighted
- Two (2) copies of "Confidential Statement of Formula" with new producer
- "Certification Statement"
- "Formulator's Exemption Statement"

If you have any questions, you are welcome to call me at (302) 636-9001, extension 203 or email me at mmaks@nichino.net. Thank you.

Sincerely,



Marie A. Maks
Senior Manager, Regulatory Affairs
Nichino America, Inc.

August 7, 2008
Submission
MOR

ET-751 Technical

For Manufacturing or Formulating Use Only

Use Pattern: Cotton, Potatoes, Field Corn, Soybeans, Wheat, Noncrop Land and Uncultivated Agricultural Areas, and Noncrop Weed Control

non food producing

Added
Basic

Active Ingredients:

Pyraflufen ethyl (Ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate) 97.9%

97.5 in CSF
fr. ACT

Other Ingredients: 2.1%

Total: 100.0%

EPA Reg. No. 71711-6

EPA Est. No. 067017-JPN-004 ✓

Alternate Brand Name: Pyraflufen-Ethyl Technical

NOTIFICATION

NOV 28 2008

KEEP OUT OF THE 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.	

→ Info on Website removed

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

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

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing 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 to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

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

Only for formulation into a herbicide for:

- (1) The following uses: cotton, potatoes, field corn, soybeans, wheat, noncrop land and uncultivated agricultural areas, and noncrop weed control
non-food products
- (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

Storage: Store in original container and keep closed. Store in a cool, dry place.

Pesticide Disposal: Do not contaminate water, food or feed by storage or 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 to loosen clinging particles. Empty residue into formulation 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 manner required for its liner.

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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.

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NOTIFICATION
JMR

NOTIFICATION

NOV 28 2008