

# New York State Department of Environmental Conservation

## Division of Solid & Hazardous Materials

Bureau of Pesticides Management

Pesticide Product Registration Section

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March 25, 2005

### **CERTIFIED MAIL**

### **RETURN RECEIPT REQUESTED**

Mr. Adrian Krygsman  
Manager, Registration  
Bayer Environmental Science  
A Business Group of Bayer CropScience LP  
95 Chestnut Ridge Road  
Montvale, New Jersey 07645

Dear Mr. Krygsman:

**Re: Registration of the New Pesticide Product, Maxforce Tick Management System (EPA Reg. No. 432-1248), Which Represents a Major Change in Labeling for the Active Ingredient Fipronil**

The New York State Department of Environmental Conservation (Department) has completed its review of your application, received October 20, 2003, and additional information, received November 5, 2003 and January 7, 2004, to register the new product **Maxforce Tick Management System** (EPA Reg. No. 432-1248) in New York State. The product represents a major change in labeling for the active ingredient **fipronil** (chemical code 129121).

The application was deemed complete for purposes of review on February 19, 2004 and a registration decision which was originally due by July 19, 2004 was waived by Bayer Environmental Science in order to allow more time for additional supporting information to be submitted and reviewed.

Maxforce Tick Management System contains 0.70% fipronil and is labeled for use as a rodent bait station system for the control of ticks which may carry Lyme disease. Small rodents (mice and chipmunks) are attracted to the stations by the use of bait. The active ingredient, fipronil, is incorporated into a fluid that saturates a wick hanging inside of a child-resistant bait station. When a rodent enters the bait station to feed on the bait, it contacts the wick, thus self applying the fipronil. The bait stations are placed about every ten meters around the perimeter of rodent habitat on residential properties.

Fipronil is currently registered in New York State for use in products labeled for flea and tick control on dogs and cats (Frontline products), as indoor/outdoor bait stations for insect control and for in-furrow application in field corn. The additional proposed use of fipronil in the Maxforce Tick Management System is the first use on wildlife as a means of reducing the number of ticks in residential settings and, therefore, represents a major change in labeling for this active ingredient in New York State.

The Department has reviewed the information supplied to date in support of registration of the new product **Maxforce Tick Management System** (EPA Reg. No. 432-1248).

### **HEALTH EFFECTS:**

The New York State Department of Health (DOH) stated that they previously evaluated the active ingredient fipronil in the pesticide products Frontline Spray Treatment, Frontline Top Spot for Cats and Frontline Top Spot for Dogs, and in a number of Combat and Maxforce bait station products. In the Frontline review, the DOH noted that fipronil caused a variety of effects, particularly neurotoxicity, in chronic animal studies at relatively low doses. For the Maxforce Tick Management System, the only additional toxicity information that was submitted was the battery of acute toxicity tests on the pesticide product Termidor SC Insecticide containing 9.1 percent fipronil. The United States Environmental Protection Agency (USEPA) allowed the registrant to use the data from Termidor SC Insecticide to support federal registration of the Maxforce Tick Management System. The studies on the Termidor SC product indicate that it is not very toxic to laboratory animals on an acute basis by the oral, dermal or inhalation routes of exposure. The Termidor SC product also was not very irritating to skin or eyes and was not a skin sensitizer. Consequently, the Maxforce Tick product (which contains fipronil at a concentration of about 10-fold less than the Termidor SC product) is not expected to be very toxic or irritating on an acute basis. A current search of the toxicological literature did not find any significant new information on the toxicity of fipronil.

Applicator risks from the use of the Maxforce Tick Management System appear minimal. Exposure to the active ingredient in the product should be very low, if any, as it is contained within a bait station. The label also requires applicators to wear long-sleeved shirt and long pants, socks and impervious rubber gloves. In addition, the Maxforce label states the following: “FOR USE BY PESTICIDE MANAGEMENT PROFESSIONALS AND PUBLIC HEALTH DEPARTMENT PERSONNEL FOR THE CONTROL OF TICKS WHICH MAY CARRY LYME DISEASE.” Therefore, this product would be classified as “Restricted Use” in New York State.

