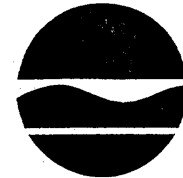


**New York State Department of Environmental Conservation
Division of Solid and Hazardous Materials**

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Active Ing. file



Erin M. Crotty
Commissioner

December 6, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Judy Fersch
BASF Corporation
26 Davis Drive, P.O. Box 13528
Research Triangle Park, North Carolina 27709-3528

Dear Ms. Fersch:

**Re: Registration of Phantom® Termiticide-Insecticide (EPA Reg. No. 241-392)
Containing the Active Ingredient Chlorfenapyr.**

The New York State Department of Environmental Conservation (Department) has completed its technical review of your application and data packages submitted in support of the registration of Phantom Termiticide/Insecticide (EPA Reg. No. 241-392) containing the active ingredient chlorfenapyr. The Department has **registered** this product for labeled use to control termites both as a barrier treatment surrounding commercial and residential structures and via application to the structure. The product is also labeled for use as general indoor pest control via crack and crevice treatment.

The active ingredient, chlorfenapyr, is a member of the family of compounds known as pyrroles. The formulated product (Phantom) is ingested by target organisms and acts to disrupt mitochondrial action which produces energy in the organism. Chlorfenapyr uncouples oxidative phosphorylation, preventing conversion of ADP to ATP. The target organism dies from the inability to generate energy after approximately one week. The Phantom product is not a repellent and thus effectively delivers a lethal dose of the active ingredient to the foraging pest and for potential transfer to its colony/nest.

The Department received the major change in labeling (MCL) application for Phantom Termiticide-Insecticide on 03/07/02 (initial application received 01/29/02 was not identified as an MCL application). The Department reviewed the application for completeness and determined the initial submission to be incomplete on 04/26/02. BASF submitted a data package on 05/29/02 in response to the Department's letter of incomplete application. The application package and second data package were acceptable to the Department and the application was declared complete as per the Department's letter dated 07/15/02. Pursuant to the review time frame specified in ECL §33-0704.2, a **registration decision date of December 12, 2002** was established. The Department conducted the following technical reviews with regard to the registration of Phantom Termiticide-Insecticide for impacts to human health, non-target organisms, and the environment. Review summaries are provided below:

Product Use:

The formulated product Phantom® (EPA Reg. No. 241-392) contains the active ingredient chlorfenapyr at 21.45%. It is a termiticide/insecticide which controls termites, ants, and cockroaches and is for use indoors and outdoors by professional applicators only. The

product is applied outdoors by several methods inclusive of rodding and trenching and foam application. The outdoor rodding and trenching applications may use up to 0.25% active ingredient in four gallons of water per ten linear feet (0.094 lb. a.i.). Re-treatment is permitted only when evidence of re-infestation is detected. Indoor crack and crevice treatment for cockroach and ant control can use up to 0.50% (0.047 lb./gallon) active ingredient and may be re-applied every four weeks as needed. The inerts do not appear to be solvent carriers. The Department has reviewed analytical methods for detection of chlorfenapyr in soil, water, air, and surface wipes and determined them to be acceptable for its use in pesticide management programs.

Human Health Summary:

The formulated end product was previously reviewed under the name Pylon Miticide-Insecticide and the active ingredient chlorfenapyr (see Registration letter to BASF dated 01/16/02). Neither the formulated end product nor the active ingredient was very toxic, irritating or a sensitizer following acute exposures in laboratory animals. Chlorfenapyr also did not cause developmental or reproductive effects in pregnant rats and rabbits. Chlorfenapyr, however, caused some effects following chronic exposure and there was suggestive evidence that this chemical may have carcinogenic potential. The United States Environmental Protection Agency (USEPA) Cancer Peer Review Committee described the carcinogenic potential of chlorfenapyr as "cannot be determined, suggestive." This determination was based on the overall absence of persuasive evidence because increases in tumors occurred with significant trends only, not by pair-wise comparison to controls, and then, only in rats. In addition, chlorfenapyr was negative in a number of genotoxicity studies. A search of the toxicological literature did not provide any new information on chlorfenapyr.

