Active Ing. File

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Denise M. Sheehan
Commissioner

July 19, 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Amy Dugger-Ronyak
Regulatory Affairs Specialist
SePRO Corporation
11550 North Meridian Street, Suite 600
Carmel, Indiana 46032-4565

Dear Ms. Dugger-Ronyak:

Re: Registration of a New Pesticide Product, Renovate 3 Herbicide (EPA Reg. No. 62719-37-67690), Which Represents a Major Change in Labeling for the Active Ingredient Triclopyr, Triethylamine Salt

The New York State Department of Environmental Conservation (Department) has reviewed your application, received February 22, 2005, supporting documentation, received January 27, 2006 and January 30, 2006, and several label submissions to register the new product **Renovate 3 Herbicide** (EPA Reg. No. 62719-37-67690) in New York State. The new product adds aquatic uses and represents a major change in labeling for the active ingredient **triclopyr, triethylamine salt** (chemical code 116002).

Renovate 3 Herbicide is labeled for the control of emersed, submersed and floating aquatic plants in aquatic sites such as ponds, lakes, reservoirs, non-irrigation canals, seasonal irrigation waters and ditches which have little or no continuous outflow, marshes and wetlands, including broadleaf and woody vegetation on banks and shores within or adjacent to these and other aquatic sites.

The master label for this product, Garlon 3A (EPA Reg. No. 62719-37), also has the following terrestrial uses: For the control of woody plants, broadleaf weeds and vines in forests and industrial non-crop areas; including manufacturing and storage sites, rights-of-way such as electrical power lines, communication lines, pipelines, roadsides, railroads, fence rows, non-irrigation ditch banks, and around farm buildings; including application to grazed areas, and establishment and maintenance of wildlife openings on these sites, and in Christmas tree plantations. Use within production forests and industrial non-crop sites, in addition to the above listed sites, may include applications to control target vegetation in and around standing water sites, such as marshes, wetlands, and the banks of ponds and lakes.

Dow AgroSciences, LLC has split the label for the basic product and SePRO Corporation has entered into an agreement with Dow AgroSciences to supplementally distribute the aquatic use portion of the master Garlon 3A label. The terrestrial uses appear only on the Garlon 3A (EPA Reg. No. 62719-37) final product label and the aquatic uses only appear on the Renovate 3 Herbicide (EPA Reg. No. 62719-37-67690) final product label.

The Department has reviewed the information supplied to date in support of the registration of Renovate 3 Herbicide (EPA Reg. No. 62719-37-67690) in New York State.

The New York State Department of Health (DOH) stated that Renovate 3 Herbicide and its active ingredient triclopyr triethylamine or acid equivalent triclopyr were not very acutely toxic to laboratory animals by the oral, dermal or inhalation routes of exposure, nor were they irritating to the skin. However, whereas the active ingredient was not very irritating to the eyes, the formulated product was corrosive to the eyes. Both the formulated product and active ingredient were skin sensitizers. Triclopyr appears to have some oncogenic properties, but did not demonstrate genotoxicity, and the United States Environmental Protection Agency (USEPA) classified triclopyr as a Group D chemical (not classifiable as to human carcinogenicity). This chemical, however, demonstrated some developmental toxicity and caused adverse kidney effects in some subchronic and chronic feeding studies as well as in a rat multi-generation reproduction study (parental toxicity). The USEPA Office of Pesticide Programs derived an oral reference dose (RfD) for triclopyr of 0.05 milligrams per kilogram body weight per day (mg/kg/day) based on the no-observed-effect level (NOEL) of 5 mg/kg/day in this latter study and an uncertainty factor of 100.

