NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

**Division of Materials Management, Bureau of Pest Management**
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October 8, 2015

**VIA E-MAIL** (Company # 100)

Ms. Susan Person
Syngenta Crop Protection, LLC
410 South Swing Road
Greensboro, North Carolina 27409

Re: Registration of Instrata (EPA Reg. No. 100-1231) at Half of the Current Application Rate on Turf in Nassau & Suffolk Counties. Active Ingredient Fludioxonil (Chemical Code: 071503)

Dear Ms. Person:

As stated in our letter dated May 7, 2015 (attached) the New York State Department of Environmental Conservation (Department) reviewed the application and data package submitted by Syngenta Crop Protection for the above-referenced product label change, received February 19, 2015. The Department conducted a full technical assessment of environmental fate based on more current data than was available for the initial review and consequent registration decision for the new active ingredient fludioxonil, dated February 4, 2003. The Department has made a determination that use of Instrata at the reduced annual application rate of 0.85 lbs. fludioxonil per acre (7 gallons of product per acre) would not negatively impact groundwater resources when used on turf sites in Nassau and Suffolk Counties, New York. The full technical assessment is provided in Attachment A of this letter.

Instrata is registered in New York State for use to control turf diseases on golf courses, lawns around commercial and industrial buildings, professional and collegiate athletic fields, and sod farms. The Department raised a concern during file review that the broadcast application of the active ingredient to turf on Long Island may impact groundwater resources based on previous assessments that stated a concern but may not have clearly identified mitigation measures to protect this resource.

Syngenta proposed the addition of mitigative language to the product label which would reduce the application rate while maintaining efficacy against turf diseases found in the Long Island area. Syngenta has provided a final product label based on U.S. EPA stamped "accepted" labeling dated August 18, 2015. The revised label contains the agreed upon New York State specific language: "Do not apply more than 7 gallons of Instrata per acre per year (20.5 oz. per 1,000 sq. ft. per year) in Nassau and Suffolk Counties, New York." The application rate is thus reduced to ½ the previous labeled rate or 0.85 lb. fludioxonil per acre per year.

The Department will generate a new registration record for the submitted labeling and mark the previous registration of Instrata as "Discontinued" to allow the older product labeling to clear the channels of trade in New York State. The "Discontinued" Instrata record must be "Suspended" by the expiration date of December 31, 2016.

The Department takes this opportunity to re-evaluate the use of fludioxonil on turf and ornamental sites and to clarify the mitigative measures to allow use of formulated products in Nassau and Suffolk Counties of New York State. As a result of the current environmental fate assessment, the Department will require:

- Addition of New York State specific language to be added to all labeling that lists applications to turf – Do not apply more than 0.85 lb. of fludioxonil /acre/yr. (or equivalent amount of formulated product) in Nassau and Suffolk Counties, New York. [or No Sale, Sale Into, Distribution, or Use in Nassau and Suffolk Counties, New York.]

- Addition of New York State specific language to all labeling with ornamental use sites as follows: "In Nassau and Suffolk Counties, New York – Use is Limited to Ornamentals Grown in Interiorscapes, Greenhouses, Lath and Shade Houses, Containers, or Other Enclosed Structures"

- All turf and ornamental use products will be "restricted use" in New York State to insure that application rates and other New York State specific label language is adhered to for the protection of groundwater resources.

As an additional outcome of this review, all currently registered general use turf and ornamental products that contain fludioxonil will be re-classified as "restricted use" in New York State to insure that these products will be used only by trained applicators. This change in registration status is in accordance with 6NYCRR Part 326.23(e) and will take effect as of December 31, 2015.

Please find attached the Certificate of Pesticide Registration and stamped "Accepted for Registration" label for Instrata (EPA Reg. No. 100-1231). The Department has generated a new record designating the lower application rate allowed for use on turf in Nassau and Suffolk Counties, New York. Please note the yes under the "restriction" column on the enclosed Certificate of Pesticide Registration and the "Classified for Restricted Use in New York State" stamp on the enclosed product labeling. As such, this product is restricted in its purchase, distribution, sale, use and possession in New York State. Furthermore, this product may only be purchased and used by a certified applicator in New York State.

The New York State Department of Environmental Conservation Regulations 6 NYCRR 326.3(a) state: "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 Reporting & Certification Section at 518-402-8748.

