

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

Bureau of Pesticides Management, 11th Floor
625 Broadway, Albany, New York 12233-7254
Phone: (518) 402-8788 • **FAX:** (518) 402-9024
Website: www.dec.ny.gov

January 7, 2008

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Leslie Garcia
Registration Submission Specialist
Valent U.S.A. Corporation
P.O. Box 8025
Walnut Creek, California 94596-8025

Dear Ms. Garcia:

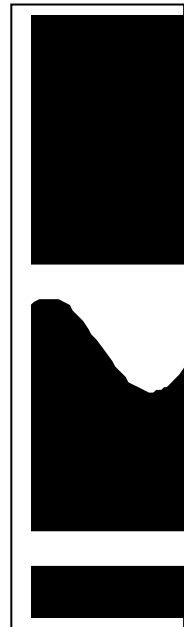
Re: Denial of Applications to Register the New Active Ingredient Dinotefuran Contained in the Pesticide Products Safari 20 SG Insecticide (EPA Reg. No. 33657-16-59639), Venom 20 SG Insecticide (EPA Reg. No. 33657-17-59639) and Venom Insecticide (EPA Reg. No. 59639-135)

The New York State Department of Environmental Conservation (Department) has reviewed the applications (received August 8, 2005 and August 15, 2005) and supplemental information (received October 27, 2005, February 21, 2007 and July 10, 2007) submitted to date by Valent U.S.A. Corporation (Valent) and Landis International (Regulatory Agent for the basic registrant Mitsui Chemicals, Inc.) regarding registration of the subject pesticide products containing the new active ingredient dinotefuran (Chemical Code 044312).

In a technical issues letter, dated October 6, 2006, the Department notified Valent of the potential for unacceptable risks to nontarget organisms and groundwater resources from use of the subject products, as labeled. These risks were also noted in the registration letter to Landis International for Dinotefuran Technical (EPA Reg. No. 33657-10). The technical issues letter and registration decision for Dinotefuran Technical are available on the Cornell University Pesticide Management Education Program (PMEP) website (<http://pmep.cce.cornell.edu/profiles/index.html>).

The active ingredient dinotefuran has subsequently been registered for indoor use and for use on dogs in New York State. As of the date of this letter, dinotefuran is not registered for outdoor use in the State.

The subject applications were deemed complete for purposes of technical review on May 8, 2006. Pursuant to the review time frame specified in Environmental Conservation Law (ECL) §33-0704.2, a registration decision date of October 5, 2006 was established. By mutual consent, the decision date was waived to allow the registrant to address anticipated adverse effects to nontarget organisms and



groundwater resources noted in the Department's technical issues letter. To date, the information provided by Valent and Landis International has not mitigated the Department's concerns.

Safari 20 SG Insecticide (EPA Reg. No. 33657-16-59639) is labeled for application as a foliar spray, broadcast spray, soil drench, and via chemigation for insect control in ornamental plants grown in commercial, industrial, and residential areas, indoor and outdoor nursery and greenhouse ornamental production. The maximum foliar spray application rate is a total of 2.7 lbs. Safari 20 SG Insecticide (0.54 lb. active ingredient) per acre per season. For outdoor and landscape ornamentals, broadcast applications cannot exceed a total of 2.7 lbs. product (0.54 lb. ai) per acre per year.

Venom 20 SG Insecticide (EPA Reg. No. 33657-17-59639) is labeled for control of sucking and chewing insects infesting leafy vegetables (except Brassica). The maximum foliar application rate is a total of 1.34 lbs. Venom 20 SG Insecticide (0.268 lb. ai) per acre per season. The maximum soil application rate is a total of 2.68 lbs. product (0.536 lb. ai) per acre per season.

Venom Insecticide (EPA Reg. No. 59639-135) is labeled for control of sucking and chewing insects infesting cotton, cucurbits, fruiting vegetables, grapes, head and stem Brassica, leafy vegetables and potatoes. Cucurbit, fruiting vegetable, head and stem Brassica and leafy vegetable maximum foliar and soil application rates are 6 oz. product (0.268 lb. ai) and 12 oz. product (0.536 lb. ai) per acre per season, respectively. Foliar applications cannot be combined with soil applications, or vice versa. Only one application method can be employed. For grapes, the maximum foliar and soil application rates are 6 oz. product (0.264 lb. ai) per acre per season. No more than a total of 0.754 lb. product (0.528 lb. ai) per acre per season can be applied regardless of application method. For potatoes, the maximum foliar application rate is a total of 4.5 oz. product (0.198 lb. ai) per acre per season. The maximum soil application rate is a total of 7.5 oz. product (0.33 lb. ai) per acre per season. Regardless of application method, no more than a total of 0.754 lb. product (0.528 lb. ai) per acre per season can be applied.

Toxicological, ecological effects and environmental fate risk assessments were conducted for dinotefuran and the three end-use products.

TOXICOLOGICAL RISK ASSESSMENT: Safari 20 SG Insecticide and Venom 20 SG Insecticide (which are identical in formulation) as well as Venom Insecticide were not very acutely toxic in laboratory animal studies by the oral, dermal or inhalation routes of exposure. Whereas Venom Insecticide was neither very irritating to the eyes or skin (tested on rabbits), the Safari/Venom 20 SG products were both moderate eye and skin irritants. None of these formulated products were dermal sensitizers (tested on guinea pigs).

