Mr. Michael Zucker  
FMC Corporation - Ag Products Group  
1735 Market Street - Rm. 1977  
Philadelphia, Pennsylvania 19103  

Dear Mr. Zucker:  


The New York State Department of Environmental Conservation (Department) has completed its technical review of the above product application received on May 9, 2006. The application was submitted as a routine product application which would contain active ingredients and use patterns already registered for use in New York State. Acetamiprid is currently registered in New York State for agricultural use, home garden use and commercial nursery uses as an insecticide. However, this application was determined to be a major change in labeled use pattern (MCL) due to the addition of indoor use for control of cockroaches. Nisso America submitted additional information, as required for technical review of the additional use pattern, on May 17, 2006 on behalf of FMC Corporation. The application package and additional information were determined incomplete on July 3, 2006 for lack of a complete set of data evaluation record reports (DERs) for the formulated product. FMC Corporation responded with documentation from the United States Environmental Protection Agency (USEPA) allowing the basic registrant to bridge data from the product Chipco Brand Tristar 70 WSP Insecticide. The Department determined the application to be complete for purposes of technical review on October 4, 2006. 

Transport Roach Bait (EPA Reg. No. 8033-91-279) is labeled for control of pest species of cockroaches including German and Brown-Banded cockroaches or large cockroaches such as American, Smoky-Brown, or Oriental in use sites that include single- and multi-family residential buildings, commercial, industrial, and institutional buildings (including restaurants, supermarkets, offices, hospitals, nursing homes, schools, warehouses, hotels, motels and utilities). The label states that Transport Roach Bait can be used indoors and outdoors as a crack and crevice treatment applied to areas frequented by cockroach pests. Transport Roach Bait can be applied at 1 to 2 - 1/4-inch spots every linear foot or a 1" to 3" bead for moderate infestations and 2 to 4 spots per linear foot or a 3" to 6" bead for severe or heavy infestations. Each 1/4-inch spot is approximately 0.5 grams of gel bait.
Pursuant to the review time frame specified in ECL S33-0704.2, a registration decision date of March 2, 2007 was established. The Department has conducted the following technical review for impacts to human health as a result of potential increased exposure to the active ingredient acetamiprid and the formulated product Transport Roach Bait. The following review summary is provided below.

**Technical Review for Impacts to Human Health:**

The New York State Department of Health (DOH) reviewed the application and supporting data submitted by FMC Corporation to register the pesticide product Transport Roach Bait (EPA Reg. No. 8033-91-279) in New York State. This product contains the active ingredient acetamiprid (\(((E)-N1-[6-chloro-3-pyridyl]-methyl]-N2-cyano-N1-methylacetamidine)\) and is labeled for indoor and outdoor use as a spot and/or crack and crevice treatment to spaces within structures and the immediate adjacent surrounding grounds for control of listed species of cockroaches.

To satisfy the requirement for acute toxicity data (except for acute oral toxicity) on Transport Roach Bait, the registrant submitted data on the formulated product Chipco Brand Tristar 70 WSP Insecticide. The USEPA considered this latter product an acceptable surrogate for Transport Roach Bait since it contains a much higher percentage of the active ingredient acetamiprid (about 200-fold greater) than the Transport product, but is otherwise similar with respect to inert ingredient composition. On an acute basis, the Chipco Brand Tristar product was not very toxic to laboratory animals by either the dermal or inhalation routes of exposure. This formulated product was not very irritating to rabbit skin or eyes and did not cause dermal sensitization (tested on guinea pigs). The acute oral toxicity study that was conducted on Transport Roach Bait showed that this formulated product was not very toxic by this exposure route.

DOH previously reviewed acetamiprid in several formulated products containing this active ingredient including Tristar 70 WSP Insecticide. Acetamiprid overall was not very acutely toxic in laboratory animal studies. Data from chronic and developmental/reproductive studies on acetamiprid showed that this chemical has the potential to cause some toxicity. Based on the weight of evidence from mouse and rat chronic feeding/oncogenicity studies and genotoxicity tests, the USEPA classified acetamiprid as “not likely to be carcinogenic to humans.” Using data from the chronic feeding/oncogenicity study in rats, the USEPA Office of Pesticide Programs calculated a reference dose (RfD) of 0.07 milligrams per kilogram body weight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 7.1 mg/kg/day (reduction in body weight gain and hepatocellular vacuolation) and an uncertainty factor of 100. A current search of the toxicological literature did not find any significant new information on the toxicity of acetamiprid.