The Maxforce Tick product label indicates that the bait stations, which contain the formulated product, are child-resistant. To support this claim of child-resistance, the registrant submitted a USEPA review of three child-resistant packaging tests of these bait stations. This review concluded that the bait stations meet the criteria for child-resistant effectiveness according to current testing procedures (16 CFR 1700.20). In one test involving 50 children, only two were able to access some of the bait stations. This represents a child-resistant effectiveness of 96 percent. The current testing procedure (16 CFR 1700.20) sets a passing criterion of 94 percent or greater for child-resistant effectiveness. In the second round of testing, one child out of 50, was able to access one bait station, whereas in the third testing round of 50 children, no child was successful.

Some field efficacy data are available for this product in the form of a three-year study conducted on Mason’s Island, Connecticut. In this study, tick populations were evaluated on both mice and habitat in areas where bait stations containing the fipronil product were installed (treated areas) compared to areas where bait stations were not installed (untreated areas). According to the study report, the number of ticks on mice was dramatically lower in the treated areas than in the untreated areas. Similarly, the number of nymphal and adult ticks in habitat (as evaluated by dragging fabric flags along vegetation) was greatly lower in treated versus untreated areas. In addition, the percentage of mice infected with the spirochete that causes Lyme disease was lower in the treated areas when compared to untreated areas.

Based on the available information, the Maxforce Tick Management System should not pose a significant health risk to workers who handle this product. While the product label allows a number of

bait stations to be placed in close proximity to residents, which could present a potential poisoning hazard to children, the child-resistant packaging should greatly reduce the risk of poisoning. Also, the product appears to be efficacious at least for certain environments, and could be a viable, lower risk alternative to the repeated broadcast application of acaricides to residential properties as is routinely done in some areas of the state. Given the above, the DOH has no objection to registration of the Maxforce Tick Management System in New York State.

### **ECOLOGICAL EFFECTS:**

The Department's Division of Fish, Wildlife & Marine Resources' Bureau of Habitat (BOH) stated that the mammalian toxicology study base for fipronil is extensive. The basic set of studies were submitted in support of the field corn insecticide, Regent 4 SC, and previously reviewed by staff. In response to staff concerns for potential adverse effects to birds from use of the Regent corn product, avian toxicity studies were submitted for several species for which testing is not normally required [pigeon, pheasant, red-legged partridge, and house sparrow]. While not as extensive as the mammalian work, these additional studies help fill in the sensitivity distribution between the standard, widely differing, Mallard duck (LD50 > 2150 mg ai/kg body weight) and Bobwhite quail (LD 50 = 11.3 mg ai/kg body weight) data. Notably absent from the reported avian toxicity data is any for predators, scavengers, or more omnivorous species.

The USEPA does not currently require toxicity testing with amphibians or reptiles to support product registration. The working assumption is that regulatory restrictions placed on a product that are protective of fish will also be protective of amphibians and that conditions protective of birds should also protect reptiles. The validity of these assumptions is questionable and is only beginning to be addressed.

Aquatic organisms, as a group, are the most sensitive to fipronil, particularly marine/estuarine species. For perspective, the USEPA classifies an active ingredient's toxicity to aquatic organisms as very highly toxic if the LC50 < 0.1 ppm in the test vessel water. The fipronil acute LC50 for the most sensitive test species, mysid shrimp, is 0.00014ppm or roughly 714 fold lower than the concentration at which it would be classified as "Very Highly Toxic."

The BOH is concerned that if this approach of controlling ticks on small rodents is effective in reducing the occurrence of human cases of Lyme disease to some degree, or is perceived to be effective, the use of the Maxforce product may be extensive over large tracts of terrain where Lyme disease is prevalent. The use of an active ingredient as toxic as fipronil, with toxicity that persists as fipronil's does, has the potential to result in lethal toxicity to aquatic organisms and produce secondary effects including reproductive inhibition and altered community structure, particularly in marine/estuarine habitat.

In summary, the BOH stated that fipronil is very highly toxic to aquatic organisms and is persistent in the environment. Major metabolites of fipronil are up to seven times more toxic than fipronil and are very persistent. The bait box use pattern has the potential to be a very large use for fipronil, exposing extensive areas of aquatic habitat to considerable risk. The toxicity and risks to reptiles and amphibians are ill-defined and undefined, respectively.

While the estimated risks posed by the Maxforce Tick Management System product are within the USEPA acceptable range, we generally have concerns for registering a pesticide product that has adverse aquatic organism and wildlife potential unless either the needs for the product are significant or it replaces products that pose greater risks. To address this issue, the Department reviewed additional

supporting information from the Centers for Disease Control and Prevention's (CDC) National Center for Infectious Diseases' Division of Vector-Borne Infectious Diseases, and from our DOH.