Concurrent with the review of the subject formulated products, the new active ingredient dinotefuran was reviewed in the product Dinotefuran Technical (labeled for formulating purposes only). On an acute basis, Dinotefuran Technical was not very toxic nor was it very irritating to the eyes or skin. Also, it was not a dermal sensitizer. Dinotefuran did not demonstrate developmental toxicity, genotoxicity or carcinogenicity. However, data from other studies indicated that this chemical has the potential to cause some neurotoxic, immunotoxic and reproductive effects. The United States Environmental Protection Agency (USEPA) classified dinotefuran as "not likely to be a human carcinogen." The USEPA Office of Pesticide Programs calculated an oral reference dose (RfD) of 0.02 milligrams per kilogram body weight per day (mg/kg/day) for dinotefuran based on the lowest-observed-effect level (LOEL) of 20 mg/kg/day in a one-year dog feeding study (decreased thymus weights in males) and an uncertainty factor of 1,000 (100x to account for

intraspecies and interspecies differences and an additional 10x to account for using a LOEL instead of a no-observed-effect level).

The USEPA established tolerances for dinotefuran residues in or on head and stem Brassica at 1.4 parts per million (ppm); grapes (0.9 ppm); potatoes (0.05 ppm); cucurbits (0.5 ppm); fruiting vegetables (0.7 ppm); and leafy vegetables except Brassica (5.0 ppm). The chronic population adjusted dose (cPAD) for dinotefuran is 0.02 mg/kg/day and has the same basis as the RfD. The USEPA estimated that the chronic dietary exposure to dinotefuran residues would be 21% of the cPAD for the general U.S. population, 18% for all infants less than one year old and 54% for children one to two years old. This chronic exposure analysis is based on the conservative assumptions that 100% of the crops are treated and that these treated crops contain tolerance level residues.

The USEPA conducted a risk assessment for dermal and inhalation exposures of workers to dinotefuran as used in the Safari and Venom pesticide products. For determining margins of exposure (MOEs), estimated dermal exposures were compared to a no-observed-effect level (NOEL) of 22 mg/kg/day obtained from a chronic toxicity study in dogs (decreased thymus weights, bodyweights and bodyweight gain in females). Estimated inhalation exposures were compared to a LOEL of 60 mg/kg/day (decreased body weight gain in males) from a 28-day rat inhalation toxicity study. In addition, the USEPA used a dermal absorption factor of 30% based on a comparison to structurally-related chemicals, and assumed 100% absorption from inhalation exposures. For dermal exposures, the estimated MOEs during applications ranged from 2,000 to 110,000 and for inhalation exposures during applications, the estimated MOEs ranged from 34,000 to 1,300,000. For all these estimates, it was assumed that workers wore a long-sleeved shirt and long pants (the product labels require the use of this personal protective equipment plus the use of chemical-resistant gloves, shoes and socks). For dermal exposures, since a NOEL was used to estimate the dermal MOEs, the USEPA considered MOEs of 100-fold or greater to provide adequate protection. For inhalation exposures, because MOEs were estimated by use of a LOEL, inhalation MOEs of 1,000-fold or greater were considered adequate for worker protection. For post-application dermal exposures to dinotefuran from agricultural activities (e.g., harvesting, weeding), the estimated MOEs ranged from 150 to 5,000.

The New York State Department of Health (NYSDOH) briefly reviewed the environmental fate data for dinotefuran. These data indicate that this chemical and at least one of its degradates, MNG (1 methyl-2-nitroguanidine), may have the ability to leach through certain soil types and contaminate groundwater; the adsorption coefficients (K_{oc}), depending on soil type, ranged from 23.3 to 33.6 for dinotefuran, and for its degradate MNG the K_{oc} range was from 8 to 31. In addition, the label for Venom Insecticide contains the environmental hazards statement, "The high water solubility of dinotefuran, and its degradate, MNG, coupled with its very high mobility, and resistance to biodegradation indicates that this compound has a strong potential to leach to the subsurface under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination." This statement does not appear on the labels for the Safari 20 SG or Venom 20 SG products.

There are no chemical specific federal or New York State drinking water/groundwater standards for dinotefuran or its degradate MNG. Based on their chemical structures, these compounds fall under the 50 microgram per liter ($\mu\text{g/L}$) 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 μ g/L.

The available information on the formulated products Safari 20 SG Insecticide, Venom 20 SG Insecticide and Venom Insecticide indicates that overall these products were not very acutely toxic in laboratory animal studies. Safari 20 SG Insecticide and Venom 20 SG Insecticide, however, are moderately irritating to the eyes and skin. Accordingly, to mitigate adverse eye and skin effects, the product labels caution: “Causes moderate eye irritation,” and advise users to “Avoid contact with skin, eyes or clothing” which is compatible with the USEPA Label Review Manual guidance. In addition, the product labels require the use of personal protective equipment (long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks). The new active ingredient dinotefuran was also tested in a battery of toxicological studies and was shown not to be very acutely toxic. Furthermore, dinotefuran did not demonstrate developmental toxicity, genotoxicity or carcinogenicity. Although data from subchronic, chronic and reproductive toxicity studies showed that this chemical has the potential to cause some toxicity, the estimated risks to workers from the use of the Safari and Venom products or to workers from post-application exposure to dinotefuran are within the range that is considered acceptable. In addition, dietary exposure of the general public to dinotefuran on currently labeled crops is not expected to pose significant health risks. However, data from other studies have indicated that this chemical has the potential to cause some neurotoxic and immunotoxic effects. Accordingly, the USEPA required the registrant of Dinotefuran Technical to submit a developmental neurotoxicity study and a developmental immunotoxicity study, both to be conducted in rats. NYSDOH requests that the Department require the registrant to submit a copy of the USEPA Data Evaluation Record reports, or if unavailable, a copy of the USEPA’s detailed review of these two studies on dinotefuran when they become available. Furthermore, because dinotefuran appears to have the potential to leach through soil and contaminate groundwater/drinking water, NYSDOH recommends that the Department consider whether mitigative measures (e.g., prohibiting its use in vulnerable areas) are necessary before registering these formulated products containing dinotefuran in New York State. Also, the Department should consider whether the environmental hazard statement that appears on the Venom label should also be included on the Safari 20 SG or Venom 20 SG product labels.

