

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

Bureau of Pesticides Management, 11<sup>th</sup> Floor  
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October 6, 2006

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

Ms. Miriam Carr  
State Regulatory Technician  
E.I. DuPont de Nemours and Company  
Stine-Haskell Research Center, Suite 300/427  
P.O. Box 30  
Newark, Delaware 19714-0030

Dear Ms. Carr:

**Re: Registration of DuPont Advion Cockroach Gel Bait (EPA Reg. No. 352-652)  
Containing the Active Ingredient Indoxacarb. Chemical Code: 067710**

The New York State Department of Environmental Conservation (Department) has completed its technical review of the above product application received on January 27, 2006 as a routine product application. Indoxacarb is currently registered in New York State in homeowner applied bait stations for control of ants and cockroaches at up to 0.1% active ingredient. However, the application was determined to be a major change in labeling (MCL) due to the increase in % active ingredient and use outside of a bait station. Dupont submitted the requested additional information on March 21, 2006. The information that was received for DuPont Advion Cockroach Gel Bait, containing the active ingredient indoxacarb, was determined to be complete for purposes of technical review per Department letter dated May 9, 2006.

DuPont Advion Cockroach Gel Bait (EPA Reg. No. 352-652) is labeled for control of pest species of cockroaches including German, American, Australian, Smoky-Brown, Brown, Asian, and Brown-Banded in use sites that include but are not limited to single- and multi-family residential buildings, schools, commercial and industrial facilities (including warehouses, apartments, supermarkets, restaurants, motels, hotels, hospitals, and food handling/storage establishments), and transportation equipment such as aircraft, trains, ships, boats, and buses. The label states that DuPont Advion Cockroach Gel Bait can be used indoors and outdoors as a crack and crevice treatment applied to areas frequented by cockroach pests. DuPont Advion Gel Bait can be applied at 3 to 5 - 1/4 inch spots every ten linear feet for heavy infestations and 1 to 3 spots every ten linear feet for light to moderate infestations. Each 1/4 inch spot is approximately 0.5 grams of gel bait.

DuPont Advion Cockroach Gel Bait (EPA Reg. No. 352-652) contains 0.6% of the active ingredient indoxacarb, which belongs to the oxadiazine chemical family. Indoxacarb acts via blockage of the sodium channels in the insect nervous system and the mode of entry is via stomach and contact routes. The label states: "For Use by Commercial Applicators Only." Therefore, Dupont Advion Cockroach Gel Bait would be classified as restricted use in New York State.

Pursuant to the review time frame specified in ECL §33-0704.2, a registration decision date of October 6, 2006 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 indoxacarb and the formulated product DuPont Advion Cockroach Gel Bait. Review summaries are provided below.

### **New York State Department of Health Review:**

On an acute basis, the formulated cockroach bait product was not very toxic to laboratory animals by either the oral or dermal routes of exposure. It also was not irritating to the eyes or skin (tested on rabbits), nor was it a skin sensitizer (tested on mice). The acute inhalation study on the formulated cockroach bait product was waived by the United States Environmental Protection Agency (USEPA) based in part on considerations of the low vapor pressure of the active ingredient indoxacarb, and product formulation (a gel) that should not result in the formation of respirable particles.

We previously reviewed the active ingredient indoxacarb in the pesticide product Avaunt Insecticide registered by the New York State Department of Environmental Conservation on March 21, 2002. Indoxacarb overall was not very acutely toxic in laboratory animal studies. It also did not cause teratogenic, reproductive or carcinogenic effects and was negative in a number of genotoxicity studies. In chronic animal feeding studies, indoxacarb caused some toxicity, including decreased body weight, body weight gain and food consumption in male and female rats as well as decreased hematocrit, hemoglobin and red blood cells in females. Using data from the chronic rat study, the USEPA Office of Pesticide Programs established a reference dose for indoxacarb of 0.02 milligrams per kilogram body weight per day (mg/kg/day) based on a no-observed-effect level (NOEL) of 2.1 mg/kg/day and an uncertainty factor of 100. A current search of the scientific literature did not find any significant new information on the toxicity of indoxacarb.