The registrant submitted a worker risk assessment for the use of the Phantom Termiticide-Insecticide product based on actual data from another termiticide and exposure estimates in the Pesticide Handler Exposure Database. For the assessment, it was assumed that mixer/loader/applicators applied 200 gallons of a 1.0 % dilution of Phantom to one home each day year round. It was assumed that workers wore long-sleeved shirts, pants and gloves as per the label. A dermal absorption factor of 5 % was assumed for estimating dose. The daily combined absorbed dermal and inhalation dose was estimated to be 0.00516 milligrams per kilogram body weight per day (mg/kg/day) for these workers. When this dose estimate is compared to the no-observed-effect level (NOEL) of 2.6 mg/kg/day from a one-year dietary neurotoxicity study in rats, a margin of exposure (MOE) of about 500 can be calculated. Adjusting for the difference between the concentration of chlorfenapyr assumed to be used by the applicators in the exposure assessment (1.0 %) and the concentration specified on the label (0.125 to 0.25 %), the MOE would then be 2,000- to 4,000-fold. Generally, MOEs of 100-fold or greater are considered to be adequate by the USEPA for worker exposure.

The registrant also submitted a study that evaluated the indoor air impacts of Phantom Termiticide-Insecticide use in homes. In the study, the Phantom product was applied by a professional applicator to four homes of different age, construction and design to create a barrier at the foundation. The concentration of chlorfenapyr in the dilution applied was 0.5 %, which is two to four times higher than the labeled rate. The total amount of chlorfenapyr applied in each home ranged from 2.16 to 7.92 pounds (0.98 to 3.6 kg). Air samples were taken on days 0, 0.1, 3, 7 and 30 days in several locations in each home. The detection limit for the air samples (taken over a six-hour period) was 0.5 ng/L. No chlorfenapyr was detected in any of the samples in any

home. This result is consistent with the low vapor pressure for chlorfenapyr ($< 1 \times 10^{-7}$ mm Hg at 25 degrees Celsius). The Phantom product does not contain any inert ingredients that would be expected to significantly impact indoor air quality and, as a result, no measurement for such materials was necessary.

There are no chemical specific federal or State drinking water/groundwater standards for chlorfenapyr. Based on its chemical structure, chlorfenapyr falls under the 50 microgram per liter ($\mu\text{g/L}$) general New York State drinking water standard for "unspecified organic contaminants" (10 NYCRR Part 5, Public Water Systems). If one uses the USEPA Peer Review Committee RfD of 0.003 mg/kg/day and procedures for deriving ambient water quality standards and guidelines based on non-oncogenic effects (6 NYCRR Part 702.5), a value of 21 $\mu\text{g/L}$ can be calculated for chlorfenapyr.

Although chlorfenapyr caused some effects following chronic exposure and there was suggestive evidence that this chemical may have carcinogenic potential, the information provided indicates that exposure from the termiticide use of the Phantom product should not pose a significant risk to workers or the general public. In addition, because of the low vapor pressure of chlorfenapyr and the lack of organic solvents, the indoor uses of the Phantom product should not pose a significant potential for inhalation exposure. Direct contact with chlorfenapyr should also be minimal for the general indoor uses of Phantom as it is labeled only for crack and crevice and spot treatments.

Non-target Organism Summary:

The formulated end product was previously reviewed under the name Pylon Miticide-Insecticide and the active ingredient chlorfenapyr (see Registration letter to BASF dated 01/16/02). Technical chlorfenapyr has a water solubility of 0.14 mg/L at pH 7. It has a low vapor pressure, 1.0×10^{-7} mmHg, thus volatilization will not contribute significantly to dissipation. Its octanol/water partition coefficient, K_{ow} , is 67,670 at 25° C. A Bluegill sunfish accumulation study yielded bioconcentration factors for edible and non-edible tissues of 830x and 3400x respectively. Its depuration half-life, $T_{1/2}$, was approximately four days. Roughly 97% of the accumulated residues had depurated within 21 days of exposure cessation.

Chlorfenapyr is slightly to highly toxic to mammals. It is highly to very highly toxic to birds, and is very highly toxic to all aquatic organisms for which data was submitted. The January 10, 1997 USEPA Environmental Fate and Effects Review of chlorfenapyr use on cotton states that chlorfenapyr is one of the most chronically toxic pesticides to avian species that they had evaluated to date.

However, fish and wildlife exposures from the labeled use of Phantom should be minimal to nonexistent. The label contains extensive warnings in the ENVIRONMENTAL HAZARDS section regarding contamination of surface waters which should prevent exposure via drainage. Labeled use of the product along with limited potential for mobility should contain the active ingredient such that its use will not adversely affect fish and wildlife resources.

Environmental Fate Summary:

Most of the information was gathered from the 8/31/98 Environmental Fate and Effects Division (EFED) memorandum. Frequently the information presented in the memorandum contradicted the information presented in the Data Evaluation Records (DER). Because the date on the EFED memorandum is subsequent to the DERs, the memorandum information was used to make the environmental fate determination.