ECOLOGICAL EFFECTS RISK ASSESSMENT: All dinotefuran use, chemical, toxicity, and environmental fate information contained herein was taken from the data submission submitted by Valent and Landis International.

USE PROFILE: Safari 20 SG Insecticide is labeled for insect control on ornamental plants in commercial or residential landscapes, greenhouses, and nurseries. The label lists seven groups of insect pests controlled on ornamental: shrubs, flowering plants, foliage plants and ground covers, evergreens and ornamental trees, and nonbearing fruit trees, nut trees, and vines. For foliar applications, the label directs the user to use 0.25 to 0.5 lbs. Safari in 100 gallons of water to treat 20,000 square feet which is equal to 0.109 to 0.218 lbs. active ingredient(ai)/acre. If necessary, a second application may be made 14 to 21 days later. No more than 2.7 lbs. product or 0.54 lbs ai may be applied per acre per year. Soil drench applications are made with 0.75 to 1.5 lbs. product per 100 gallons of water; 4 fluid ounces of the finished solution are applied to a 6-inch pot.

The Venom 20 SG Insecticide label includes directions for control of sucking and chewing insects on leafy vegetables except Brassica. Foliar applications of 0.045 to 0.134 lbs. ai/acre are made using ground, aerial, or irrigation equipment. Repeat applications can be made after seven days. No more than three foliar applications or a total of 0.268 lbs. ai/acre may be made per year. Venom 20 SG may be applied to soil to be taken up by crop root systems either before, during, or after

planting. It may be applied at 0.226 to 0.268 lbs. ai/acre with ground or aerial spray equipment, or through irrigation systems. No more than 0.536 lbs. ai/acre may be applied via soil applications per year. Foliar and soil applications may not be made within 7 and 21 days of harvest, respectively.

Venom Insecticide is labeled for use on cotton, cucurbits, fruiting vegetables, leafy vegetables, head and stem Brassica, grapes, and potatoes. Application directions and limits are the same for cucurbits, fruiting vegetables, and head and stem Brassica. Foliar applications of 0.045 to 0.179 lbs. ai/acre are made using ground, aerial, or irrigation equipment. Repeat applications can be made after seven days. No more than three foliar applications or 0.268 lbs. ai/acre total may be applied per season. Soil application methods and ai rates are the same as those described for the Venom 20 SG product.

Applications to leafy vegetables are the same as those described for cucurbits, fruiting vegetables, and Brassica except the upper limit for a single application to leafy vegetables is slightly lower at 0.134 lbs. ai/acre. Leafy vegetable soil application methods and limits are the same as those described for Venom 20 SG. Single foliar grape applications are made at 0.045 to 0.132 lbs. ai/acre with 14-day intervals. Only one soil application may be made to grapes per year at a maximum of 0.264 lbs. ai/acre. Potato foliar single applications are made at 0.05 to 0.066 lbs. ai/acre with 14-day intervals if retreatment is needed. No more than 0.198 lbs. ai/acre may be applied per season. One soil application may be made per year at 0.28 to 0.33 lbs. ai/acre. The Venom Insecticide Pre-Harvest Interval (PHI) or the number of days between last application and harvest varies by crop. The foliar and soil PHI for cucurbits, fruiting vegetables, and head and stem Brassica are one and 21 days, respectively. Grape foliar and soil PHI's are one and 28 days. Leafy vegetable PHI's are seven and 21 days. The label gives only a foliar PHI of seven days for potatoes.

CHEMICAL DESCRIPTION & MODE OF ACTION: Dinotefuran, RS-1-methyl-2-nitro-3(tetrahydro-3-furylmethyl)guanidine, is a new nitroguanidine neonicotinoid insecticidal active ingredient. Safari 20 SG and Venom 20 SG are 20% dinotefuran, and Venom Insecticide is 70%.

Dinotefuran is highly soluble in water with a limit of 39.83 g/L. Its octanol/water partitioning coefficient (K_{OW}) is low at 0.283; bioaccumulation is not likely to occur. The requirement for a fish bioaccumulation study was waived. With its low vapor pressure, $<1.3 \times 10^{-8}$ mmHg, volatilization from soil or water will not contribute significantly to its dissipation. With soil organic carbon partitioning coefficients (K_{OCs}) ranging from 6 to 42 ml/g in five U.S. soils with a mean of 25.4, dinotefuran is expected to be highly mobile in soil following application.

Dinotefuran is a neurotoxin that functions by binding to the nicotinic acetylcholine receptors, disrupting nervous system function.

TOXICITY & ENVIRONMENTAL FATE: Dinotefuran is practically nontoxic to birds, mammals, fish, *Daphnia*, algae and aquatic macrophytes on an acute basis. It is, however, highly toxic to marine/estuarine mysid shrimp. It can produce chronic mammalian toxicity at concentrations slightly higher than food-item vegetation residue levels expected in the field with labeled use. It is highly toxic to honey bees by all routes of administration.

Results from five acceptable mammalian cytotoxicity and/or genotoxicity studies were submitted. All results were negative, dinotefuran should not produce genotoxic or mutagenic effects in the field.

USEPA DERs, from laboratory toxicity trials conducted with three beneficial terrestrial arthropods, were submitted. Interiors of treatment test chambers were sprayed at a range of rates, results of all three studies are expressed as ai/unit area, e.g., $LC_{50} = X$ lbs. ai/acre. It is not stated in any of the study review materials if the test animals were in the treatment chambers at the time of treatment or not.

