

# New York State Department of Environmental Conservation

## Division of Solid and Hazardous Materials

Bureau of Pesticides Management, 11th Floor

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June 21, 2005

**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: Registration of a Major Change in Labeled Use Pattern for Flutolanil Contained in the Pesticide Product Moncut<sup>®</sup> 70-DF Fungicide (EPA Reg. No. 71711-14)**

The New York State Department of Environmental Conservation (Department) has completed a technical review of the application (received December 1, 2004) and supporting information submitted in reference to registration of the subject product. Moncut<sup>®</sup> 70-DF Fungicide (EPA Reg. No. 71711-14) contains the active ingredient flutolanil (Chemical Code 128975).

Moncut<sup>®</sup> 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 pounds per acre for control of black scurf (*Rhizoctonia solani*). In-furrow use on potatoes represents a major change in labeled (MCL) use pattern for flutolanil.

**The Department hereby accepts Moncut<sup>®</sup> 70-DF Fungicide (EPA Reg. No. 71711-14) for registration in New York State.** Acceptable labeling bears the following New York State specific use restriction under the the General Information section of the labeling: “**Moncut 70-DF is not for sale, sale into, distribution and or use in Nassau and Suffolk counties of New York State.**” A synopsis of the technical review follows:

The subject application package was deemed complete for purposes of technical review on January 25, 2005. Pursuant to the review time frame specified in Environmental Conservation Law (ECL) §33-0704.2, a registration decision date of June 24, 2005 was established.

Toxicological, ecotoxicity and environmental fate risk assessments were conducted for flutolanil and the Moncut<sup>®</sup> 70-DF Fungicide product.

**TOXICOLOGICAL RISK ASSESSMENT:** On an acute basis, Moncut<sup>®</sup> 70-DF Fungicide was not very toxic to laboratory animals by the oral, dermal or inhalation routes of exposure. This pesticide product also was neither very irritating to the skin or eyes (tested on rabbits) nor did it cause dermal sensitization (tested on guinea pigs).

Toxicological risk assessments were previously conducted for flutolanil in the pesticide products Prostar 50 WP, Prostar 70 WP Fungicide and Contrast 70 WSP Fungicide and MonCoat MZ<sup>™</sup> Potato Seed-Piece Treatment. Flutolanil was not very acutely toxic in laboratory animal studies, did not cause oncogenic effects, and was generally negative in genotoxicity studies (flutolanil was positive in an *in vitro* chromosomal aberration assay in Chinese hamster lung cells). In addition, the reproductive/developmental toxicity studies in rats and rabbits indicate that flutolanil caused neither parental toxicity nor adverse reproductive/developmental effects. The United States Environmental Protection Agency's (USEPA) Office of Pesticide Programs (OPP) established a reference dose (RfD) for flutolanil of 0.87 milligrams per kilogram bodyweight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 87 mg/kg/day from a chronic feeding/oncogenicity study in rats (decreases in bodyweight and bodyweight gain and increases in absolute and relative liver weights) and an uncertainty factor of 100. This RfD has not yet been adopted by the USEPA's Integrated Risk Information System (IRIS), which in 1989 adopted a RfD of 0.06 mg/kg/day based on decreased body weights and body weight gains in a rat multigeneration reproduction study and an uncertainty factor of 1,000 (at that time, USEPA used an additional uncertainty factor of 10 to account for the determination that a NOEL was not identified in that study). The study that formed the basis of the older RfD was later determined to be unacceptable due to inadequate histopathology data and uncertainties in dosing. A current search of the toxicological literature did not find any significant new information on the toxicity of flutolanil.

The USEPA established a tolerance for flutolanil residues in or on potatoes at 0.2 parts per million. The chronic population adjusted dose (cPAD) for flutolanil residues is 0.87 mg/kg/day and has the same basis as the OPP RfD. The USEPA estimated that chronic dietary exposure to these residues would be less than 1.0% of the cPAD for the general U.S. population and 1.0% of the cPAD for infants less than one year old. This chronic exposure analysis is based on the assumption that 100% of the currently registered crops are treated and contain tolerance level residues.

The registrant submitted a risk assessment for dermal and inhalation exposures of workers to flutolanil from in-furrow application to potatoes. For mixers/loaders/applicators, the estimated margins of exposure (MOEs) for dermal and inhalation exposures were about 8,000 and 43,000, respectively. For these estimates, it was assumed that workers wore long-sleeved shirt, long pants, shoes and socks and chemical-resistant gloves as required by the Moncut 70-DF Fungicide product label. An absorption factor of 100% was used for both dermal and inhalation exposures. The NOEL used for estimating the dermal MOE was 1,000 mg/kg/day from a 21-day dermal toxicity study in rats, and the NOEL of 87 mg/kg/day from a rat chronic feeding study was used for calculating the inhalation MOE. Generally, the USEPA considers MOEs of 100-fold or greater to provide adequate worker protection.

There are no chemical specific federal or New York State drinking water/groundwater standards for flutolanil. Based on its chemical structure, flutolanil falls under the 50 microgram per liter general New York State drinking water standards for an “unspecified organic contaminant” (10 NYCRR Part 5, Public Water Systems).