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

Aqueous Photolysis: Chlorfenapyr has half-lives of 5.1-5.4, 6.9-8.1 and 4.8-4.9 days in sterile aqueous solutions of pH 5, 7 and 9 respectively. One degradate was found, CL-357806, ranging from 55% to 73% of applied based on pH. However, aqueous photolysis is not a major degradation route because this is an indoor, soil, or subsurface application.

Soil Photolysis: Chlorfenapyr has a half-life in a sandy loam soil of approximately 75 ± 21 days (MRID 42770242). According to the 8/31/98 memorandum, the half-life is approximately 0.4 years (146 days).

Aerobic Soil Metabolism: Chlorfenapyr has a half-life in sandy loam of 3.8 years (MRID42770243); however, USEPA felt this data was anomalous. In the 8/31/98 EFED memorandum, USEPA indicated that the half life is 1.4 years based on five soils (MRID 44452621—not presented with application).

Aerobic Aquatic Metabolism: Chlorfenapyr has a half-life of 0.8 years in the aqueous portion and 1.1 years in the soil portion, according to the 8/31/98 EFED memorandum.

Anaerobic Soil Metabolism: Chlorfenapyr has an estimated half-life of two years according to the 8/31/98 EFED memorandum and the DER for MRID 434928-47.

Adsorption/Desorption: This study was found to be upgradable and partially satisfied the data requirements; however, USEPA believed that despite the shortcomings of the study, chlorfenapyr was strongly bound to all test soils and would not be expected to be mobile. The K_{oc} s for the parent are 13214 in loamy sand, 14117 in sandy loam, 12321 in loam and 18095 in silt loam. In the 8/31/98 memorandum, USEPA indicated that chlorfenapyr has a relatively high K_{oc} of about 12,000 and as such, leaching would not be significant in soil dissipation studies.

The study for the degradate (in the same soils as the parent) was acceptable and found the K_{oc} s for the degradate are 5000 in loamy sand, 2352 in sandy loam, 2774 in loam and 2095 in silt loam.

Field Dissipation: Five studies were done, and all were upgradable, and further information was needed. The studies did not investigate or attempt to identify degradates, so the routes of dissipation cannot be established. USEPA stated in the DER that "However, it is clear from these studies that parent pesticide AC303,630 is indeed persistent, as defined below, and does not leach." Minimum field dissipation half-lives were stated to be 0.4-0.6 years in loamy sand, 0.4-0.8 years in sandy loam, 0.6-0.9 years in silt loam, 0.6-1.4 years in clay loam, and 0.8-2.1 years in sand.

A May 6, 1997 letter to the USEPA presented data indicating that the registrant went back and did degradate work and found an average field dissipation half-life of the parent of 273 days (175-418 days). They indicated that CL 312,094 was found at a maximum of 30% and two minor (<10%) degradates, CL 303268 and CL 322118 were found. These degradates further degraded to form CL303267, CL325195 and CL322250. However, there is nothing in the application from USEPA indicating that they found this supplemental data acceptable.

In the 8/31/98 memorandum, USEPA indicated that two supplemental multi-year soil dissipation studies demonstrated the trend towards increasing concentrations over time. Soil concentrations ranged from 0.1 ppm in the first year to 0.3 and 0.4 ppm in the fourth year of the study.

In the 8/31/98 memorandum, USEPA indicated that the half-life was 1.3 years based on five small-plot cotton studies in four cotton states (MRID 43492850).

USGS Review: The Department contracted with the United States Geological Survey (USGS) to modify the LEACHP model to address termiticides. As part of their review, they used the data submitted for Phantom. Their review concluded that chlorfenapyr did not degrade within the time frames specified by the registrant's studies of field dissipation. The model simulations indicated that more than 50% of the applied chlorfenapyr was still present after 20 years in the simulated profile, despite the specified half-life decay rate of 1.4 years. It was subsequently determined that the relatively large application that is specified by the registrant was remaining as an unsorted, undissolved suspension in the application zone, which precluded active degradation by the typical degradation pathways that are represented by the model (first-order decay of sorbed and dissolved mass). These results indicated that the chlorfenapyr degradation rates that were supplied by the registrant were potentially incorrect, most likely because the rates were estimated through studies of its use as an insecticide applied at considerably lower rates in field-crop or greenhouse settings. The model indicates that degradation rates estimated through these studies are probably not applicable to the proposed use of chlorfenapyr as a termiticide on Long Island.

USEPA Review: The USEPA required the registrant to put a groundwater advisory statement on the product label at the time of registration. Our Department's groundwater review did not indicate that the active ingredient was likely to migrate into groundwater or to surface waters. It is our understanding that BASF is currently seeking to amend the Phantom label to remove the groundwater advisory statement from the label. Early indications from the USEPA are that the amendment will be accepted.