A Survival & Reproduction study, MRID# 45640120, conducted with the predacious mite *Typhlodromus pyri* yielded the following results:

- $LC_{50} = 0.0269$ lbs. ai/acre
NOEC < 0.0134 lbs. ai/acre

41% reproduction inhibition at 0.0134 lbs. ai/acre
51% reproduction inhibition at 0.0178 lbs. ai/acre

The aphid parasitoid wasp *Aphidius rhopalosiphi* proved to be considerably more sensitive, MRID# 45640121:

- $LC_{50} = 0.000068$ lbs. ai/acre (31 mg ai/acre)
NOEC = 2.7 mg ai/acre

67% fecundity decrease at 8.0 mg ai/acre

Of the results submitted, the predacious bug *Orius laevigatus* was most sensitive, MRID# 45640122:

- $LC_{50} = 5.4$ mg ai/acre
LOEC = 3.6 mg ai/acre
NOEC < 0.55 mg ai/acre

Dinotefuran will be moderately persistent and mobile following application. Degradation will be primarily due to slow microbial metabolism. It is stable to hydrolysis at environmentally relevant temperatures. Its aqueous photolysis half-life ($T_{1/2}$), is 2.3 days so it should not persist in shallow, clear waters. No valid soil photolysis study results were submitted. Laboratory aerobic soil metabolism $T_{1/2}$ s in seven soils ranged from 17 to 100 days with a mean of 48 days. A supplemental aerobic sediment/water system study using river water and sediments, and pond water and sediments, yielded $T_{1/2}$ s of 73, 108, and 79 days for water column, sediment, and overall system respectively with river water, and 53, 131, and 76 days, respectively, using the pond water. The study was classified supplemental because the sediments were anaerobic for much of the study. A supplemental (poor metabolite tracking, study design et. al.) anaerobic sediment/water study yielded $T_{1/2}$ s of 51, 62, and 65 days for water column, sediment, and system, respectively. Two soil adsorption/desorption studies were submitted, one using U.S. soils, the other Japanese soils. In the five U.S. soils, the soil organic carbon partitioning coefficient (K_{OC}) ranged from 6 to 45 ml/g with a mean of 25.4 ml/g. The mean Japanese soil K_{OC} was 28 ml/g. Terrestrial field dissipation trials were conducted in New York, Georgia, and California. Field $T_{1/2}$ s were 19, 56, and 65 days in GA, NY, and CA, respectively. Times to 90% dissipation (DT_{90} s) for the three study locations were 75, 197, and 217 days, respectively. In NY, parent dinotefuran was detected to a depth of 45cm on days 30 to 60 and 120 post-application.

EXPOSURE MODELING: AVTOX, MAMTOX, and PONDTOX modeling were conducted to estimate terrestrial and aquatic nontarget organism exposure to dinotefuran from labeled use of the three subject products.

Conservative, screening level terrestrial food item residue estimates resulting from foliar applications show that there should be little or no risk of avian or mammalian acute toxicity. The highest predicted (Upper Limit) residues immediately following application of the yearly maximum rate in a single application are below acute toxicity thresholds. Additionally, no avian chronic thresholds were exceeded at this rate. The initial screening did, however, show potential for chronic mammalian toxicity. Subsequent modeling iterations using typical foliar residues instead of the upper limit residues show that the lower, more probable, residues exceed toxicity thresholds less frequently.

PONDTOX modeling simulated direct application of dinotefuran containing products to the surface of a water body and a highly conservative post-application runoff simulation. Highly conservative surface water concentration estimates suggest there should be no adverse impacts to taxa for which data was submitted from labeled dinotefuran use. No acute aquatic toxicity thresholds are exceeded when the highest seasonal dinotefuran application rate (0.54 lbs. ai/acre) is added directly to the surface of a water body six inches deep. It should be noted, however, that the supporting study-base is limited and is likely inadequate to accurately describe the aquatic risks associated with dinotefuran use. Dinotefuran sensitivity of the two representative arthropod taxa, *Daphnia* and *Mysidae*, differ by at least four orders of magnitude. The results reported in the dinotefuran data package show that mysid shrimp are at least 1,225 times more sensitive than *Daphnia*. The information submitted is inadequate to demonstrate that these two taxa represent the full range of dinotefuran sensitivities. Also, no Mysid chronic toxicity study results were submitted and the submitted Rainbow Trout Early Life Stage study was deemed invalid and has to be repeated. No valid chronic aquatic toxicity data except that for the resistant *Daphnia* was available for use in this assessment.

RISK ASSESSMENT: With the exception of some potential for mammalian chronic toxicity and the substantial uncertainty resulting from the chronic aquatic toxicity data gap, standard screening level exposure modeling suggests limited concern for nontarget organism impacts from dinotefuran. The standard Bureau of Habitat exposure modeling programs, however, do not evaluate risks to nontarget beneficial predator or pollinator arthropods. As with other compounds in this chemical family, dinotefuran is systemic in treated plants. It persists in them for weeks or months following application and is highly toxic to honey bees. Current end-use product label language intended to be protective of pollinators is inconsistent between labels and is inadequate on all. Additionally, the statements on these products labels regarding their low toxicity to beneficial arthropods and their suitability for use in IPM programs are not supported by the submitted data.

MAMTOX screening simulated three scenarios: upper limit residue estimate following application of the seasonal maximum rate, typical residues to be expected following a single application at the highest label rate, and typical residues expected after the seasonal maximum is applied. The single high rate application exceeds several mammalian NOECs but does not exceed any LOELs. The last dinotefuran application of the season slightly exceeds the mouse chronic LOEL on short grass. If even a minimal application efficiency of 30% of applied material is assumed to adhere to the target plants, the residue on nontarget plants, like the modeled short grass, fall below the LOEL threshold. There may be instances of inadvertent full rate application to noncrop areas, but they should be minimal if prudent application practices are followed. Chronic toxicity may occur in small

mammals if they feed exclusively in treated areas, but widespread significant impacts will probably not occur.

