

New York State Department of Environmental Conservation  
Division of Solid & Hazardous Materials

Bureau of Pesticides Management

Pesticide Product Registration Section

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January 10, 2006

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ms. Catherine Elmi  
State Regulatory Manager  
Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, Illinois 60173

Dear Ms. Elmi:

Re: **Registration with Conditions of One New Pesticide Product, Pre-Strike Outdoor Fogger (EPA Reg. No. 11715-325-2724), Which Represents a Major Change in Labeling for the Active Ingredient Etofenprox**

The New York State Department of Environmental Conservation (Department) has completed its review of your application, received June 21, 2005, to register the new product **Pre-Strike Outdoor Fogger** (EPA Reg. No. 11715-325-2724) in New York State. The new product adds outdoor uses and represents a major change in labeling for the active ingredient **etofenprox** (chemical code 128965).

Etofenprox is currently registered as an indoor use product to kill cockroaches, ants, fleas, ticks, spiders and other listed insects in homes, apartment buildings, and the nonfood/feed areas of hotels, stores, warehouses, office buildings, schools, nursing homes, hospitals and industrial buildings, and as a "spot-on" application on cats and kittens for the control of fleas, ticks and mosquitoes. The **Pre-Strike Outdoor Fogger** is labeled for control of a variety of insects including mosquitoes, bees and wasps in backyards, patios, picnic areas and outside surfaces of buildings.

The application was deemed complete for purposes of review on August 19, 2005 and a registration decision is due by January 16, 2006.

The Department has reviewed the information supplied to date in support of registration of the new product **Pre-Strike Outdoor Fogger** (EPA Reg. No. 11715-325-2724).

Outdoor Fogger. The Etofenprox Crawling Insect Killer I product contains the active ingredient etofenprox at a concentration two-fold greater than Pre-Strike Outdoor Fogger (1 percent versus 0.5 percent), as well as the other co-active ingredients and similar inerts, and as such appears to be an acceptable surrogate for the Pre-Strike product. On an acute basis, Etofenprox Crawling Insect Killer I was not very toxic to laboratory animals by the oral, dermal or inhalation routes of exposure. This formulated product also was not very irritating to rabbit skin or eyes and it did not cause dermal sensitization (tested on guinea pigs).

The DOH stated that etofenprox was not very toxic nor irritating and did not cause skin sensitization following acute exposures in laboratory animals. Also, etofenprox did not cause any significant neurotoxic (based on DOH review of studies not yet evaluated by United States Environmental Protection Agency (USEPA)), developmental or reproductive effects. However, chronic oral exposures to etofenprox caused several non-cancer effects at relatively low doses. The USEPA Office of Pesticide Programs calculated an oral reference dose (RfD) for etofenprox of 0.037 milligrams per kilogram body weight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 3.7 mg/kg/day in a chronic rat feeding study (increase in thyroid gland weights in male rats) and an uncertainty factor of 100. In addition, this active ingredient caused thyroid tumors in rats exposed over their lifetime. The USEPA classified etofenprox as a Group C, “possible human carcinogen” and derived a cancer potency slope factor for this chemical of  $5.1 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup> for the quantification of risk. A current search of the toxicological literature did not find any significant new information on the toxicity of etofenprox.

The USEPA conducted a risk assessment on the exposure of adults and children to etofenprox from the outdoor fogging use of this product. For adults, the short-term margin-of-exposure (MOE) from inhalation of etofenprox during both handling and post-application activities combined was estimated to be 650 (dermal exposures were not evaluated for non-cancer risks because no dermal endpoints were identified in the 28-day dermal exposure study in rabbits at doses up to the limit dose of 1,000 mg/kg/day). The NOEL used for estimating this MOE was 10.6 mg/kg/day from a 90-day rat inhalation study (increased heart, lung, liver, and kidney weights and decreased red blood cell and hemoglobin levels). Generally, the USEPA considers MOEs of 100-fold or greater to provide adequate protection. The USEPA also calculated an increased lifetime cancer risk of  $1.9 \times 10^{-6}$  for these adults, using the cancer potency slope factor of  $5.1 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup>. This cancer risk “...is within a margin of error that does not exceed HED’s [USEPA’s Health Effects Division] level of concern.” MOEs also were determined for children from post-application exposure (inhalation and ingestion from hand to mouth, object to mouth activity and soil ingestion) to etofenprox. For short-term exposure, using the NOEL of 100 mg/kg/day from a rabbit developmental toxicity study (post-implantation loss and decreased fetal weights), the estimated MOE was 400,000. For intermediate exposure, the MOE was estimated to be 340 using the NOEL of 10.6 mg/kg/day from the 90-day rat inhalation study.