The USEPA did not conduct a risk assessment for exposure of workers to triclopyr. The USEPA stated, "Short-term and intermediate-term dermal and inhalation exposure assessments are not required because there are no toxicological endpoints of concern. At this time, no chronic risk assessment is required for handler exposures to triclopyr, since none of the current handler exposure scenarios is likely to result in chronic exposure." Despite this statement, the DOH conducted an occupational risk assessment for the labeled use of triclopyr in the Renovate product based on the toxicological endpoint of kidney damage from the rat subchronic feeding study (and multi-generation reproduction study) where a NOEL of 5 mg/kg/day was reported. Accordingly, the DOH calculated a margin of exposure (MOE) of over 100 for combined dermal and inhalation exposures to triclopyr as used in the Renovate product. To calculate this MOE the DOH used the USEPA Pesticide Handler Exposure Database (PHED) to obtain dermal and inhalation exposures to triclopyr of 0.036 and 0.0013 mg per pound of this active ingredient applied. The maximum labeled application rate for triclopyr in the Renovate product is 6 pounds per acre. The DOH conservatively assumed that a worker would treat 200 acres per day. The DOH also used an experimentally derived dermal absorption factor of 1.5 percent provided by the registrant and assumed an inhalation absorption factor of 100 percent. The DOH further assumed that workers (mixer/loader/applicators) wore a single layer of clothing and gloves (the Renovate product requires long-sleeved shirt, long pants, shoes plus sock, chemical-resistant gloves). The USEPA generally considers MOEs of 100-fold or greater to provide adequate worker protection.

There are no chemical-specific federal or New York State drinking water/groundwater standards for triclopyr or its 3,5,6-trichloro-2-pyridol (TCP) degradate. Based on their chemical structures these compounds fall under the 50 microgram per liter (µg/L) New York State drinking water standard for "unspecified organic contaminants" (10 NYCRR Part 5, Public Water Systems). The New York State drinking water standard for the sum of "unspecified organic contaminants" and "principal organic contaminants" is 100 µg/L.

The DOH has several concerns with the Renovate product as labeled. Firstly, because this product is corrosive to the eyes, they have concerns for potential eye damage occurring to swimmers who may enter bodies of water that have been recently treated with the Renovate

product. While the label states that "There are no restrictions on use of water in the treatment area for recreational purposes, including swimming and fishing," the DOH believes that this product should have some swimming restriction on the label to provide time for the product's mixing and dissipation. Secondly, the application instructions for areas near potable water intakes are not compatible with New York State drinking water standards. That is, the apparent acceptable water concentration on the Renovate label is 400 µg/L, but the applicable New York State drinking water standard is 50 µg/L. Consequently, labeled use of Renovate near potable water intakes could result in violations of the drinking water standard. Lastly, the instructions for calculating setback distances from potable water intakes in lakes, reservoirs and ponds are somewhat complicated and require calculations involving logarithms. Such instructions may pose difficulties for some applicators and could result in application of the product at the wrong rate.

In order to address all of the concerns raised by the DOH, a Special Local Need (SLN) label was submitted which specifies the following:

1. The "Recreational Use of Water in Treatment Area" statement has been revised to include a swimming restriction. The SLN label bears the revised statement: "Do not swim in water treated with Renovate 3 for three (3) hours after treatment. There are no restrictions on use of the water in the treatment area for fishing."

2. The application instructions for areas near potable water intakes have been revised to correspond to the New York State drinking water standard of 50 µg/L. The acceptable level has been revised from 400 ppb to 50 ppb. The SLN label states that "the intake must be turned off until the triclopyr level in the intake water is determined to be 50 parts per billion (ppb) or less by laboratory analysis or immunoassay."

3. The setback distances from potable water intakes have been clarified. Charts which specify the required setback distances from functioning potable water intakes for the control of floating and emerged weeds and for the control of submerged weeds have been added. A revised formula for the calculation of setback distances for the control of submerged weeds has also been added.

The Department's Division of Fish, Wildlife & Marine Resources' Bureau of Habitat stated that they have no objection to the registration of Renovate 3 Herbicide.

The Department's groundwater staff stated that triclopyr was first registered with the USEPA in 1979 and is an older chemical. Therefore, the information below was taken from the Reregistration Eligibility Decision (RED) document dated October 1998.

Triclopyr comes in three forms. The acid, which breaks down into the pyridine (TCP) product and an oxamic acid; the salt (TEA), which immediately breaks down into the amine and pyridine products, and the ester (BEE), which breaks down in half a day into an alcohol and the pyridine product. This application is concerned with the salt (TEA); however, the documentation submitted discusses all three forms.