The available information on flutolanil and the formulated product Moncut<sup>®</sup> 70-DF Fungicide indicates that they were not very acutely toxic in laboratory animal studies. Flutolanil also was not very toxic in chronic feeding studies and did not cause any oncogenic or teratogenic effects. In addition, the expected exposures from the labeled use of this active ingredient in the Moncut<sup>®</sup> 70-DF product should not pose a significant risk to workers or the general public.

**ECOTOXICITY RISK ASSESSMENT:** Although screening modeling was conducted for the Moncut<sup>®</sup> 70-DF product, a complete technical assessment document was not produced. Flutolanil was reviewed by the Bureau of Habitat in 1995 for foliar turf use. In that review, adverse nontarget organism impacts were not predicted at higher rate, multiple, soil surface applications. Since the Moncut<sup>®</sup> 70-DF in-furrow potato use poses less potential for nontarget exposure than the turf use pattern, adverse impacts to fish or wildlife resources are unlikely.

**ENVIRONMENTAL FATE RISK ASSESSMENT:** Moncut<sup>®</sup> 70-DF is a dry flowable end-use product containing 70% flutolanil. The maximum application rate is 1.1 lb Moncut<sup>®</sup> 70-DF/acre/year, or 0.77 lb flutolanil/acre/year.

**Hydrolysis:** Flutolanil is stable at pHs 5, 7 and 9.

**Aqueous Photolysis:** Flutolanil degraded slowly, 8% over the 30-day study. No half-life was indicated.

**Soil Photolysis:** This study was found unacceptable, and no useful data was presented.

**Aerobic Soil Metabolism:** Flutolanil had a half-life in sandy loam of 300 days.

**Anaerobic Aquatic Metabolism:** Flutolanil had a half-life of >13 years.

**Adsorption/Desorption:** Flutolanil had adsorption  $K_{oc}$ s of 288 in sand, 293 in loam, 395 in clay loam, and 317 in loamy sand (pH 4.8). Flutolanil had desorption  $K_{oc}$ s of 339 in sand, 375 in loam, 522 in clay loam, and 527 in loamy sand (pH 4.8). Mobility is directly proportional to the pH; the  $K_{oc}$ s increase with decreasing pH.

**Computer Modeling:** LEACHM simulation was run using Riverhead soil, the maximum application rate of 0.77 pounds of flutolanil, a  $K_{oc}$  of 527, and an aerobic half-life of 300 days. The model projected leachate concentrations reaching a maximum of between 1.5 and 2 ppb after five years and persisting at this level over the ten-year modeling cycle.

Flutolanil has a low  $K_{oc}$ , a very long half-life and the in-furrow method of application ensures that all product is available for leaching. Even though the mobility of this product decreases with decreasing pH (Long Island sands tend to have slightly acidic pHs), LEACHM

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modeling projects that flutolanil will leach into groundwater of the sandy soils on Long Island when Moncut<sup>®</sup> 70-DF is used as labeled.

**DISCUSSION:** Flutolanil's environmental fate and expression data and the Department's leaching simulations indicate that labeled use of Moncut<sup>®</sup> 70-DF Fungicide has the potential to adversely impact groundwater/drinking water resources in New York State. Of particular concern are groundwater resources on Long Island, where sandy soils and shallow depth to groundwater are prevalent.

Nichino America, Inc., updated the Moncut<sup>®</sup> 70-DF Fungicide federal label to include the following text under the General Information section of the labeling: "**Moncut 70-DF is not for sale, sale into, distribution and or use in Nassau and Suffolk counties of New York State.**" On June 15, 2005, the registrant submitted a copy of the USEPA stamped label (06/10/05) and notification/submission of final printed labeling to USEPA (06/15/05) regarding this labeling change together with updated product labeling for the Department's review.

**REGISTRATION ACTION:** The Department hereby accepts Moncut<sup>®</sup> 70-DF Fungicide (EPA Reg. No. 71711-14) for registration in New York State. Acceptable labeling (identified as 050205 061005 EPA) bears the following New York State specific use restriction under the General Information section of the labeling: "**Moncut 70-DF is not for sale, sale into, distribution and or use in Nassau and Suffolk counties of New York State.**" Enclosed for your files are the Certificate of Pesticide Registration and New York State stamped "ACCEPTED" label.

Please note that a proposal by Nichino America, Inc., or any other registrant to register a product containing flutolanil, whose labeled uses are likely to increase the potential for significant exposure to humans or impact to the environment, would constitute a major change in labeled (MCL) use pattern. Such an application must be accompanied by a new application fee and meet the requirements specified in 6 NYCRR Part 326.17.

Please contact Samuel Jackling, Chief of our Pesticide Product Registration Section, at (518) 402-8768, if you have any questions.

Sincerely,

***Maureen P***

***Serafini***

Maureen P. Serafini  
Director  
Bureau of Pesticides Management

Enclosures

cc: w/enc. - N. Kim/D. Luttinger, NYS Dept. of Health  
R. Zimmerman/R. Mungari, NYS Dept. of Ag. & Markets  
W. Smith, Cornell University, PSUR