Dr. Lyle Petersen, Director of the Division of Vector-Borne Infectious Diseases, strongly supported the registration. Dr. Petersen stated that they recently completed and published a study on community-based Lyme disease control. In the study, they evaluated the efficacy of fipronil to control immature deer ticks by utilizing a self-contained, FDA-approved, host-targeted device. Their results showed that host-targeted bait boxes were effective at delivering fipronil to mice and thereby reducing nymphal and larval tick infestations on mice by 68% and 84%, respectively. Passive application of fipronil also significantly reduced the infection rate of mice by 53%. In addition, the abundance of questing adult and nymphal deer ticks on treated properties were reduced by 77% and >50%, respectively. Finally, infection rates in questing nymphal deer ticks for Lyme disease and Ehrlichiosis were reduced by 67% and 64% after only two years of treatment. Their results show that a host-targeted approach to control Lyme disease can be an effective and environmentally acceptable means to control ticks, and decrease the infection rate of ticks. Dr. Petersen stated that they are very enthusiastic about this methodology and feel that it will provide a safe and effective public health intervention for the control of tick-borne diseases.

Our DOH stated that their initial evaluation of the Maxforce Tick Management System was favorable overall and that they did not object to registration of the product in New York State. However, fish and wildlife concerns were identified and Maxforce has not been registered to date. Because the proper use of the Maxforce product could result in some public health benefits (i.e., a reduction in the risk of Lyme and other tick-borne diseases), the DOH recommends that the Department considers the potential health benefits of the Maxforce Tick Management System product when weighing the concerns expressed for fish and wildlife issues.

The DOH stated that at the time of their initial review of the Maxforce product, there were two alternative chemical-based methods to control ticks that were considered for comparison. These alternatives were the 4-Poster Tickicide system (this product was then under review for registration in New York State) that directly applies pesticide to deer, and a variety of chemical insecticide/acaricides that can be applied directly to lawns and landscaping. Both of these alternatives, however, pose some potential concerns from both a public health, and a fish and wildlife standpoint. In comparison to these alternatives, the Maxforce product poses fewer risks to children and pets as it is in child-resistant packaging and does not have the potential for pesticide contact as does the 4-Poster product and the broadcast insecticide/acaricide products. The Maxforce product is also a much more accurate means of dispensing the active ingredient to the target than that of the broadcast insecticide/acaricides. The amount of active ingredient in the Maxforce product is also very small (25.5 milligrams fipronil per bait station) and is generally not available for contact with non-target organisms. In comparison to the 4-Poster product, Maxforce also requires much less maintenance and is easier to place in appropriate locations. The Maxforce product also targets earlier life stages of black-legged ticks, thereby helping to disrupt spirochete transmission to other host organisms. Subsequent to the DOH's review of the Maxforce product, the 4-Poster product was denied registration in New York State due to the 2003 regulations that generally prohibit the feeding of deer, and thus is not a viable alternative to the Maxforce product at this time.

The efficacy data submitted for the Maxforce product comes from two studies, one that was conducted on an island off the coast of Connecticut, and another from a study in New Jersey. The treated area in the Connecticut study was about 360 acres total. In this study, the number of nymphal black-legged ticks in untreated areas (as determined by dragging fabric flags across tick habitat) ranged from 0.93 to 1.03 nymphs per minute flagging, whereas the rate on treated areas was 0.03 to 0.94

nymphs per minute flagging. For adult ticks, the rates were 1.5 to 1.86 and 0.013 to 0.36 adult ticks per minute of flagging in the untreated and treated areas, respectively. The percentage of mice that were hosting ticks ranged from about 60 to 95 percent in untreated areas, whereas generally 0 to 30 percent of mice had ticks in the area that had been treated. Also, the percentage of mice (29.1 versus 67.9 percent) and adult ticks (31.1 to 34 versus 45 to 48 percent) infected with the spirochete that causes Lyme disease was lower in treated areas than in untreated areas.

The other efficacy data come from a Section 18 Emergency Exemption report on the use of Maxforce in an area of about 144 acres in New Jersey. This report states that the Maxforce product provided about 80 percent control of nymphal ticks on white-footed mice and Eastern chipmunks during the year 2002, but that no additional control of larval ticks was provided by late season bait box use (the time of year when larvae are most actively feeding). In 2003, no significant differences in nymphal tick populations were noted between treated and non-treated areas, or before and after bait box placement. The number of nymphal ticks on rodents, however, was reduced by about 26.5 percent in areas where bait boxes were placed. No significant effect was noted for larval ticks on rodents in the treated area following placement of bait boxes. The study authors stated that the poor efficacy observed could have been due to the late placement of bait boxes and the traps used to catch rodents, as well as the limited use of the boxes by rodents.