Hydrolysis: Triclopyr acid is stable at pHs 5, 7, and 9. Triclopyr BEE had half-lives of 84, 8.7 and 0.3 days at pHs 5, 7, and 9, respectively. The USEPA found both studies acceptable.

Solubility: Triclopyr acid has a solubility of 430 mg/L, triclopyr TEA has a solublity of 4.12 x 10^5 mg/L, and triclopyr BEE has low solubility of 6.8 ppm.

Soil Photolysis: No data was available for the USEPA to review, and the data requirement for BEE and TEA has been waived since both quickly degrade to the acid.

Aqueous Photolysis: Triclopyr acid had a photolysis half-life at pH 7 of 0.6 days in sterile water. The half-life in river water was 1.7 days. Major degradates in both studies were 5-chloro-3,6-dihydroxy-2-pyridinyloxyacetic acid ("acetic acid degradate") and oxamic acid at 48% and 16%, respectively. Triclopyr BEE had a half-life of 6.6 days in a sterile pH 5 aqueous buffer solution. The major degradate was CO_2 at 29.4%. The USEPA found both studies acceptable.

Aerobic Soil Metabolism: Triclopyr acid had a half-life of 8 days in a silty clay loam and 18 days in a silt loam. Degradate TCP was found at 26%, but was not persistent. Triclopyr TEA had a half-life of 5.6 days in a sandy loam and 13.7 days in a silt loam soil. CO_2 was the major degradate at >60% at 24 days after treatment (DAT) in the sandy loam and 91 DAT in the silt loam. The USEPA found both studies acceptable.

Aerobic Aquatic Metabolism: Triclopyr acid had a half-life of 142 days in a silty clay soil:water system. TCP was found at <5%. For triclopyr TEA, degradation was slow during the first 14 days, then rapid in the next 4 days, leaving only 5% of parent. 2-butoxyethanol degraded with a first order half-life of 0.6-3.4 days. The intermediate metabolite, 2-butoxyacetic acid, reached 53.9% at 3 DAT, and declined with an observed half-life of approximately 1 day. These studies only partially fulfilled the guideline.

Anaerobic Aquatic Metabolism: Triclopyr BEE degraded to triclopyr acid in 5 hours in two sandy loams. The triclopyr acid then was persistent with a registrant calculated half-life of about 3.5 years. TCP was found at 25% at 365 DAT. Triclopyr TEA had a calculated half-life of 2 years. 2-butoxyethanol degraded with a first order half-life of 1.4 days. The intermediate metabolite, 2-butoxyacetic acid reached 71.8% at 7 DAT, with a half-life of 73.3 days, eventually degrading to CO_2. The USEPA found all the studies acceptable.

Adsorption/Desorption: The USEPA found this study acceptable. Triclopyr acid was very mobile in sand, silt loam, clay loam and sandy loam soils with K_{oc}s of 134, 25, 25, and 53, respectively. Adsorption was not related to percent organic carbon. The triclopyr degradates were very mobile in sand, sandy loam, silt loam and clay loam with K_{oc}s ranging from 74-384. The USEPA found these studies acceptable.

Field Dissipation: Triclopyr BEE degraded in a sandy loam soil with a calculated half-life of 1.1 days. Total triclopyr (triclopyr acid and BEE) degraded in the 0-7.5 cm depth with a calculated half-life of 10.6 days. Total triclopyr was detected up to 45 cm at a maximum of 0.14 ppm. Two degradates were found, TCP at up to 0.33 ppm at 26 DAT, decreasing to 0.03 ppm at 52 weeks after treatment. TMP was found at a maximum of 0.17 ppm at 7 DAT, decreasing to 0.02 at 52 weeks after treatment. Triclopyr BEE degraded in a loam soil with a calculated half-life of about 14 DAT. Total triclopyr (triclopyr acid and BEE) degraded with a calculated half-life of 33 days. Two degradates were found, TCP at 0.067 at 28 weeks and TMP at 0.05 in all test intervals. EPA found the BEE studies acceptable.

