NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

Division of Materials Management, Bureau of Pest Management
625 Broadway, 9th Floor, Albany, New York 12233-7257
P: (518) 402-8768 F: (518) 402-9024
www.dec.ny.gov ppr@dec.ny.gov

July 6, 2016

VIA E-MAIL (Company # 10163)

Ms. Kyla Smith
Gowan Company
P.O. Box 5569
Yuma, Arizona 85366

Re: Registration of Magister SC Miticide (EPA Reg. No. 10163-322) for Application to Food Crops. Contains the Active Ingredient: Fenazaquin (chemical code: 044501).

Dear Ms. Smith:

The New York State Department of Environmental Conservation (Department) has completed the technical review of the application and data package for the above-referenced product received on August 7, 2015. Magister SC Miticide contains the active ingredient fenazaquin and was submitted as a major change in labeled use application (MCL) for the first use on food crops in New York State.

The active ingredient fenazaquin was reviewed as a new active ingredient (NAI) and registered by the Department on May 20, 2011 for use on indoor and outdoor ornamental plants, Christmas tree plantations, and non-bearing fruit and nut trees at a maximum outdoor use rate of 0.30 lb. fenazaquin per acre. The current MCL application reviews use on food crops (almond trees and cherry trees) and increases the application rate to 0.45 lb. fenazaquin per acre on these crops.

Magister SC Miticide contains 18.79% fenazaquin and is applied at a maximum rate of 36 ounces of formulated product or 0.45 lb. fenazaquin per acre. Magister SC Miticide is applied by ground sprayer or airblast foliar application after petal fall and is limited to one application per year. The product labeling contains restrictive label language to protect pollinators and aquatic organisms. Fenazaquin belongs to the quinazoline class of chemicals and is a mitochondrial electron transport inhibitor.

Pursuant to the review time frame specified in ECL 33-0704.2, a registration decision date of August 7, 2016 had been established. The application was fully reviewed for impacts with regard to human health, non-target organisms, and groundwater. The complete assessments are located in the appendix of this letter.
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There were no outstanding issues or concerns related to the active ingredient fenazaquin. The Department has therefore **registered** Magister SC Miticide. Attached for your record are copies of the Certificate of Pesticide Registration and stamped "Accepted for Registration" label.

Please note that a proposal by Gowan Company or any other registrant to register a product that contains fenazaquin, and whose labeled uses are likely to increase the potential for significant impact on humans, non-target organisms, especially pollinators, or the environment, would constitute a major change in labeled (MCL) use application. Such an application must be accompanied by a new application fee and meet the requirements for major change in labeling applications as listed on our website: [http://www.dec.ny.gov/chemical/99260.html](http://www.dec.ny.gov/chemical/99260.html).

Please be aware that any unregistered product or labeling may not be sold, offered for sale, distributed, or used in New York State.

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, P.E.
Director
Bureau of Pest Management

Enclosures
APPENDIX

HUMAN HEALTH ASSESSMENT

The New York State Department of Health, Bureau of Toxic Substance Assessment (DOH) reviewed the application and supporting data submitted by Gowan Company to register the pesticide product Magister SC Miticide (EPA Reg. No. 10163-322) in New York State. This pesticide product contains the active ingredient fenazaquin and is labeled for control of mites and whiteflies on cherries and almonds. Fenazaquin is currently registered in the state for use on ornamental plants, Christmas tree plantations, non-bearing fruit and nut trees, and established ornamental landscape plantings. The proposed use of fenazaquin on cherries and almonds represents the first food use for this active ingredient and has been determined by Pesticide Product Registration Section staff to represent a major change in labeled use pattern for this active ingredient in New York State.

Toxicity Review

We have previously reviewed the active ingredient fenazaquin in the pesticide product Magus Miticide. On an acute basis, the technical grade active ingredient fenazaquin and the formulated product Magister SC Miticide were moderately acutely toxic by the oral route of exposure, but not very acutely toxic via the dermal and inhalation routes of exposure in laboratory animal studies. Neither the active ingredient nor the formulated product were eye or skin irritants (tested on rabbits), but both were presumed (in lieu of acceptable dermal sensitization studies demonstrating otherwise) to be skin sensitizers (tested on guinea pigs).