There are no chemical specific federal or New York State drinking water/groundwater standards for etofenprox. Based on its chemical structure, etofenprox falls under the 50 microgram per liter general New York State drinking water standard for “unspecified organic contaminants” (10 NYCRR Part 5, Public Water Systems). Using the USEPA cancer potency slope factor of  $5.1 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup> and 6 NYCRR Part 702.4 procedures for deriving ambient water quality standards and guidelines based on oncogenic effects, the ambient water quality value associated with a one in one million increased lifetime cancer risk is 7 micrograms per liter

Ms. Catherine Elmi

for etofenprox.

The available information on etofenprox and the formulated product Pre-Strike Outdoor Fogger (using Etofenprox Crawling Insect Killer I as a surrogate) indicates that neither the active ingredient nor the formulated product was very acutely toxic, nor did etofenprox cause significant neurotoxic, developmental or reproductive effects. Although etofenprox caused effects at relatively low doses in chronic toxicity studies, the expected exposures from using the Pre-Strike product as well as post-application exposures of adults and children to this chemical should not pose significant non-cancer risks. However, etofenprox caused thyroid tumors in rats and although the estimated risks from application and post-application activities are low, we generally have concerns for pesticides that have carcinogenic potential unless either the needs for the product are significant or it replaces those that pose greater risks.

The DOH compared the toxicological properties of etofenprox to 15 other active ingredients (mostly pyrethroids) that are registered in the state for outdoor fogging use. A brief evaluation of these alternative active ingredients indicates that several (cypermethrin, permethrin and tetramethrin) are also classified as group C carcinogens, and one (propoxur) is classified as a B<sub>2</sub> carcinogen. Also, the two active ingredients for which cancer potency slope factors are available (permethrin and propoxur) have slope factors that indicate a similar or greater potency than that of etofenprox. In addition, all but one of the alternatives (resmethrin) for which there are RfDs (d-trans-allethrin and tetramethrin apparently do not have RfDs), have numerically lower RfDs, suggesting greater toxicity. It is difficult to compare application rates between outdoor fogging use products, but the use pattern and the overall percent active ingredients appear similar between Pre-Strike and a sampling of other outdoor fogging products. This comparison of toxicity and use, though not comprehensive, indicates that there are other active ingredients registered for the same uses that may pose similar or greater risks than those posed by etofenprox. In view of the above information, the DOH does not object to the registration of Pre-Strike Outdoor Fogger in New York State. However, the DOH recommends that this registration be conditional pending the USEPA's review and concurrence with the Department's recent evaluation of the acute, subchronic and developmental neurotoxicity studies on etofenprox.

Even though this is the first outdoor use of etofenprox, the USEPA did not require any environmental fate data to support the registration. The USEPA stated that they did not anticipate any significant environmental exposure from this product based on the active ingredient's stability to hydrolysis and insolubility in water, the small amount of etofenprox in the formulation and the product's limited spot application by homeowners from a 20 ounce pressurized container. Environmental fate data will be required by the USEPA if agricultural or other outdoor uses of etofenprox are proposed.

The Department concludes that Pre-Strike Outdoor Fogger should not have an adverse effect on the health of the general public when used as labeled.

Therefore, the Department hereby **accepts for registration with conditions** the new product **Pre-Strike Outdoor Fogger** (EPA Reg. No. 11715-325-2724). The registration of this product in New York State, as well as all other etofenprox containing products, is dependent upon USEPA's review and concurrence with the Department's evaluation of the acute, subchronic and developmental neurotoxicity studies on etofenprox.

The Certificate of Pesticide Registration and a copy of the New York State stamped "ACCEPTED" labeling for Pre-Strike Outdoor Fogger are enclosed for your records.

Wellmark International is reminded that if New York State registration is requested for this product or for any other product which contains etofenprox with an increased application rate and/or expanded use sites, the product will be considered a **Major Change in Labeling and the Department will require an extensive review.**

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

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, PMEP

cc: w/o enc. - E. David Lewis - Lewis & Harrison