

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

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January 10, 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Beth Anderson
State Registration Specialist
Bayer CropScience
P.O. Box 12014
Research Triangle Park, North Carolina 27709

Dear Ms. Anderson:

Re: Major Change in Labeling (MCL) Application to Register Three New Pesticide Products: Bayer Advanced Garden Disease Control for Roses, Flowers, & Shrubs Concentrate (EPA Reg. No. 72155-14); Bayer Advanced All-in-One Rose & Flower Care Concentrate (EPA Reg. No. 72155-21); Bayer Advanced Dual Protection ACR Insect & Disease Control Concentrate (EPA Reg. No. 72155-61).
Contains the Active Ingredient Tebuconazole - Chemical Code: 128997

The New York State Department of Environmental Conservation (Department) has **denied** registration of the above-listed pesticide products in New York State. The Department has concerns for the homeowner use of these product formulations that is not countered by a demonstrated need for these products in the homeowner marketplace. The Department previously reviewed the application for Bayer Advanced Garden Disease Control for Roses, Flowers, and Shrubs Concentrate (EPA Reg. No. 72155-14) which contains 2.9% tebuconazole. That application was denied registration per Department letter dated 3/4/2005 (see letter at <http://pmep.cce.cornell.edu>; *select chemical information and search on tebuconazole*). The letter states "The potential repetitive handling and use of the concentrate and diluted product, coupled with the detection of noncancer effects and developmental toxicity at relatively low doses of the active ingredient, raise concerns...for use of this product by homeowners."

The Department has completed its current technical review of the above-referenced product formulations containing tebuconazole and a combination of tebuconazole and imidacloprid. These products were submitted to the Department on October 27, 2005 and November 1, 2005; additional information was received on December 19, 2005, February 14, 2006, and October 30, 2006. Bayer Advanced All-in-One Rose & Flower Care Concentrate (EPA Reg. No. 72155-21) and Bayer Advanced Dual Protection ACR Insect & Disease Control Concentrate (EPA Reg. No. 72155-61) both contain tebuconazole and imidacloprid (chemical code 129099) and act as a dual action fungicide and insecticide.

The New York State Department of Health (NYSDOH) has reviewed the recently submitted data (dated October 30, 2006). Even though revised modeling scenarios of exposure to homeowners were demonstrated to be within margins of safety, the Department and the NYSDOH still have concerns with regard to chronic and developmental toxicity (as detailed in the Department's letter dated August 3, 2006 to Bayer Advanced, LLC).

Also, the Department's environmental fate review determined a potential groundwater impact in sensitive areas of New York State. Bayer Advanced, LLC has suggested that the tebuconazole and imidacloprid combination products would be prohibited from use on Long Island per previous agreement whereby homeowner products which contain imidacloprid are prohibited from sale, distribution or use in Nassau, Suffolk, Kings, or Queens Counties in New York State. The agreement was made between the Department and Bayer after imidacloprid was detected in groundwater on Long Island. The Department will not entertain a similar agreement for homeowner use products containing tebuconazole.

The NYSDOH has provided the following review which incorporates the additional information provided by Bayer Advanced, LLC in their submission to this Department dated October 30, 2006.

Toxicological Risk Assessment:

This review includes the additional information submitted by Bayer Advanced/A Business Unit of Bayer CropScience, LP on October 30, 2006, to register the following pesticide products containing the active ingredient tebuconazole (2-(4-chlorophenyl)-ethyl-2-(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol) in New York State:

1. Bayer Advanced Garden Disease Control for Roses, Flowers & Shrubs Concentrate (EPA Reg. No. 72155-14) contains 2.9% tebuconazole; 1 quart of concentrate makes 42 gallons of use solution for foliar treatment.
2. Bayer Advanced All-in-One Rose & Flower Care Concentrate (EPA Reg. No. 72155-21) contains 0.8% tebuconazole and 0.15% imidacloprid; 1 quart of concentrate makes between 4 gallons of use solution for drench treatment of rose bushes and 32 gallons of use solution for flower beds.
3. Bayer Advanced Dual Protection ACR Insect & Disease Control Concentrate (EPA Reg. No. 72155-61) contains 1.0% tebuconazole and 0.2% imidacloprid; and 1 quart of concentrate makes between 4 gallons of use solution for drench treatment of selected shrubs and 32 gallons of use solution for flower beds.

The Bayer Advanced Garden Disease Control product is labeled to control all major fungal diseases that harm roses, flowers and shrubs. The Bayer Advanced All-in-One product is labeled to feed and protect against insects and fungal diseases that harm roses, flowers and shrubs. The Bayer Advanced Dual Protection product is labeled to protect against insects and fungal diseases that harm flowers, azaleas, camellias and rhododendrons and other shrubs.

Tebuconazole is currently registered in the State for use in a number of agricultural, wood preservative, and tree injection products, none of which are labeled for homeowner use. Pesticide Product Registration Section staff determined that the current application to register tebuconazole for homeowner use represents a major change in labeled use pattern in New York State for this active ingredient. The Bayer Advanced All-in-One and Dual Protection products also contain the active ingredient imidacloprid.