Fenazaquin caused similar, non-specific effects (decreases in body weight, body weight gain, food intake, and food efficiency) in rats, dogs and hamsters in chronic feeding studies. Fenazaquin did not cause significant reproductive/developmental toxicity or carcinogenicity and was mostly negative for genotoxicity. The U.S. Environmental Protection Agency (U.S. EPA) Office of Pesticide Programs (OPP) calculated acute oral reference doses (aRfD) for fenazaquin of 0.15 milligrams per kilogram body weight per day (mg/kg/day) for the general U.S. population based on a no-observed-effect-level (NOEL) of 15 mg/kg/day in an immunotoxicity study in rats (general ataxia and hypoactivity) and an uncertainty factor of 100. The U.S. EPA OPP additionally derived a chronic oral reference dose (cRfD) for all population groups of 0.05 mg/kg/day based on NOELs of 5 mg/kg/day from two co-critical feeding studies (subchronic and chronic) in dogs (decreased body weight, food consumption and food efficiency) and an uncertainty factor of 100. A current search of the toxicological literature did not find any significant new information on the toxicity of fenazaquin.

Dietary Risk Assessment

The U.S. EPA established tolerances for fenazaquin residues in or on almonds and cherries (Federal Register 80(87):25,953-8, May 6, 2015). The acute population
adjusted dose (aPAD) for fenazaquin is 0.15 mg/kg/day and has the same basis as the aRfD. The U.S. EPA estimated that acute dietary exposures to fenazaquin residues from all crops for which there are tolerances and from drinking water would be three percent of the aPAD for the general U.S. population, five percent for all infants less than one-year-old and ten percent for children one to two years old, the highest exposed subgroup. The chronic population adjusted dose (cPAD) for all population subgroups is 0.05 mg/kg/day and has the same basis as the cRfD. The U.S. EPA estimated that chronic dietary exposure to fenazaquin residues from all crops for which there are tolerances and drinking water would be two percent of the cPAD for the general U.S. population, four percent for all infants less than one-year-old and ten percent for children one to two years old, the most highly exposed subgroup. These exposure analyses are based on the conservative assumption that 100 percent of the crops are treated, and that treated crops contain average residues as determined in field trials. Actual exposure levels are likely to be less than those determined in this assessment.

Occupational Risk Assessment

The U.S. EPA reported the results of an occupational risk assessment for short-term (1-30 days) inhalation exposures to fenazaquin from use on almonds and cherries via aerial, airblast and mechanically pressurized handgun application methods. Dermal risks were not assessed because a hazard for the dermal route of exposure was not observed for fenazaquin. For determining margins of exposure (MOEs), the U.S. EPA compared estimated short-term inhalation exposures to a NOEL of 5 mg/kg/day from co-critical sub-chronic and chronic feeding studies in dogs (decreased body weight, food consumption and food efficiency). For aerial applications (350 acres per day), the short-term inhalation MOEs for mixer/loaders were 12,000 and 100,000 for aerial and airblast applications, respectively. The inhalation MOEs for applicators in these scenarios were 520,000 and 4,700, respectively. The short-term MOE for mixers/loaders/applicators of fenazaquin via mechanically pressurized handgun was 11,000 for inhalation exposures. These estimates assumed a single application per season and that workers wore long-sleeved shirt and pants, shoes plus socks and chemical-resistant gloves (as well as coveralls for mixing/loading/applying Magister via mechanically pressurized handgun) as per label requirements. The U.S. EPA considered MOEs of 100-fold or greater in these scenarios to provide adequate worker protection from fenazaquin exposures.

Drinking Water/Groundwater Standards

There are no chemical specific federal or New York State drinking water/groundwater standards for fenazaquin. Based on its chemical structure, this chemical falls under the 50 micrograms per liter (µg/L) New York State drinking water standard for “unspecified organic contaminants” (10 NYCRR Part 5, Public Water Systems). In addition, the U.S. EPA has established non-cancer Human Health Benchmark guideline values (i.e., levels in drinking water at or below which adverse health effects are not anticipated from onetime or lifetime exposures) for fenazaquin of 1,000 µg/L for acute exposures to children and 350 µg/L for chronic exposures to the general public. The U.S. EPA
Benchmark guideline values have been developed for pesticide active ingredients that may be found in surface or groundwater sources of drinking water to enable "stakeholders to better determine whether the detection of a pesticide in drinking water or source waters for drinking water may indicate a potential health risk."

**Summary/NYS DOH Recommendation**

The available information indicates that fenazaquin and the formulated product were moderately acutely toxic by the oral route of exposure, but not very acutely toxic via the dermal and inhalation routes of exposure in laboratory animal studies. Fenazaquin consistently caused decreases in body weight, food consumption and food efficiency regardless of species, sex or duration in laboratory animal studies. However, this active ingredient was not teratogenic, neurotoxic or carcinogenic and has been classified by the U.S. EPA as "not likely to be carcinogenic to humans." The estimated acute and chronic dietary risks from exposure to fenazaquin on treated crops and in drinking water were within the range considered acceptable by the U.S. EPA. In addition, the expected exposure from the labeled use of the formulated product should not pose significant risks to workers. Given the above, we do not object to the registration of Magister SC Miticide in the state on the basis of health risks from worker use or dietary exposures.