The Pesticide Reporting Law within 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 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.ny.gov/chemical/27506.html or call the Reporting & Certification Section at 518-402-8748.

Please note that a proposal by Syngenta Crop Protection, Inc. or any other registrant to register a product that contains fludioxonil, and whose labeled uses are likely to increase the potential for significant impact on humans, nontarget organisms, or the environment, would constitute a major change in labeling. 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" (November 2014). Such information, as well as forms, can be accessed at our website as listed in our letterhead.

Please contact Paula McBath, of the Pesticide Product Registration Section, at 518-402-8768 if you have any questions regarding this letter.

Sincerely,

Scott Menrath

Scott Menrath, P.E.
Director
Bureau of Pest Management

**ATTACHMENT A**

Environmental Fate Assessment:

The following groundwater re-evaluation for the active ingredient fludioxonil was conducted by Department's engineering geology staff. Fludioxonil is the active ingredient contained in Instrata Fungicide and is labeled for the control of turf disease. Based on a February 2003 groundwater technical review, fludioxonil use in Nassau and Suffolk Counties was limited to ornamentals grown in interiorscapes, greenhouses, lath, and shadehouses, containers, or other enclosed structures. Due to groundwater leaching concerns identified during the 2003 technical review, the use of fludioxonil on turf was not allowed in Nassau and Suffolk Counties.

In the February 19, 2015 letter, Syngenta indicated that half the current labeled application rate was effective on golf course turf in Nassau and Suffolk Counties. As such, Syngenta requested approval from the Department to add an application rate reduction statement to the NYS label for Nassau and Suffolk Counties instead of completely prohibiting the sale, use, and distribution of Instrata on Long Island. Based on this, the following groundwater re-evaluation was completed using a fludioxonil application rate of 0.85 pounds of active ingredient per acre per year (lbs ai/acre/year).

The re-evaluation included a review of earlier groundwater technical reviews and environmental fate studies along with updated modeling to assess leaching potential using the Leaching Estimation and Chemistry Model for Pesticides (LEACHP). Fludioxonil and two major degradates (CGA-192155 and CGA-265378) were included as part of the groundwater review. Both CGA-192155 and CGA-265378 were major degradates that formed during the soil photolysis study. Since fludioxonil is applied foliarly and likely to undergo degradation through photolysis, it was determined that these two degradates would be modeled with LEACHP even though they were not produced during aerobic soil metabolism processes. No major fludioxonil degradates were produced during the aerobic soil metabolism study.

Summary of Updated LEACHP Modeling

As summarized in the table below, both fludioxonil and CGA-192155 were modeled with a single set of LEACHP parameters. Degradate CGA-265378 was modeled under two scenarios due to the range in estimated soil adsorption coefficients (Koc). With the exception of the CGA-265378 half-life, the model input parameters were derived from either environmental fate studies or parameter estimates provided by Syngenta. The CGA-265378 half-life of 19 days was obtained from a European Food Safety Authority (EFSA) 2007 Scientific Report. Data provided by Syngenta suggested that the actual half-life of CGA-265378 may be considerably less than 19 days so this half-life is considered to be conservative.

| Fludioxonil | | |
|---|---|---|
| **Parameter** | **Value** | **Source** |
| Solubility | 1.53 mg/l | Fludioxonil aerobic soil metabolism study |
| Koc | 1,490 mL/g | Fludioxonil soil adsorption/desorption study |
| $T_{1/2}$ | 346.6 days | Fludioxonil aerobic soil metabolism study |
| Application Rate | 0.85 lbs/acre/yr | Reduced application rate requested by Syngenta |
| **Maximum LEACHP Modeled Leaching Concentration = 0.00997 ppb** | | |