The registrant conducted a risk assessment for dermal exposure during the use and handling of Transport Roach Bait. Typically, risk assessments for dermal exposure are not required for those active ingredients that did not cause effects at the limit dose in dermal toxicity studies (acetamiprid did not cause any effects in a 21-day rabbit dermal toxicity study at doses of 1,000 mg/kg/day). Nevertheless, the registrant’s assessment assumed that one-half the surface of the applicator’s hands was covered with the gel and that 30% of acetamiprid was absorbed. The margin of exposure (MOE) was determined by comparing the estimated absorbed dose to a NOEL of 17.9 mg/kg/day from a rat multigeneration reproduction study in which the toxicological effects included a decrease in litter size and pup weights, as well as decreases in
Mr. Michael Zucker

Parental body weights and body weight gains, at a dose level of 51.0 mg/kg/day. The MOE so calculated for dermal contact with acetamiprid in this formulated product was about 1,050. Generally, the USEPA considers MOEs of 100-fold or greater to provide adequate protection.

Inhalation exposure to acetamiprid from application of Transport Roach Bait is expected to be negligible because of acetamiprid’s low vapor pressure (less than 1 x 10^{-8} millimeters mercury at 25 degrees Celsius) and that the formulation is a gel which makes the generation of respirable particles unlikely. For post-application dermal exposures in adults, the registrant estimated a MOE of about 300. This estimate conservatively assumed that one-half the surface area of the hands and forearms was coated with the bait gel, that 30% of the acetamiprid was absorbed and that there were five such events per day. The registrant did not estimate a dermal MOE for a child because of the generally inaccessible placement of the gel bait. However, by adjusting for differences in body weight (70 kg vs. 15 kg) and assuming one-half the dermal surface area of an adult for a child, we estimated a MOE of about 130 for a child.

The available information on acetamiprid and the formulated product Transport Roach Bait indicates that overall they were not very acutely toxic in laboratory animal studies. Although data from chronic and developmental/reproductive studies on acetamiprid showed that this chemical has the potential to cause some toxicity, the expected exposure from the labeled uses of Transport Roach Bait should not pose a significant risk to workers or the general public. While the formulated product is labeled in part for indoor pest control, this use should not significantly impact indoor air since the active ingredient acetamiprid has a low vapor pressure (less than 1 x 10^{-8} millimeters mercury at 25 degrees Celsius) and relatively little is applied per site. In addition, the formulated product does not contain volatile components, and the active ingredient is in a gel matrix. Accidental ingestion of the product by children is unlikely given the application sites (spot, or crack and crevice treatments), and that the formulation contains a bittering agent. Given the above, DOH does not object to the registration of Transport Roach Bait in New York State.

Product Registration Summary:

The Department will register Transport Roach Bait (EPA Reg. No. 8033-91-279) for general use in New York State. However, the statement “Do not spray bait gel” in the “Directions For Use” part of the product label is confusing and may be interpreted as the product is not intended to be applied by spraying. We believe that the intent of this statement is to alert applicators not to apply insecticide sprays to the gel bait. This concept is more clearly stated under “Outdoor Pest Control” section of the label. Therefore, FMC has agreed to replace “Do not spray bait gel” with the statement “Do not apply this product to areas that have been recently sprayed with insecticides, and do not spray insecticides over gel, as it may cause the bait to become repellent.” This label correction will be required on or before renewal of the product on March 31, 2008.

Enclosed for your record, is a copy of the stamped accepted labeling and the Certificate of Registration for Transport Roach Bait (EPA Reg. No. 8033-91-279). Please note that a proposal by FMC Corporation or any other registrant, to register a product that contains acetamiprid, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a MCL. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of “New York State Pesticide Product Registration Procedures” (September 2005). Such information as well as forms can be accessed at our website as listed in our letterhead.
Mr. Michael Zucker

Please be aware that any unregistered product may not be sold, offered for sale, distributed, or used in New York State.

Please contact 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

Enclosure

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