Forestry: Triclopyr BEE was applied to forested sites; triclopyr was recovered from surface water as triclopyr BEE, from sediment as triclopyr acid, and total triclopyr from foliage, soil, litter, aquatic plants and fish. TCP was found in foliage, soil, litter, aquatic plants and fish.

Methoxypyridine was detected at 0.01 ppm only in the soil. Total triclopyr in the foliage was >500 ppm at day 0 and decreased to 200 ppm and stayed there for 29 days, the last test day. Total triclopyr and TCP dissipated from soil with half-lives of 26 and 85 days, respectively.

Groundwater Monitoring: The USEPA presented limited groundwater monitoring data in the RED. Detections were reported in 5 wells in two states out of 379 analyzed for triclopyr. One well in Texas contained 0.58 ppb triclopyr, and four wells in Virginia were found to contain 0.006 to 0.018 ppb of triclopyr. No information was provided on the use of triclopyr near the wells.

USEPA Comments: Triclopyr acid is somewhat persistent, and is mobile. The predominant degradation pathway for triclopyr in water is photodegradation. The predominant degradation pathway in soil is microbial degradation to the major degradate TCP, which is both persistent and mobile.

SUMMARY

Even though triclopyr is mobile, it has a short half-life. Data from the USGS NAWQA site for "triclopyr" indicates about a 1.5% rate of detection in groundwater in the US for 1998.

The Department currently has about 40 triclopyr products registered for use in New York State. This major change in label adds application to control emersed, submersed and floating aquatic plants in aquatic sites such as ponds, lakes, reservoirs, non-irrigation canals, seasonal irrigation waters and ditches which have little or no continuous outflow, marshes and wetlands, including broadleaf and woody vegetation on banks and shores within or adjacent to these and other aquatic sites. Application to water bodies does not generally have a significant negative impact on groundwater, and therefore, groundwater staff have no objection to the registration of Renovate 3 Herbicide as labeled.

The Department concludes that Renovate 3 Herbicide 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 of New York State when used in accordance with the Special Local Need labeling.

The SLN labeling specifies the use restrictions and the aquatic uses allowed in New York State for **Renovate 3 Herbicide** (EPA Reg. No. 62719-37-67690).

Therefore, under the authority of Section 24(c) of FIFRA, the Department hereby grants a Special Local Need registration for Renovate 3 Herbicide (EPA Reg. No. 62719-37-67690). The product is assigned the registration number **SLN No. NY-060001**.

The supplemental SLN labeling contains the only aquatic uses allowed in New York State. All precautionary statements, applicable use directions, use precautions and limitations of the labeling affixed to the Renovate 3 Herbicide container must be followed.

The product, Renovate 3 Herbicide (SLN No. NY-060001), as noted on the "restriction" column on the certificate, is classified as "restricted use" in New York State under rules and regulations 6NYCRR 326.2(h). 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."

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/dshm/pesticid/prl.htm* or call (518) 402-8748.

The Certificate of Pesticide Registration and a copy of the New York State stamped "ACCEPTED" SLN labeling for Renovate 3 Herbicide are enclosed for your records.

Please be reminded that a copy of the accepted SLN label **must** be distributed with all product sold in New York State and be in the possession of the user at the time of pesticide application.

The Department received, on July 13, 2006, the draft Supplemental Environmental Impact Statement (SEIS) entitled "Use of the Aquatic Herbicide Triclopyr - Renovate 3 in the State of New York - Supplemental Environmental Impact Statement - Draft." The draft SEIS was prepared and submitted by ENSR Corporation on behalf of SePRO Corporation. In accordance with New York's **State Environmental Quality Review Act** (SEQR), the use of Renovate 3 Herbicide in New York State is dependent on the review and approval of the draft Supplemental Environmental Impact Statement (SEIS).

If you have any questions, please contact 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

bcc: w/enc. - PCS III, Reg. 1
PCS II's - Regions 2 - 9
J. Broughel
Product File
Chemical File
Active Ingredient File

bcc: w/o enc. - Daybook

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