| Fludioxonil Degradate - CGA-192155 | | |
|---|---|---|
| **Parameter** | **Value** | **Source** |
| Solubility | 2.09 mg/l | Syngenta provided solubility in water at pH ~7 |
| Koc | 166 mL/g | CGA-192155 soil adsorption/desorption study from Lakeland sand |
| $T_{1/2}$ | 23.8 days | Syngenta provided rate of degradation study from Pappelacker loamy sand |
| Application Rate | 0.081 lbs/acre/yr | 11.7% of formation from the applied parent during soil photolysis study |
| **Maximum LEACHP Modeled Leaching Concentration = 0.00312 ppb** | | |
| Fludioxonil Degradate - CGA-265378 Model Run #1 | | |
| **Parameter** | **Value** | **Source** |
| Solubility | 7.39 mg/l | Syngenta provided solubility estimate |
| Koc | 27 mL/g | Syngenta provided estimate per EPA Estimation Programs Interface (EPI) software. Koc derived using a representation of the chemical structure. |
| $T_{1/2}$ | 19 days | Modeled estimate from the European Food Safety Authority (EFSA) 2007 Scientific Report |
| Application Rate | 0.117 lbs/acre/yr | 12.3% of formation from the applied parent during soil photolysis study |
| **Maximum LEACHP Modeled Leaching Concentration = 1.51 ppb** | | |
| Fludioxonil Degradate - CGA-265378 Model Run #2 | | |
| **Parameter** | **Value** | **Source** |
| Solubility | 7.39 mg/l | Syngenta provided solubility in water at pH ~7 |
| Koc | 2,522 mL/g | Syngenta provided estimate per EPA Estimation Programs Interface (EPI) software. Koc derived using a log Kow method. |
| $T_{1/2}$ | 19 days | Modeled estimate from the EFSA 2007 Scientific Report |
| Application Rate | 0.117 lbs/acre/yr | 12.3% of formation from the applied parent during soil photolysis study |
| **No Leaching to the 1 Meter Depth Occurred** | | |

LEACHP Modeling Results

Modeling fludioxonil suggests very little leaching from the Riverhead soil occurs. Specifically, the LEACHP model suggested that fludioxonil leaches from the soil column at an estimated concentration of 0.0099 ppb. This leaching concentration is generally consistent with modeling completed in 2003 using an application rate of 0.88 lbs ai/acre/year. The earlier modeling suggested that fludioxonil will leach from the soil column at concentrations below 0.006 ppb. Similar to the parent, the LEACHP modeling suggests that the major degradate CGA-192155 will leach from the Riverhead soil column at a maximum concentration of 0.00312 ppb.

Major degradate CGA-265378 was modeled using adsorption coefficients of 27 and 2,522 mL/g. The modeling suggests that the major degradate CGA-265378 will leach from the Riverhead soil column at a maximum concentration of 1.51 ppb using the 27 mL/g adsorption coefficient while

modeling with the higher Koc value (2,522 mL/g) indicates that no CGA-265378 leaching occurs.

The attached graph is based on the modeling and illustrates the predicted concentrations of fludioxonil and the two major degradates that will leach from a Riverhead soil type during a ten year period with annual applications. The scale on the primary axis is used for degradate CGA-265378 and the secondary axis (right-side of graph) is used for both fludioxonil and CGA-192155. The modeling suggests a gradual accumulation of fludioxonil in pore water leaching from the soil column reaching a peak of approximately 0.01 ppb after ten years of annual usage. With the exception of a single peak concentration of approximately 0.003 ppb, the degradate CGA-192155 leaching concentrations are below 0.001 ppb during the 10-year model period. Modeling of degradate CGA-265378 suggests a cyclic leaching pattern with short duration peaks and a maximum leaching concentration of approximately 1.51 ppb. The leaching concentrations decrease to well below approximately 0.001 ppb after each peak suggesting that CGA-265378 will not accumulate in the groundwater system.