The registrant submitted a USEPA occupational risk assessment for the handling of DuPont Advion Cockroach Gel Bait. The estimated dermal margin of exposure (MOE) from occupational exposure to the active ingredient indoxacarb in this formulated product was 147. This MOE was determined by comparing the estimated dermal exposure to a NOEL of 50 mg/kg/day. This NOEL was obtained from a 28-day dermal toxicity study conducted on rats in which the toxicological effects included decreases in body weights and body weight gains as well as the occurrence of hematological effects at a dose level of 500 mg/kg/day. Generally, the USEPA considers MOEs of 100-fold or greater to provide adequate worker protection. Inhalation worker exposure to indoxacarb from the application of DuPont Advion Cockroach Gel Bait is expected to be negligible because of indoxacarb's low vapor pressure ( $1.9 \times 10^{-10}$  millimeters mercury at 25 degrees Celsius) and that the formulation is a gel which makes the generation of respirable particles unlikely. Post-application dermal or ingestion exposures also are expected to be negligible since the product label instructs users to apply to indoor areas that are "...not able to be contacted by children or pets."

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

The available information on indoxacarb and the formulated product DuPont Advion Cockroach Gel Bait indicates that overall they were not very acutely toxic in laboratory animal studies. Indoxacarb also did not cause teratogenic, reproductive or carcinogenic effects. Although data from subchronic dermal and chronic animal feeding studies on indoxacarb showed that this chemical has the potential to cause some toxicity, the expected exposure from using this chemical should not pose a significant risk to workers or the general public.

The labeled use of the formulated product requires placement of gel bait so that it is not able to be contacted by children or pets. While the formulated cockroach bait product is labeled for indoor pest control and impacts to indoor air could be of concern, this appears very unlikely because the active ingredient indoxacarb has a low vapor pressure ( $1.9 \times 10^{-10}$  millimeters mercury at 25 degrees Celsius) and the formulated product does not contain volatile components. In addition, the active ingredient is in a gel matrix and relatively little is applied. Given the above, we do not object to the registration of DuPont Advion Cockroach Gel Bait in New York State.

### **Registration Summary:**

The Department will register DuPont Advion Cockroach Gel Bait (EPA Reg. No. 352-652) in “**restricted use**” status to ensure proper application by “commercial applicators only” as directed by the label.

Enclosed for your record, is a copy of the stamped accepted labeling and the Certificate of Registration for DuPont Advion Cockroach Gel Bait (EPA Reg. No. 352-652). Please note that a proposal by DuPont or any other registrant, to register a product that contains indoxacarb, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a major change in labeled use (MCL) pattern. 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.

Please note that the DuPont Advion Cockroach Gel Bait, as noted on the “restriction” column on the Certificate, is to be classified as “**restricted use**” under rules and regulations 6 NYCRR 326.2(g). As such, this product is restricted in its purchase, distribution, sale, use and possession in New York State.

According to New York State Department of Environmental Conservation Regulations 6 NYCRR 326.3(a): “It shall be unlawful for any person to distribute, sell, offer for sale, purchase for the purpose of resale, or possess for the purpose of resale, any restricted pesticide unless said person shall have applied for, and been issued a commercial permit.”

The Pesticide Reporting Law (PRL) requires all certified commercial pesticide applicators to report information annually to the Department regarding each pesticide application they make. **Commercial pesticide retailers are required to report all sales of restricted pesticide products and sales of general use pesticide products to private applicators for use in agricultural crop production.** If no sales are made within New York State, a report still must be filed with the Department indicating this is the case.

If you need information relating to the Pesticide Reporting Law, or annual report forms, please visit the Department’s website at <http://www.dec.state.ny.us> or contact the Pesticide Reporting & Certification Section, at (518) 402-8748.

Should you require information to obtain a commercial permit, please also contact the Pesticide Reporting & Certification Section, at (518) 402-8748.

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

Ms. Miriam Carr 4.

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

Sincerely,

*Serafini*

*Maureen*

*P*

Maureen P. Serafini  
Director  
Bureau of Pesticides Management

Enclosure

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