Summary: Given the very long half-lives and the very high K_{oc} s for chlorfenapyr, it is not probable that this product, when used as directed as a termiticide, will cause any significant impact to groundwater. However, this active ingredient is very persistent and accumulates in soil when used as labeled. As the USGS indicated, the relatively large application that is specified by the registrant remains as an **unsorted, undissolved suspension in the application zone**, which precludes active degradation by the typical degradation pathways that are represented by the model. The model supports the proposed use of the product as a subsurface termiticide which requires that the formulated product remain suspended in the application zone, forming a curtain around the structure.

Registration Summary:

The Department will register Phantom Termiticide-Insecticide as a "Restricted Use" product in New York State. This status will limit the use of Phantom to certified applicators or those working directly with a certified applicator. The "Restricted Use" status will also provide a high level of assurance that the product will be applied according to label directions. Please note that New York State has specific Termiticide Use Regulations as per 6 NYCRR 325.3 for application of liquid termiticides.

As determined by the USGS model, the Department has some concern about the potential for the active ingredient to accumulate in soil. Additionally, there is concern if the active ingredient is found in drinking water or ingested in other ways (home vegetable gardens planted within the treatment zone). The New York State Department of Health review indicates that there is "suggestive" evidence that chlorfenapyr could be carcinogenic. A level of 21 $\mu\text{g/L}$ (ppb)

in drinking water would be of concern to human health. The label contains extensive warnings in the ENVIRONMENTAL HAZARDS section regarding toxicity to fish and wildlife as well as contamination to surface waters. The Department believes that labeled use of the Phantom product should not adversely affect fish and wildlife resources.

Based on the above, any new product applications containing this active ingredient, which demonstrate a labeled use outside of the controlled environment of a commercial greenhouse or a subsurface termiticide application with adequate protection of water resources, will be reviewed with a high degree of caution towards the protection of aquatic, wildlife, and avian resources.

The Phantom product labeling complies with 6 NYCRR 325.3 for application of a liquid termiticide in New York State, and is protective of drinking water sources specifically wells and cisterns. The USGS groundwater review indicates that the active ingredient is not mobile and is not likely to migrate into groundwater. New York State Regulation 6 NYCRR 325.3, prohibits the application of liquid termiticides at or below the level of the local water table, thereby limiting impacts in areas with shallow water tables such as Long Island. The Phantom product labeling also restricts the use of this product in food/feed areas for indoor applications and cautions against the planting, for the purpose of consumption, edible plants into the treated areas of soil in the case of subsurface termiticide treatment. In New York State, certified applicators must provide the homeowner with a copy of the product labeling in accordance with ECL §33.0905.

The Department believes that the registration of this product will provide a suitable alternative for chlorpyrifos based termiticide products that are being phased out by USEPA. Technical reviews have determined the use of this active ingredient in termiticide applications as applied under New York State rules and regulations for "Restricted Use" termiticides are protective of human health and the environment. BASF has provided product literature and decontamination procedures available to product users and we believe that labeled use of the product and technical support provided by BASF will limit inadvertent contamination of the environment or loss of property value due to chemical contamination.

Please note that the Phantom Termiticide-Insecticide product, as noted on the "restriction" column on the Certificate, is to be classified as "**restricted use**" under rules and regulations 6NYCRR 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 6NYCRR 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.

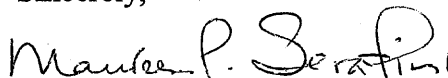
If you need information relating to the Pesticide Reporting Law, or annual report forms, please visit the Department's website at <http://www.dec.state.ny.us> or call 1-888-457-0110 (toll free within New York State). Out-of-State callers may contact the Pesticide Reporting Section at (518) 402-8765.

Should you require information to obtain a commercial permit, please contact Thomas Lynch, Chief, Pesticide Certification Section, at (518) 402-8748.

Enclosed for your records are a copy of the stamped accepted label and the Certificate of Registration for Phantom Termiticide-Insecticide (EPA Reg. No. 241-392). Please note that a proposal by BASF Corporation or any other registrant, to register a product that contains chlorfenapyr, and whose labeled uses are likely to increase the potential for significant impact to humans, non-target organisms, or 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 listed in Appendix 1.B. of "New York State Pesticide Product Registration Procedures" (August 1996). Such information as well as forms can be accessed at our website as listed in our letterhead.

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

Sincerely,



Maureen 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
G. Good/W. Smith - Cornell University, PMEPP