As with other neonicotinoid active ingredients, the systemic nature and high toxicity of dinotefuran to honey bees raises concerns for toxicity to individual bees and over time to whole hives. No data has been submitted to date describing the toxicity of dinotefuran to other pollinator taxa.

The dinotefuran end-use labels contain uses on 19 different human food crops. DERs for 257 crop residue trials, 255 field and 2 container-grown, were submitted in the data package. The USEPA Health Effects Division (HED) classified the dinotefuran metabolites identified as MNG and DN as being structurally similar to the parent compound or retaining the active moiety and identified them as metabolites of toxic concern. They are considered to be as toxic as dinotefuran for risk assessment purposes. In crops treated at application rates allowed on the three labels under consideration, reported dinotefuran residue concentrations ranged from negligible amounts in potato tubers to 10.8 ppm in apple tree foliage 21 days after treatment.

Three honey bee acute oral toxicity studies were included in the dinotefuran data package, MRID#s 45639725, 45639726 and 45639727. In these studies, the dinotefuran LC₅₀ and NOECs were determined to be 0.23/0.003, 0.032/0.005, and 0.0076/0.0013, respectively. The acute oral test is a European, Organisation for Economic Cooperation and Development (OECD), requirement; USEPA only requires direct contact and vegetation contact acute studies. The OECD Acute Oral Honey Bee study protocol is fairly straightforward, its basic elements are as follows:

- 3 replicates of 10 bees each at each test concentration
- each test group receives 100 to 200 ul of 50% sucrose/water solution containing the compound being tested at the appropriate concentration
- consumption is monitored
- once consumed, usually within 3 to 4 hours, the dosing feeder is removed and replaced with one containing untreated sucrose solution.

From this, it can be seen that, on average, one bee will consume approximately 15 ul of solution in 3 to 4 hours. Using the LC₅₀ values from the submitted studies, the ug/bee results can be converted to ppm concentrations that result in 50% mortality after 3 to 4 hours of consumption, e.g., the mean of the reported LC₅₀s is 0.018 ug/bee, 0.018/15 ul consumed = 0.0012 ug/ul or 1.2 ppm. The highest reported LC₅₀ using this conversion is 3.2 ppm, the lowest is 0.38 ppm.

When treated at label allowed rates, mean residues in leaf lettuce, head lettuce, spinach, broccoli, rice straw, and apples exceed a honey bee LC₅₀ using the above conversion. Virtually all reported residue concentrations fall between a honey bee NOEC and an LC₅₀. It should be noted that the bee study LC₅₀s were established with limited 3 to 4 hour feeding exposures. A reference describing the daily dietary requirements of honey bees was not located for this review but it is likely that feeding over the course of 24 hours would require lower ppm concentrations to achieve a lethal dose.

There were no studies submitted that measured dinotefuran concentrations in nectar or pollen, but there is clearly reason for concern given the observed plant tissue residue levels. The presence of residues in pollen and nectar is a known concern with this class of compounds, testing for such residues should be a preregistration requirement for any neonicotinoid active ingredient coming into the market. Concern for effects to honey bees was significant enough during federal registration

review that the USEPA required a honey bee hive study extending over two complete life-cycles, where dinotefuran exposure results from pollen and nectar foraged from treated plants.

Both Venom labels include the statement that they should have minimal impact on beneficial arthropods and their use is compatible with IPM programs. These statements are not supported by the nontarget arthropod data submitted. The three such studies reported in the Toxicity & Environmental Fate section of this review yielded LC₅₀s of 0.027 lbs. ai/acre, 77.2 mg ai/acre, and 13.3 mg ai/acre. The lowest labeled dinotefuran single application rate is 0.045 lbs. ai/acre, which is 1.7, 264, and 1,535 *times* the respective reported LC₅₀s.

All proposed uses present an unacceptable risk to honey bees and other organisms dependant on plant pollen and nectar. No new information was presented in Landis International's response, dated February 19, 2007 to the Department's technical issues letter.

ENVIRONMENTAL FATE RISK ASSESSMENT: During the completeness phase of this review, no information was available indicating that the aerobic metabolism study had been successfully upgraded. Upon submission of the review performed by the California Department of Pesticide Regulation, staff declared the applications as complete as possible for determining impact to groundwater.

Dinotefuran is a systemic nicotinoid insecticide, and belongs to the nitroguanidine subclass, along with clothianidin, imidacloprid and thiamethoxam. The active ingredient is toxic to shrimp and bees. The Venom Insecticide label has a groundwater advisory statement on the label.

Valent is applying to use Safari 20 SG Insecticide (EPA Reg. No. 33657-16-59639) as a foliar spray, a broadcast application, or a soil drench for insect control in ornamental plants in commercial or residential landscapes, greenhouses and nurseries. It may be applied through chemigation systems. The maximum application rate was not at all clear from the label directions. It appears that the product can be applied as a foliar application (0.54 lb ai/a/yr), a broadcast application (0.54 lb ai/a/yr), and a drench application (maximum rate unclear). There is no indication on the label of what the maximum application rate of the combined applications is. As written, all three types of applications may be applied, each with their own application rate. However, staff assumed for modeling purposes that only one method of application will be used. Label language should be added clarifying this issue. If more than one application method may be used in one year and the total maximum application rate is greater than 0.54 lb ai/a/yr, then the modeling as presented greatly underestimates the impact to groundwater.