Summary of Terrestrial Field Dissipation Studies

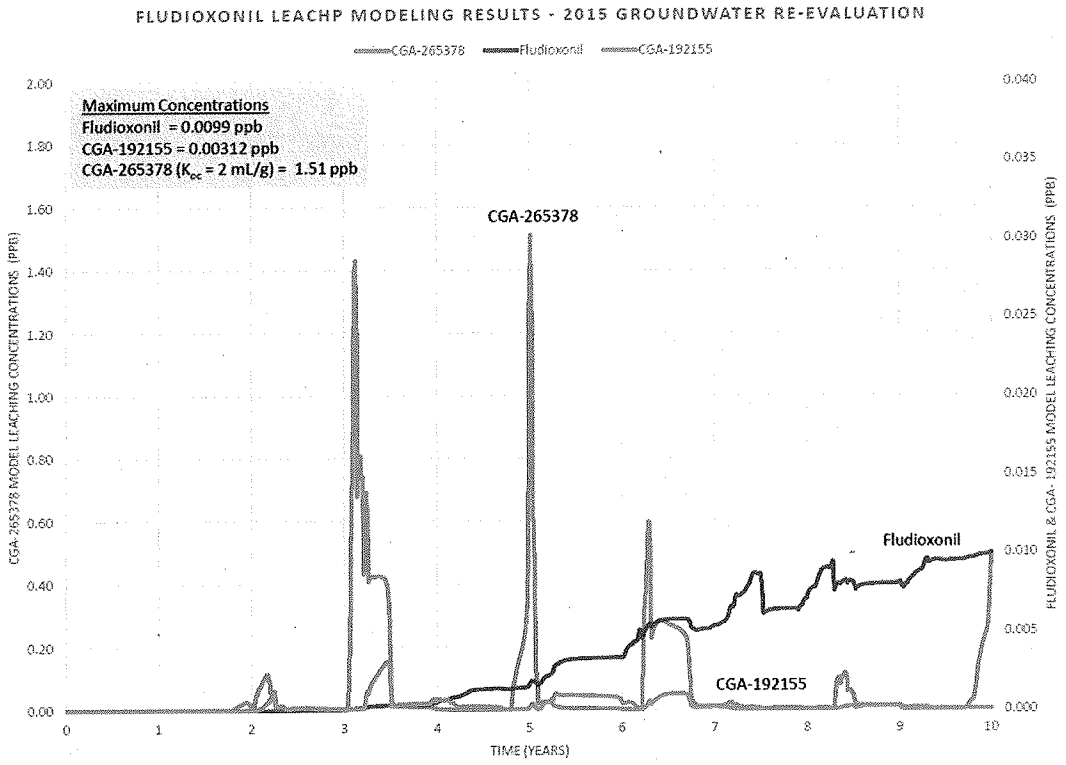
Five separate terrestrial field dissipation studies involving a combination of bareground and turf plots were reviewed as part of this re-evaluation. In each of the terrestrial field dissipation studies, fludioxonil was applied at rates (4.4 lbs ai/acre/year) that exceed the proposed application rate of 0.85 lbs ai/acre/year. The terrestrial field dissipation studies showed most parent and degradate detections occurred in the 0-6 inch depth interval. In a study using a sandy loam soil, the parent and CGA-265378 were not detected below the 0-6 inch depth interval. Degradate CGA-192155 was detected in three soil samples from the 12-18 inch depth interval at concentrations ranging from 10-12 ppb with the last detection occurring 73 days following treatment. In the two field studies using turf plots, no degradates were detected in the soil at any of the depth intervals.

Fludioxonil Environmental Fate Re-Evaluation Summary

Review of project files, environmental fate studies, and related literature for fludioxonil combined with updated LEACHP modeling using the reduced application rate (0.85 lbs ai/acre/year) proposed by Syngenta, suggest that the use of Instrata on turf grass will not result in leaching of fludioxonil and fludioxonil degradates from the soil column at concentrations that will adversely impact Long Island's groundwater. Furthermore, the LEACHP modeling results tend to be consistent with the results from five separate terrestrial field dissipation studies involving a combination of bareground and turf plots.

As described above, to account for some uncertainty associated with Koc and half-life values used for major degradate CGA-265378, the LEACHP model was run under two different scenarios. The modeling results ranged from no leaching occurring from the root zone to a maximum of approximately 1.51 ppb using the most conservative scenario. With this variability, the product should be registered as a restricted use pesticide. This will ensure that properly trained and certified personnel are responsible for the handling and use of this pesticide. It is important that the rate reduction statement be followed when using this pesticide because the two major degradates possess low adsorption coefficients and may have a tendency to leach.

Based on this re-evaluation, groundwater staff approve of the use of fludioxonil at the proposed reduced application rate (0.85 lbs ai/acre/year) in Nassau and Suffolk Counties in New York State.


FLUDIOXONIL LEACHP MODELING RESULTS - 2015 GROUNDWATER RE-EVALUATION
CGA-265378
Fludioxonil
CGA-192155
Maximum Concentrations
Fludioxonil = 0.0099 ppb
CGA-192155 = 0.00312 ppb
CGA-265378 ($K_{oc}$ = 2 mL/g) = 1.51 ppb
CGA-265378
Fludioxonil
CGA-192155
CGA-265378 MODEL LEACHING CONCENTRATIONS (PPB)
FLUDIOXONIL & CGA-192155 MODEL LEACHING CONCENTRATIONS (PPB)
TIME (YEARS)
2.00
1.80
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
0.040
0.035
0.030
0.025
0.020
0.015
0.010
0.005
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