**ENVIRONMENTAL FATE ASSESSMENT**

The following is the groundwater environmental fate technical review for the major change in labeling application for fenazaquin contained in Magister SC Miticide (EPA Reg. No. 10163-322). The fenazaquin application was submitted on August 4, 2015 by Gowan Company (Gowan). The MCL is necessary because the registrant is proposing use of fenazaquin on food crops at an increased application rate. Specifically, the initial technical review evaluated a maximum annual application rate of 0.30 pounds active ingredient per acre (lbs ai/acre) on non-food crops while the current application proposes a maximum annual application rate of 0.45 lbs ai/acre on cherry and almond crops.

The groundwater review indicates that the labelled use of Magister SC Miticide does not represent a groundwater quality concern when applied at the increased maximum application rate. Specifically, the leaching estimation and chemistry model for pesticides (LEACHP) predicted no leaching of fenazaquin and the fenazaquin major degradates from the Riverhead soil profile. This modeling is generally consistent with the results of environmental fate studies provided by the registrant and the March 8, 2012 US EPA Drinking Water Assessment for fenazaquin. Based on this evaluation, and as summarized in the following sections, the results of this groundwater technical review support registration of fenazaquin at the increased application rate included in the Magister SC Miticide product label.

**Overview**

This groundwater technical review is based on an assessment of environmental fate studies, US EPA registration assessment documents, and modeling results using LEACHP. Of particular importance for LEACHP modeling is the selection of representative environmental fate parameters. This includes values for half-life, solubility, adsorption coefficient, and application rates for both the parent and major...
degradates. As such, review of the environmental fate studies submitted by Gowan focused on identifying these model input parameters. This groundwater technical review provides a summary of the environmental fate studies and their relation to the selection of model input parameters along with a summary of the LEACHP modeling results.

Since the proposed label allows for use of Magister SC Miticide on Long Island, the product was modeled under the Long Island soil scenario using the Riverhead soil type. This includes the selection of environmental fate parameters derived from soil types containing a high percentage of sand (preferably greater than 85%), a pH of approximately 5.5, and a percent organic matter of approximately one percent or less. As discussed below, two major fenazaquin degradates (metabolites identified at greater than 10% of the total applied radioactivity) were identified during a soil photolysis study and were also included in the LEACHP modeling.

**Summary of Environmental Fate Studies**

To evaluate the degradation of fenazaquin, the registrant completed a single aerobic soil metabolism study on a sandy loam soil type. The soil originated from Indiana and contained 66% sand, 21% silt, 13% clay, 0.9% organic carbon, and had a pH of 7.7. No major degradates were identified during the aerobic soil metabolism study.

The aerobic soil metabolism study indicates that fenazaquin is not overly persistent and degrades with half-lives ranging from approximately 56 to 121.6 days. As discussed below, this range in aerobic soil metabolism half-life values is consistent with the half-life values (20.7 to 82.5 days) derived from nine terrestrial field dissipation studies. As summarized in Table 1, the half-life value of 121.6 days was used to evaluate fenazaquin behavior with the LEACHP model.

Although aerobic soil metabolism studies were not completed on two major fenazaquin degradates identified during the soil photolysis study, half-life values for 4-hydroxyquinazoline and 4-tert-butylphenylethyl alcohol were obtained from a Pesticide Properties Database (http://sitem.herts.ac.uk/aeru/ppdb/en/). As summarized in Table 1, the two fenazaquin degradates are not persistent with half-life values for both estimated to be less than one day.

In addition to evaluating the microbial breakdown of fenazaquin, a soil photolysis study was completed to evaluate photodegradation. The soil photolysis study showed that fenazaquin photodegraded with a half-life of 13.9 days and that two major degradates are produced. Specifically, 4-hydroxyquinazoline and 4-tert-butylphenylethyl alcohol formed at maximum percentages of 37.9% and 18.5% respectively. As major degradates, both 4-hydroxyquinazoline and 4-tert-butylphenylethyl alcohol were modeled with LEACHP as part of this groundwater technical review.