Safari 20 SG contains 20% by weight active ingredient. The soil drench application is 4 fluid ounces of finished solution per 6-inch pot. The solution is 24 oz product (or 0.3 lb ai) per 100 gallons of water. It is not clear what the maximum application rate in lbs/acre would be. The foliar and the broadcast application rates are both 0.54 lb ai/a/yr or 2.7 lbs product.

Valent is applying to use Venom 20 SG Insecticide (EPA Reg. No. 33657-17-59639) via soil or foliar application, for control of sucking and chewing insects infesting leafy vegetables (except Brassica). It may be applied through chemigation systems. The product contains 20% by weight active ingredient, and the maximum foliar application rate is 1.34 lbs of product or 0.268 lb ai/a/year. It may not be applied within seven days of harvest. The maximum soil application (surface or in-furrow) rate is 2.68 lbs of product or 0.536 lb ai/a/year. It may not be applied within 21 days of harvest. For resistance management, no more than three applications are allowed per

growing seasons. Again, it is not clear on this label whether more than one application method may be used in one year and what the total maximum application rate is.

Safari 20 SG Insecticide and Venom 20 SG Insecticide had, as conditions of registration, the following requirements:

1. A confirmatory photodegradation in soil study to evaluate photodegradation as a major degradation pathway. This study was due to the USEPA by September 14, 2005.
2. Either an upgraded aerobic soil metabolism study, or a complete new study, addressing the fate of the major transformation products. This study was due to the USEPA by September 14, 2005.
3. A new anaerobic aquatic/soil metabolism study.
4. An aerobic aquatic metabolism study to assess future aquatic uses may be needed.

Information was submitted to the USEPA, but it appears that several of the studies are still considered supplemental and more information is needed.

Valent USA Corporation is applying to use Venom Insecticide (EPA Reg. No. 59639-135) via soil or foliar application for control of sucking and chewing insects infesting cotton, cucurbits, fruiting vegetables, grapes, head & stem brassica, leafy vegetables and potatoes. The product contains 70% by weight active ingredient. The inerts do not appear to be solvent carriers. For all uses, the label states that no more than three applications should be made per growing season.

Venom Insecticide (EPA Reg. No. 59639-135)						
Crop	App. Rate Foliar (lb ai/a/yr)	App. Rate drench (lb ai/a/yr)	Max. App. Rate Combined Applications (lb ai/a/yr)	Pre-harvest Interval (days)	Number of Applications	Time between applications
Cucurbits, fruiting vegetables, head & stem brassica	0.268	0.536	Cannot combine application methods	1 foliar 21 drench	As needed	>7 days
Grapes	0.264	0.264	0.528	1 foliar 28 days	1 app soil	Foliar: >14 days
Leafy vegetables	0.268	0.536	Cannot combine application methods	7 foliar 21 drench	As needed	>7 days
Potatoes (foliar)	0.198		0.528	7 foliar	As needed	>14 days
Potatoes (drench)		0.33		NA	1	
Cotton	0.268			14		>7 days

Transformation products:

UF	M1; 1-methyl-3-(tetrahydro-3-furylmethyl)urea
unidentified	M3
guanidine	M9
MU N-methylurea	M11
MG hydrogen chloride	M13; 1-methylguanidinium chloride
DN-2-OH + DN-3-OH	M14
BCDN succinate.	M15; 3-(methylamino-0-oxa-2-aza-4-azoniabicyclo[4.3.0]non-3-ene
hydrogen succinate	
MNG	1, methyl-2-nitroguanidine
DN	1-methyl-3-(tetrahydro-3-furylmethyl)guanidinium
NG	Nitroguanidine
MG	1-methylguanidine

Solubility: The solubility of dinotefuran is 39,830 ppm.

Solubility of MNG: The solubility of degradate MNG is 11,480 ppm.

Hydrolysis: In a study that USEPA found supplemental (MRID# 45640101), dinotefuran had half-lives of 7,701, 3,465, 1,155 days in pH 4, 7 and 9 buffer solutions, respectively. In a study that USEPA found acceptable (MRID# 45640102), dinotefuran was stable at in pH 4, 7 and 9 buffer solutions at 25°C.

Hydrolysis of DN: In a study that USEPA found supplemental (MRID# 45640104), no significant degradation occurred during the 5-day study.

Hydrolysis of MNG: In a study that USEPA found supplemental (MRID# 45640103), MNG was stable at pHs 4, 7 and 9 at 51°C.

Aqueous Photolysis: In a study that USEPA felt provided useful information but needed to be upgraded (MRID# 45640105), the photo-transformation half-life was 1.8 days. The environmental photo-transformation half-life, determined by the study author, was 2.3 to 2.4 days at 30 to 50° N latitude. Major transformation products including M1, M13, M14 and M15.

In a study that USEPA found unacceptable (MRID# 45640106), the photo-transformation half-lives in river water was 2.3 hours and in purified water was 2.5 hours. The environmental half-life is expected to be 2.4 hours.

Aqueous Photolysis of DN: In a study that USEPA found supplemental (MRID# 45640108), the photo-transformation half-life at pH5 was 26.7 days with one major degradate: MG at 10.8%. At pH 7, the half-life was 266.6 days. At pH 9, DN was stable.

Aqueous Photolysis of MNG: In a study that USEPA found supplemental (MRID# 45640107), the photo-transformation half-life at pH 7 was 1.2 days with major degradates M3, M9, and M11.

Soil Photolysis: In a study that USEPA found unacceptable (MRID# 45640109) for many reasons, in a loamy sand soil the half-life in the irradiated soil was 46.2 days.