In our previous review of the Bayer Advanced products (see Department letter dated August 3, 2006), we noted that these products raised several concerns given that they are intended for homeowner use. Major issues of concern are: 1) the toxicological properties of tebuconazole and the low margins of exposure (MOEs) for some exposures to this active ingredient; 2) the lack of submission by the registrant of a user risk assessment for the Bayer Advanced All-in-One and Bayer Advanced Dual Protection products; 3) the use of products (i.e., All-in-One and Dual Protection) that have multiple pesticide activities; 4) the relatively large package sizes and quantities that would be handled by homeowners; and 5) the potential for tebuconazole to exceed an estimated NYSDOH possible chemical specific drinking water standard. These issues were discussed on September 18, 2006, with the registrant in a conference call in which both NYSDOH and DEC staff participated. The registrant

agreed to submit information to address these issues, including a comparative risk assessment of current federal and New York State registered alternative products.

The registrant recently submitted information (see correspondence from B. Anderson to S. Jackling, dated October 30, 2006), in regard to some of the above-noted concerns. In our previous review of the registrant's homeowner use risk assessment for the Bayer Advanced Garden Disease Control product, we noted that the registrant's approach did not account for all available toxicity data on tebuconazole, nor use of certain criteria for characterizing adequate MOEs. In response to this concern, the registrant submitted a revised risk assessment in which different toxicity data were used and the assumed volume of diluted product applied was reduced from 100 gallons per day to 30 gallons per day to more closely reflect likely use. For determining MOEs, dermal exposure estimates (inhalation exposures were determined to be negligible in comparison to dermal exposures) were compared to the lowest-observed-effect level (LOEL) of 8.8 milligrams per kilogram body weight per day (mg/kg/day), which was the lowest dose of tebuconazole tested in an oral rat developmental neurotoxicity study (decrease in absolute brain weights of the offspring). The use of this LOEL and the reduced quantity applied value resulted in increasing the estimated MOE from 420 to 1,400, a value that can now be considered to provide adequate homeowner protection, as long as homeowners do not use more than 30 gallons of diluted product (0.75 fluid ounces of product per gallon of water) per day. Since a LOEL was used instead of a no-observed-effect level (NOEL) in comparing dermal exposures of children and women of child-bearing age to tebuconazole to account for developmental and reproductive effects, MOEs of 1,000-fold or greater are appropriate values for determining adequate protection.

The registrant also submitted a risk assessment for the labeled uses of the Bayer Advanced All-in-One and Dual Protection products, which was missing from the initial submission. These two products are applied as either a drench or pour-on treatment and are not spray applied as is the Bayer Advanced Garden Disease Control product. The registrant's assessment of the two products used several conservative assumptions including that homeowners wore shorts and a tee shirt with no gloves (whereas the labels for these two Bayer Advanced products require the use of long-sleeved shirt, long pants and waterproof gloves), and spray rather than drench/pour-on treatment. The same LOEL of 8.8 mg/kg/day used to assess risks from the Bayer Advanced Garden Disease Control product was used to determine the MOEs for these two products. For homeowners involved in mixing, loading and application of the Bayer Advanced All-in-One product to roses (the plant with the highest label application rate), the estimated MOE was 2,100. In estimating the MOE of 2,100, the registrant assumed that no more than 5 gallons of diluted product were applied (by spray) on a daily basis. Therefore, adequate protection (i.e., the MOE is at least 1,000-fold) for homeowner use of the Bayer Advanced All-in-One product would be provided if no more than 10 gallons of diluted product were applied per day. For the Bayer Advanced Dual Protection product, where the labeled dilution rate results in tebuconazole concentrations of about half those of the All-in-One product assumed in the exposure assessment, adequate protection would be provided if homeowners did not use more than 20 gallons of diluted product per day. For post-application dermal exposures to residues from the All-in-One product (cutting of flowers), the MOEs estimated by the registrant were 1,600 for adults and 1,000 for children.

In regard to concerns about the comparative risks of tebuconazole in the Bayer Advanced products to the currently registered alternative products, the registrant provided no data. Instead, the registrant provided the names of a number of pesticide products labeled for use on flowers and shrubs as possible alternatives to the Bayer Advanced products. These alternatives contain the fungicidal active ingredients, chlorothalonil, triforine, myclobutanil or propiconazole. Using these alternatives, we conducted a comparison of the acute toxicity categories, oral reference doses (RfD) and their bases, and United States Environmental Protection Agency (USEPA) carcinogenicity classifications. This comparison indicates that all the active ingredients (including tebuconazole) can be categorized as not very acutely toxic, and overall have comparable RfDs, generally indicating a similar degree of chronic toxicity. With respect to carcinogenicity, all the active ingredients, except myclobutanil, were classified as having some degree of human carcinogenic potential. Whereas tebuconazole and propiconazole are each classified as a "possible human carcinogen," chlorothalonil and triforine are classified respectively as a "likely human carcinogen" and "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." Based on our limited comparison, tebuconazole does not appear to be

less toxic than the alternate active ingredients. A comparison of exposure and the resulting health risks was not addressed in the registrant's response for tebuconazole and the alternative active ingredients.

