

71711-27

08-01-2011

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Tim Formella  
Nichino America.  
4550 New Linden Hill Road - Suite 501  
Wilmington, DE 19808

AUG - 1 2011

Dear Mr. Formella

Subject: Add New Formulating Uses  
ET-751 40MB  
EPA Registration No. 71711-27  
Your Submissions Dated March 30, 2010 and July 7, 2011

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
2. Submit by April 19, 2012 the following Studies conducted on accordance with the Good Laboratory Practice Standards, 40 CFR Part 160 and appropriate test guidelines as referenced in EPA's Data Requirements for Registration Regulations, 40 CFR Part 158:
  - a. 28-day Inhalation Toxicity Study (OPPTS 875.1300)
  - b. Acute and Subchronic Neurotoxicity Studies (OPPTS 870.6200)
  - c. Immunotoxicity Study (OPPTS 780.7800)
3. Submit by August 6, 2013 the following Studies conducted on accordance with the Good Laboratory Practice Standards, 40 CFR Part 160 and appropriate test guidelines as referenced in EPA's Data Requirements for Registration Regulations, 40 CFR Part 158:
  - a. Information on sample storage conditions and durations for samples analyzed in the Orange Plant Metabolism Study (OPPTS 860.1300)

b. Method validation data for the method development of Metabolite E-9 (PTRL West Study 1837W) should be submitted for confirming its limit of quantification (LOQ). (OPPTS 860.1340)

c. Data are required reflecting recovery of pyraflufen-ethyl and Metabolite E-1 through the FDA Protocols C and D with and without the use of Florisil cleanup. (OPPTS 860.1360)

d. Since Metabolite E-9 should also be included in the tolerance definition for livestock commodities, data will be required reflecting recovery of Metabolite E-9 through the FDA multiresidue methods. (OPPTS 860.1360)

e. No storage stability data were submitted for Metabolite E-9. A storage stability study for Metabolite E-9 in milk and liver under frozen conditions for 3 months is required. (OPPTS 860.1380)

f. A cattle feeding study to be conducted at the 10X dose of 18 ppm is required. (OPPTS 860.1480)

g. Analytical standards for Metabolites E-1 and E-9 must be submitted to the National Pesticide Standards Repository. (OPPTS 860.1650)

4. Submit one (1) copy of your final printed labeling before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Mr. James Stone at 703-305-7391.

Sincerely yours,



Kathryn V. Montague  
Product Manager 23  
Herbicide Branch  
Registration Division (7505P)

Enclosure

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**ET-751 40MB**  
**For Manufacturing or Formulating Use Only**

**Active Ingredients:**

Pyraflufen ethyl (Ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate ..... 40.0%

**Other Ingredients:** ..... 60.0%

**Total:** ..... 100.0%

EPA Reg. No. 71711-27

EPA Est. No. 67017-JPN-004

Alternate Brand Name: Pyraflufen-Ethyl 40MB

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
**AUG - 1 2011**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

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

FIRST AID	
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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.	

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

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

**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.

**Net Contents: 20kg**

Formulated and Packaged in Japan  
**Nichino America, Inc.**  
4550 New Linden Hill Road, Suite 501  
Wilmington, DE 19808  
1-888-740-7700

## 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:

- Bulb Vegetables (Crop Group 3), Cereal Grains (Crop Group 15), Cole Crops (Crop Group 5), Cotton, Cucurbits (Crop Group 9), Dates, Feijoa, Figs, Fruiting Vegetables (Crop Group 8), Grapes, Kiwi Fruit, Leafy Vegetables (Crop Group 4), Legume Vegetables (Crop Group 6), Mango, Oil Seed Crops (Crop Group 20), Olive Trees, Persimmon, Pome Fruit (Crop Group 11), Pomegranates, Root and Tuber Vegetables (Crop Group 1), Soybeans, Stone Fruit (Crop Group 12), Sugarcane, Tree Nuts (Crop Group 14)
- Nonbearing tree fruit, nut trees, and vine crops (excluding citrus)
- Non-cropland, Uncultivated Agricultural Areas, Conservation Reserve Program (CRP) Land/Federal Set-Aside Acreage (nonfood producing)
- Noncrop Weed Control including: airports and airfields, commercial plants, storage and lumber yards, fence lines and fence rows, farmyards and farm buildings, barrier strips and firebreaks, equipment areas, nurseries and ornamental plantings, Christmas trees and conifer plantation site preparation, railroads, roadside and utility rights-of-way, fuel tank farms and pumping stations, dry ditches and ditch banks, vacant lots, and other EPA listed agricultural and industrial non-crop sites
- Established ornamental turf lawns (residential, industrial, and institutional), parks, cemeteries, athletic fields, golf courses (fairways, aprons, tees, and roughs), sod farms, and similar turf areas
- Pasture and rangeland
- Preplant fallow beds and crop stubble

(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.**

**Pesticide Storage:** Store in original container and keep closed. Store in a cool, 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:** Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State or local authorities, by burning. If burned, stay out of smoke.

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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 must 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. To the extent consistent with applicable law, all such risks are assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, 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. To the extent consistent with applicable law, 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:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.

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**Label Code: D-66 070611**