Anaerobic Aquatic Metabolism: In a study that USEPA found supplemental (MRID# 45891616), in a demineralized water-silt loam soil, the half-life in the entire system was 65 days, in the water was 51 days and in the soil was 62 days. DN was the only major degradate found.

Anaerobic Soil Metabolism: A copy of California's review indicates that the study requirements have not been satisfied for this active ingredient.

Aerobic Aquatic Metabolism: In a study that USEPA found supplemental (MRID# 45640117), in a river water/sandy loam sediment, the half-life in the entire system was 79.3 days, in the water was 73.2 days and in the sediment was 108.5 days. DN phosphate was the only major degradate found. In a pond water/loam system, in the entire system the half-life was 76 days, in the water was 52.6 days and in the sediment was 131.2 days. DN was the only major degradate was found.

Aerobic Soil Metabolism: Two studies were done that USEPA found supplemental (MRID#s 45640111 and 45640112). California's concurrent review (dated September 18, 2003) indicated that the studies were acceptable. USEPA documentation indicated that the deficiencies in the aerobic metabolism studies had not been explained to their satisfaction. In the August 9, 2005 USEPA Memorandum from José Luis Meléndez to Rita Kumar, USEPA stated, "The registrant did not provide sufficient information to upgrade the aerobic soil metabolism study MRID# 45640111. The study is still considered supplemental." "At this time, the EFED does not have sufficient information to do a comprehensive evaluation of the aerobic soil metabolism study of dinotefuran (MRID# 4560112¹). The study remains supplemental."

Soil	% OM	pH	t _ in days	Degradates
Madison Farm Loamy sand	1.2	7.2	38	MNG 14.6%
Findak Garden Loam	5.5	7.5	17	MNG 15%
Van Ess Loam	2.2	7.3	78	
Misich Loam	4.9	5.3	89	
R. Myron N Loamy sand	5.6	7.1	20	MNG 23.96% NG 14.33%
Loamy sand ¹	1.1	6.9	100	MNG 13.7%

Aerobic Soil Metabolism of MNG: According to the USEPA memorandum dated August 9, 2005, in Table 2 under MRID# 45640112, the USEPA stated, “Furthermore, the above-mentioned study gives sufficient data on the dissipation of MNG, the major transformation product of dinotefuran. The registrant reported a DT50 = 87.7 days and the DT90 = 291 days at 20°C.” USEPA still found this study supplemental.

USEPA went on in that same memorandum to discuss a separate study (RCC Study No. 844180) and reported that half-lives in a silt loam, sandy loam and clay loam (no parameters provided) were 45.4, 173 and 64.3 days, respectively. However, the study itself was not submitted to USEPA, only the results.

Adsorption/Desorption: For the parent, two studies were done, one found supplemental (MRID# 45640115)¹ and one found acceptable (MRID# 45640114)²:

Soil Type	Adsorption K _{oc}	Desorption K _{oc}	% Organic Carbon	pH
clay loam ¹	23.3	NP	2.6	6.7
loam ¹	31.4	NP	1.21	7.5
clay ¹	33.6		3.33	7.0
loamy sand ¹	25.3		1.5	5.9
loamy sand ²	6	66	2.17	5.7
silt loam ²	22	178	1.0	5.8
loam ²	42	397	2.4	6.2
sandy loam ²	45	213	1.6	5.8
clay loam ²	42	299	2.9	5.7

For degradate MNG (MRID# 45640116), USEPA found this study supplemental:

Soil Type	Adsorption K _{oc}	Desorption K _{oc}	% Organic Carbon	pH
loamy sand	8	12	2.17	5.7
silt loam	16	ND	1.0	5.8
loam	31	25	2.4	6.2
sandy loam	8	ND	1.6	5.8
clay loam	24	28	2.9	5.7

For degradate DN (MRID# 45640113), USEPA found this study supplemental:

Soil Type	Adsorption K_{oc}	Desorption K_{oc}	% Organic Carbon	pH
clay	270	335	2.63	7.0
sandy loam	413	516	0.71	6.5
loam	87	128	2.4	5.5
sandy loam	58	84	3.6	5.1
clay loam	2502	3130	2.9	5.7

Terrestrial Field Dissipation: In a study that USEPA found acceptable (MRID# 45640118):

Soil Type	% Organic Carbon	pH	T _{1/2}	% Degradate
California sandy loam	0.27	8.8	65.4 days	MNG 31.5%
Georgia sandy loam	0.43	6.5	19.4 days	MNG 5.3%
New York sandy loam	3.91	6.6	55.9	MNG 6.6%

Computer Modeling: It was difficult to determine which parameters to use for the parent since none of the soils used in the studies had pH and % organic carbon values similar to Long Island soils. It was also difficult to determine the actual maximum application rate of two of the products, so staff assumed a maximum application rate of 0.54 lb ai/a/yr, and ran “best case” and “worst case” scenarios for the other parameters.

Running LEACHP on Riverhead soil for dinotefuran using a desorption K_{oc} of 213, a half-life of 38 days and an application rate of 0.54 lb ai/a/yr (best case parameters), the model projected cyclic peaks up to about 0.28 ppb. Changing the half-life to 100 days and the adsorption K_{oc} to 25.3 (worst case parameters), the model projected cyclic peaks up to 65 ppb.

Running the degradate MNG using a half-life of 87.7 days, a K_{oc} of 8, and an application rate of 0.074 lb ai/a/yr (13.7% of applied rate), the model projected cyclic peaks up to 19 ppb. Changing the half-life to 173 days, the model predicted cyclic peaks up to 25 ppb.

Note that these projections may underestimate the actual leaching based on the application rate modeled. The projections may actually be as much as three times higher if all three types of application methods (broadcast, foliar and drench) are used on the same location in the same year.