Based on four separate studies to evaluate adsorption characteristics (Koc), fenazaquin is considered to have a low mobility in soil. Specifically, fenazaquin Koc values ranged from 31,333 to 101,083 mL/g in sand and clay loam soil types. For reference, compounds with Koc values greater than 5,000 mL/g are considered immobile according to a commonly used McCall soil mobility classification system. The Koc value of 31,333 mL/g was used as a LEACHP input parameter for fenazaquin since this value was derived from a sand soil type most similar in composition to Long Island soil. In particular, this soil was comprised of nearly 90% sand and contained less than 1% organic carbon.
Similar to the source for major degradate half-life values, Koc values for the major degradates (Table 1) were derived from the Pesticide Properties Data Base described above. The fenazaquin major degradates are considered moderately mobile in soil with Koc values for 4-hydroxyquinazoline and 4-tert-butylphenylethyl alcohol estimated at 227 and 168 mL/g respectively.

Nine separate terrestrial field dissipation studies were completed using a combination of foreign and domestic soil types (Indiana, Germany, and Italy). Each study included a single fenazaquin application to bare ground plots that ranged from 0.134 to 0.20 lbs ai/acre. Based on the terrestrial field dissipation studies, the half-lives for fenazaquin ranged from 20.7 days to 82.5 days. During the terrestrial field dissipation studies the fenazaquin degradates were not quantified. As such, the mobility of the transformation products and fenazaquin dissipation routes could not be determined during the terrestrial field dissipation studies.

In addition to the terrestrial field dissipation studies, two soil column leaching studies were completed to assess fenazaquin leaching and transformation. Similar to the aerobic soil metabolism study and the terrestrial field dissipation studies, fenazaquin half-life values ranged from 33 to 37 days based on the soil column leaching studies. No major degradates were identified during either of the soil column leaching studies. The soil column leaching studies also confirmed that fenazaquin has an overall low mobility in soil.

Fenazaquin and the fenazaquin degradates have a broad range in aqueous solubility values. As summarized in Table 1 below, fenazaquin has a low to moderate solubility (0.102 parts per million (ppm)), 4-tert-butylphenylethyl alcohol is moderately soluble (577 ppm) and 4-hydroxyquinazoline is highly soluble (17,400 ppm).

<table>
<thead>
<tr>
<th>Parent/Degradate</th>
<th>Solubility (ppm)</th>
<th>Half-Life (days)</th>
<th>Koc (mL/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenazaquin</td>
<td>0.102</td>
<td>121.6</td>
<td>31,333</td>
</tr>
<tr>
<td>4-hydroxyquinazoline</td>
<td>17,400</td>
<td>0.1</td>
<td>227</td>
</tr>
<tr>
<td>4-tert-butylphenylethanol</td>
<td>577</td>
<td>0.16</td>
<td>168</td>
</tr>
</tbody>
</table>

**LEACHP Modeling of Fenazaquin**

The environmental fate parameters described above and as summarized in Table 1 were used as LEACHP model input values to assess the leaching potential of fenazaquin and two major fenazaquin degradates (4-hydroxyquinazoline and 4-tert-butylphenylethyl alcohol) from the Riverhead soil profile. With a high sand percentage and low organic carbon content, the Riverhead soil profile is considered representative of conditions occurring on Long Island. The LEACHP modeling suggests that no leaching of fenazaquin and the two major fenazaquin degradates occurs from the Riverhead soil column during the 10 year modeling period.

**Groundwater Technical Review Summary**

In summary, results of the groundwater technical review support registration of the major change in label application for Magister SC Miticide containing the active ingredient fenazaquin. Based on review of the environmental fate studies, fenazaquin is not mobile and not overly persistent in the natural environment. When modeled using conditions representative of Long Island, New York, no leaching of fenazaquin occurs from the
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Riverhead soil profile. This LEACHP modeling is also consistent with terrestrial field dissipation studies that showed no patterns indicative of leaching.

Although the fenazaquin degradates are moderately mobile relative to the parent, they have short half-lives and are not expected to persist in the natural environment. These characteristics are evident in the results of LEACHP modeling along with a series of soil column leaching studies. Specifically, and similar to the parent, the LEACHP modeling suggested no leaching of the fenazaquin major degradates during the 10 year model period. Similarly, the column leaching studies showed very little downward movement of the fenazaquin degradates and these degradates were not detected above 10% of the applied radioactivity (i.e. minor transformation products). The LEACHP results are also consistent with the US EPA Tier 1 screening as part of the Drinking Water Assessment for fenazaquin. The EPA total estimated drinking water concentration for fenazaquin and two metabolites was conservatively estimated at 0.0704 ppb.

Overall, the groundwater technical review associated with the increased application rate for fenazaquin indicates that the use of Magister SC Miticide in accordance with the submitted label does not represent a groundwater concern in New York State. This includes the use of fenazaquin in areas like Nassau and Suffolk Counties where groundwater resources tend to have an increased susceptibility to surface contaminants. Based on this review, groundwater staff approve of the major change in label use of fenazaquin in New York State.