The Maxforce product is in a child-resistant bait box and the possibility that the general public and applicators will have contact with the active ingredient is minimal. The efficacy data have weaknesses, but suggest that the product has the potential to reduce tick populations and perhaps the presence of the *Borrelia burgdorferi* spirochete (the cause of Lyme disease) in ticks and mice in treated areas. This in turn could reduce the potential for people to acquire the causative agent of Lyme disease. As such, the health risks associated with the Maxforce product are minimal while health benefits, although difficult to quantify, are possible. Given the above, we strongly support the registration of the Maxforce Tick Management System in New York State.

The label contains the following statement:

“FOR USE BY PESTICIDE MANAGEMENT PROFESSIONALS AND PUBLIC HEALTH DEPARTMENT PERSONNEL FOR THE CONTROL OF TICKS WHICH MAY CARRY LYME DISEASE.”

Due to the above-mentioned statement and the specific labeling on this product, it is considered “restricted use” in New York State. This product may only be sold by and to certified applicators. Furthermore, only certified applicators are allowed to apply and use the product. Since the product can only be handled by trained applicators in New York State, the likelihood of the product being used and disposed of according to the Federally approved label is very high.

The label contains extensive directions for use regarding the handling, placement, and collection of the bait boxes. Also, the timing and replacement of bait boxes is very specific.

The label states the following: “Boxes are placed in locations in early spring for three months, then replaced with new boxes for an additional three months.” According to this statement, no bait boxes should be left in place for more than three months (90 days). Therefore, in order to follow the product label, the certified applicator is responsible for collecting and disposing of the used bait boxes according to labeled directions.

Also, the label contains the following statements under the “**Additional Tips**” heading:

- Impervious rubber gloves must be worn when working with the Maxforce Tick Management System.
- At the end of the treatment period, Maxforce Tick Management System boxes should be gathered and disposed of according to Federal, State and Local regulations using rubber disposable gloves.
- During replacement and removal of used boxes, a half-mask air purifying respirator with a N-95 or N-100 filter type and rubber gloves should be worn. This is a precaution against the unlikely but possible exposure to mouse-borne hantavirus.
- Each Maxforce Tick Management System unit that is removed from a property should be placed in a large plastic bag; tie or tape the bag closed after it contains 10-15 units and before it is transported from the application site.

Obviously, this product is intended to be used, handled and disposed of by trained personnel and a homeowner would not be expected to follow the above-mentioned directions and wear “a half-mask air purifying respirator with a N-95 or N-100 filter type and rubber gloves.”

The Department concludes that Maxforce Tick Management System should not have an adverse effect on the health of workers or the general public, the fish and wildlife resources, or the ground and surface water when used strictly as labeled.

Therefore, the Department hereby accepts for “Restricted Use” registration the new product **Maxforce Tick Management System** (EPA Reg. No. 432-1248).

Maxforce Tick Management System is classified as restricted use in New York State in accordance with rules and regulations 6 NYCRR 326.2(g) and 6 NYCRR 326.23(e). As such the product is restricted in its purchase, distribution, sale, use, and possession in New York State.

According to the 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.”

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

The Pesticide Reporting Law (PRL) in the Environmental Conservation Law Article 33 Title 12 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/website/dshh/pesticid/prl.htm> or call (518) 402-8748.

The Certificate of Pesticide Registration and a copy of the New York State stamped “ACCEPTED” labeling for Maxforce Tick Management System (EPA Reg. No. 432-1248) is enclosed for your records.

Bayer Environmental Science is reminded that if New York State registration is requested for Maxforce Tick Management System or for any other similar product which contains fipronil with an increased application rate, different application method and/or expanded use sites, the product will be considered a **Major Change in Labeling and the Department will require an extensive review.**

Also, any proposed use expansion of the Maxforce Tick Management System would require the following in order to address and mitigate the concerns of our BOH:

1. Conduct a fipronil amphibian embryo/larval, FETAX, assay.
2. Develop acute fipronil terrestrial predatory reptile (snake) toxicity data.
3. Conduct surface water monitoring for fipronil and metabolite residues in areas of use.

If you have any questions, please contact Mr. 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