Label Statements: The Venom Insecticide (EPA Reg. No. 59639-135) label has the following groundwater advisory statement:

“Dinotefuran and its degradate, MNG, have the properties and characteristics associated with chemicals detected in groundwater. The high water solubility of dinotefuran, and its degradate, MNG, coupled with its very high mobility and resistance to biodegradation, indicates that this compound has a strong potential to leach to the subsurface under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable,

particularly where the water table is shallow, may result in groundwater contamination. Periodic monitoring of shallow groundwater in the use area is recommended.”

Label issues for Safari 20 SG: The final product label is not clear on how many applications of each type may be applied and what the maximum combined application rate is.

Label issues for Venom 20 SG: The final product label is not clear on how many applications of each type may be applied and what the maximum combined application rate is.

E-Fate Summary: These applications contained information that does not support the registration of these products in New York State; the uncertainty in the adequacy of the data from the studies that were not fully acceptable to the USEPA, the very high solubilities and low K_{oc} s, of both the parent and the degradate MNG, the fact that this chemical is in the same family as clothianidin, imidacloprid and thiamethoxam, all of which are chemicals of concern regarding groundwater contamination, the fact that MNG is more mobile than the parent, the uncertainty in the application rate, and the projected modeling results. The data provided do not support the use of these products in sandy, vulnerable areas of New York State. Greenhouse use anywhere in New York is not acceptable because greenhouse floors are generally not an impermeable surface and infiltration to the subsurface is possible. The degradate MNG would still be of concern in all areas even if the products were used at a reduced application rate.

Engineering Geology staff reviewed the environmental fate DERs received from Landis International on July 10, 2007. According to the USEPA, the aerobic metabolism study done on the parent dinotefuran (MRID# 46751101/45640112) was acceptable. On a loamy sand, dinotefuran had a linear half-life of 87.7 days and a nonlinear half-life of 80.6 days. MNG was the major transformation product at 14.47% of maximum. A second aerobic metabolism study was found to be supplemental (MRID# 46711201). On a silt loam soil from Switzerland, the linear half-life was 15.9 days and the nonlinear half life was 10.1 days with MNG found at 15.7%.

In an aerobic metabolism study on the transformation product MNG, rated supplemental by USEPA due to use of foreign soils (MRID# 46711202), MNG had a linear half-life of 72.5 days and a nonlinear half-life of 68.8 days in a clay loam soil with the major transformation product NG (nitroguanidine) at 35.8% of applied. It had a linear half-life of 66.9 days and a nonlinear half-life of 58.7 days in a silt loam soil with the major transformation product NG at 19% of applied. It had a linear half-life of 166 days and a nonlinear half-life of 154 days in a sandy loam soil with the major transformation product NG at 19.1% of applied. Staff would prefer a DER indicating that USEPA found the aerobic metabolism study on the transformation product MNG acceptable rather than supplemental, but can work with the information on the DER submitted.

Staff still need DERs for the adsorption-desorption studies for the parent and the transformation product MNG on Long Island type soils, better maximum application rates and any available groundwater monitoring data.

ISSUES SUMMARY: The uses proposed by the subject products present an unacceptable risk to honey bees and other organisms dependant on plant pollen and nectar. Product labels should instruct the user to not make any dinotefuran applications until after the target plants are through blooming and pollen and nectar are no longer present. Label statements claiming that these products will have minimal impacts to nontarget beneficial arthropods are not supported by the data submitted with the applications. The submitted data demonstrate that the opposite is in fact the case. The Department’s Bureau of Habitat cannot further evaluate the subject products until:

- 1) The honey bee hive study has been validated and reviewed by the USEPA Environmental Fate and Effects Division (EFED) and the results of the study and EFED evaluations are submitted to the Department;
- 2) Results for plant residue studies in which the concentration of dinotefuran in pollen and nectar are determined are also submitted; and
- 3) Any and all study results for dinotefuran toxicity trials conducted with invertebrate taxa which include species that function as pollinators are also submitted.

Based on the environmental fate data, the groundwater advisory statement and LEACHP simulations, the potential for dinotefuran and its degradate MNG to impact groundwater/drinking water resources in New York State cannot be discounted. In order to reevaluate the subject outdoor use products, the Department needs adsorption-desorption study DERs for dinotefuran and the transformation product MNG on Long Island type soils, a better indication of maximum application rates, and any available groundwater monitoring data.

CONCLUSION: When used as labeled, the subject products have the potential to adversely impact nontarget organisms and groundwater resources in New York State. **Therefore, the Department hereby denies the applications to register Safari 20 SG Insecticide (EPA Reg. No. 33657-16-59639), Venom 20 SG Insecticide (EPA Reg. No. 33657-17-59639) and Venom Insecticide (EPA Reg. No. 59639-135).**

Valent may pursue the options available under Article 33-0711 of the New York State Environmental Conservation Law or reapply for registration. If you elect to reapply, you must submit a complete new application, application fee and information to mitigate the identified risks to nontarget organisms and groundwater/drinking water.

The Department is willing to reassess the nontarget organism and groundwater impacts of dinotefuran when the ecotoxicology and environmental fate databases are more completely defined. During the interim, there are registered pesticide products that offer similar pest control available to growers.

You are reminded that an unregistered product may not be sold, offered for sale, distributed, or used in New York State.

Please contact Samuel Jackling, Chief of our Pesticide Product Registration Section, at (518) 402-8768, if you have any questions regarding this action.

Sincerely,

Maureen P Serafini

Maureen P. Serafini
Director
Bureau of Pesticides Management

cc: W. Ronald Landis, Landis International, Inc.
R. Mungari, NYS Dept. of Ag. & Markets
W. Smith, Cornell University, PSUR