The registrant briefly addressed the issue of potential groundwater contamination by the Bayer Advanced products. In their response, the registrant noted that because the Bayer Advanced All-in-One and Dual Protection products contain imidacloprid, both product labels will already be required to bear the label restriction: "Not for sale, sale into, distribution and or use in Nassau, Suffolk, Kings and Queens counties in New York." This restriction, however, would not be automatically applicable to the Bayer Advanced Garden Disease Control product which does not contain imidacloprid. Furthermore, there may be areas in New York State, other than Nassau, Suffolk, Kings and Queens counties, which also have "vulnerable/sandy aquifers." The issue of whether tebuconazole itself would be a groundwater concern was not addressed in the registrant's response.

Two other issues of concern that the registrant either did not adequately address or did not address, are the potential for tebuconazole to exceed an estimated NYSDOH possible chemical specific drinking water standard and the use of the Bayer Advanced All-in-One and Dual Protection products which have multiple pesticide functions. In regard to this latter point, both of these products contain the active ingredients tebuconazole and imidacloprid, which have fungicidal and insecticidal activity, respectively. Such pesticide products with dual activities have the potential to lead to unnecessary applications of the additional active ingredient (e.g., insecticide) when only one active ingredient (e.g., fungicide) may be needed.

Based on the limited information that was provided in the registrant's response, and from our limited evaluation, the NYSDOH cannot conclude that the Bayer Advanced products pose lesser risks than the alternative products. Given that tebuconazole has carcinogenic potential and overall does not appear to pose lesser risks than the alternative active ingredients, we continue to have reservations about registering these three Bayer Advanced products in New York State.

Environmental Fate Risk Assessment:

In consideration of the NYSDOH estimate of a potential chemical specific drinking water standard of 6.2 µg/L, a screening level assessment of groundwater impacts was conducted by Department staff. The application rate was based on use directions for the Bayer Advanced Garden Disease Control for Roses, Flowers & Shrubs Concentrate (EPA Reg. No. 72155-14). An application rate of 0.007 lb. ai/1,000 ft.² and 12 applications per season was modeled for groundwater impacts.

Modeling:

Tebuconazole was modeled using Riverhead soil, a K_{OC} of 1,025, a half-life of 610 days and an application rate of 0.084 lb. ai/1000 ft.²/yr. (407.02 mg/m²). The model projected breakthrough in year three and steadily increasing values which exceed the NYSDOH proposed drinking water threshold for impacts to human health (6.2 µg/L) in year nine.

Since the modeling projects that the potential proposed drinking water limit of 6.2 µg/L (ppb) will be exceeded if the product is used as labeled, staff object to the registration of these products in New York State. While labeled use of the product might be acceptable in non-sandy areas of New York State, there is no apparent way to label the product to limit impacts to vulnerable/sandy aquifers in New York State.

Registration Summary:

The Department continues to have reservations regarding the registration of homeowner products which contain the active ingredient tebuconazole. Bayer Advanced, LLC has failed to demonstrate a compelling need for these products/active ingredient in the homeowner marketplace. There are several fungicide products already on the market and the tebuconazole concentrates do not demonstrate a safer alternative to other formulations that contain either **chlorothalonil**, **triforine**,

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myclobutanil or **propiconazole**. Tebuconazole is a possible carcinogen and is mobile in sandy loam soils such as found in areas of New York State. The relatively large product package size/quantity, and the frequency of some recommended applications raise concerns for use of Bayer Advanced Garden Disease Control Concentrate by homeowners. When used as labeled, this product may cause unreasonable adverse effects to human health and the environment. Additionally, the dual action products (fungicide and insecticide) may lead to unnecessary applications of either the insecticide or fungicide when only one control measure may be needed.

The Department has **denied** registration of the three products in MCL review and rejected the following product application that has also been submitted by Bayer Advanced products as a routine product application:

Bayer Advanced 3-in-1 Insect Disease and Mite Control Concentrate (EPA Reg. No. 72155-73) contains the active ingredients tau-fluvalinate (chemical code: 109302); tebuconazole (chemical code: 128997) and imidacloprid (chemical code: 129099).

You are reminded that the application fee is **nonrefundable**. If you wish to reapply, you must submit a complete new application for registration with all required documents and new application fee to register the above-mentioned products.

Requirements and application forms can be found on our website, the address is noted in our letterhead. Please be aware that any unregistered product may not be sold, offered for sale, distributed, or used in New York State.

If you have any questions on this matter, please contact Pesticide Product Registration Section staff, at (518) 402-8768.

Sincerely,

Maureen P Serafini

Maureen P. Serafini

irector

ureau of Pesticides Management

cc: Charles Boyd, Bayer Environmental Science
N. Kim/D. Luttinger - NYS Dept. of Health
R. Zimmerman/R. Mungari - NYS Dept. of Ag. & Markets
W. Smith - Cornell University, PSUR