

New York State Department of Environmental Conservation

Division of Solid & Hazardous Materials

Bureau of Pesticides Management

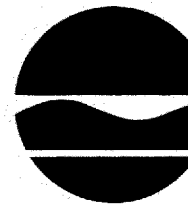
Pesticide Product Registration Section

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Erin M. Crotty
Commissioner

June 25, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Marie A. Maks
Manager, Regulatory Affairs
Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, Delaware 19808

Dear Ms. Maks:

Re: Denial of Application to Register a Major Change in Labeled Use Pattern for Flutolanil Contained in the Pesticide Product Moncut® 70-DF Fungicide (EPA Reg. No. 71711-14)

The New York State Department of Environmental Conservation (Department) has reviewed the information submitted by Nichino America, Inc. (Nichino), on April 27, 2004 in response to the Department's second incompleteness letter, dated March 1, 2004. The registration package for Moncut® 70-DF Fungicide remains incomplete.

Moncut® 70-DF Fungicide (70.0% flutolanil) is a systemic fungicide for use on peanuts, rice, and potatoes. Product is applied to potatoes (in-furrow use only) at the rate of 0.71 - 1.1 lb. per acre for control of Black scurf. The first food crop use of flutolanil (MonCoat MZ™ Potato Seed-Piece Treatment) in New York State was registered on December 19, 2002. The subject application represents a major change in labeled use pattern (MCL) for flutolanil due to the potential for increased exposure to humans and/or the environment resulting from the in-furrow application to potatoes.

In a letter dated December 1, 2003, the Department notified Nichino that the subject MCL application was incomplete. Following review of the information submitted by Nichino on January 7, 2004, the Department issued a second notice of incompleteness on March 1, 2004. The subject action stems from the following review of the information received on April 26, 2004 in response to the Department's second incompleteness letter:

- The registrant still has not complied with the request for United States Environmental Protection Agency (USEPA) Data Evaluation Record reports (DERs) or USEPA reviews for the battery of acute toxicity studies on the formulated product. Instead, Nichino resubmitted the "Acute Tox One-Liners" which do not contain any study details. As indicated in the Department's second

incompleteness letter, the New York State Department of Health does not accept one-liners as an adequate substitute for toxicological information. Moreover, the one-liners resubmitted are for a different product than Moncut 70-DF Fungicide and the registrant did not supply DERs for this product either, even though USEPA stated that they are toxicologically equivalent.

- In response to the Department's request to submit a worker exposure risk assessment for the labeled application of flutolanil to potatoes (in-furrow use only), Nichino submitted a September 2000 occupational risk assessment on flutolanil conducted by the USEPA. However, this risk assessment is not applicable to the subject MCL for flutolanil use on potatoes. Instead, the risk assessment is applicable to the use of this active ingredient for potato seed pieces as used in the pesticide product MonCoat MZTM Potato-Seed Piece Treatment, which was reviewed and registered on December 19, 2002.

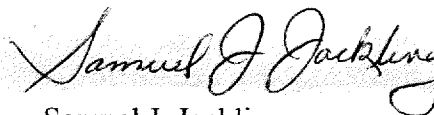
Since the Department is required to operate under legislatively mandated time frames and no pertinent new information has been submitted in response to two incompleteness notices, **the review process has been terminated and the subject MCL application denied due to incompleteness.**

You are reminded that the application fee is nonrefundable. If you wish to reapply, you must submit a new application for registration of a MCL, application fee and application requirements specified in 6 NYCRR Part 326.17. The application should be resubmitted only when the items requested in the Department's incompleteness letters are available.

Please be aware that Moncut[®] 70-DF Fungicide (EPA Reg. No. 71711-14) may not be sold, offered for sale, distributed, or used in New York State.

If you have any questions on this action, please contact me, at (518) 402-8768.

Sincerely,



Samuel J. Jackling

Chief

Pesticide Product Registration Section

Enclosure

cc: w/enc. - N. Kim/D. Luttinger, NYSDOH
W. Smith, Cornell University, PSUR