**ECOLOGICAL ASSESSMENT**

The New York State Department of Environmental Conservation, Bureau of Habitat (BOH) initially reviewed fenazaquin in 2010 for whitefly and mite control on indoor and outdoor non-food crops- ornamentals, Christmas tree plantations, and non-bearing fruit and nut trees. The current submission, Magister SC, is the first food use label for fenazaquin.

The Magister SC label increases application fenazaquin rates to a maximum of 0.45 pounds active ingredient per acre (lbs. ai/A) from the previously reviewed 0.30 lbs.ai/A. The initial federal application included many agricultural crops grown in New York State but the current label only includes cherries and almonds.

**USE PROFILE**

Magister SC is labeled for Tetranychidae mite control on cherries and almonds. One application per year is allowed at 0.3-0.45 pounds active ingredient per acre. The application is made only after all trees in the treated orchard have completed the petal fall growth stage. Only ground sprayer or airblast applications are allowed, no aerial application or chemigation is permitted.

The Magister SC label includes extensive warnings and directions to avoid impacts to bees and other insect pollinators in use areas. It may not be applied within 25 feet of surface waters.
MODE OF ACTION

Fenazaquin, 4-tert-butylphenethyl quinazolin-4-yl ether, is a contact mitochondrial Complex I electron transport inhibitor belonging to the Group 21 Acaricides/Insecticides. It disrupts cellular respiration in exposed organisms. It is the first of quinazoline class active ingredients.

I. PHYSICAL/CHEMICAL PROPERTIES

Fenazaquin has a water solubility of 0.102 mg/L. Its octanol/water partition coefficient (Kow) is 512,861, Log Kow is 5.71. It has low vapor pressure, 1.4 x 10^{-7} mm Hg, partitioning coefficient (Koc) ranges from 15,800- 101,083 L/kg, with a mean of 26,175.

II. TOXICITY

Fenazaquin is slightly toxic to birds and mammals on an acute basis. Predicted field food item residues at the maximum label rate approach mammalian chronic toxicity thresholds. Fenazaquin is very highly toxic to aquatic organisms.

III. EXPOSURE

Fenazaquin is persistent post application, the parent compound is virtually immobile in soil. The environmental fate description is weak. The formation and decline of degradation products produced during terrestrial field dissipation studies was not determined.

Fenazaquin hydrolysis is pH dependent, its half-life (T_{1/2}) at pH 5, 7, and 9 is 9.6, 131, and 217 days respectively. The aquatic photolysis T_{1/2} is 54 days. Its aerobic soil metabolism T_{1/2}s range from 64-174 days in different soils. Aerobic aquatic metabolism T_{1/2} values are 59-143 days. Reported terrestrial field dissipation T_{1/2}s are 34-44 days for parent compound. Two metabolites of toxic concern are produced but were not monitored for during field studies. In laboratory degradation studies inclusion of the metabolites in a total toxic residue approach lengthen the dissipation T_{1/2}s to 73-197 days in aerobic soil tests, and 65-291 days in aerobic aquatic tests.

Non-target exposures to fenazaquin are expected to be limited given the relatively small use pattern and immobility of the parent compound following application.

Standard BOH terrestrial and aquatic non-target organism screening level (worst-case) exposure modeling was conducted for fenazaquin. Refined aquatic modeling simulations were also run using more realistic field parameters. Field parameters were set to 55% foliar interception and 40% runoff with the percentage of applied pesticide dissolved in the runoff set at 0.25%; 0.5%; and 1% for the pond scenarios.
IV. MODELING RESULTS AND RISK ASSESSMENT

No avian toxicity thresholds were exceeded on any food items when modeled using the highest label application rate and Upper Limit residue levels (those expected immediately following application). Mammalian chronic toxicity thresholds were slightly exceeded on 2 of the higher-residue food items (short grass and leafy crops) using the same parameters.

Using screening level post-application runoff parameters acute and chronic toxicity thresholds are exceeded for both freshwater and marine organisms. When more field-appropriate parameters are used the predicted toxicity drops significantly, to acceptable levels.

V. BOH SUMMARY

For this limited application, cherries are a relatively small use at 2,600 NY acres, and limited to 1 application per year. Fenazaquin used as labeled is not likely to negatively impact non-target resources. The acreage of NY crops represented by the federally approved master label is significantly larger than this current label. There are additional fenazaquin pollinator studies underway which will need to be included in review of any new or expanded use. Therefore, BOH has no objection to the labeled use of this product on cherry trees in New York State.