Apply Timorex Gold at a concentration of 0.06 to 0.64 fl. oz. per gallon. Make applications in the early stages of plant growth for initial control. Early treatment prevents diseases from developing. Apply Timorex Gold in the greenhouse, nursery or field using conventional equipment as a spray, fog or drench to the point of saturation. Good coverage and wetting of the foliage is required. Use enough spray solution to completely penetrate the leaf canopy and both cover the top and underside of all leaves until runoff. The amount of spray solution to apply will vary depending on the type of crop. Most field-grown crops will require up to 100 gallons of spray per acre. Prepare enough solution based on plant density and soil conditions to insure thorough coverage, maintaining a concentration of 0.06-0.64 fl. oz. per gallon. Reapply at 7-14 day intervals or as needed throughout the growing season for preventative control up until 48 hours of harvest.

Refer to the Dilution Table for the appropriate amount of Timorex Gold needed to achieve a concentration of 0.06-0.64 fl. oz. per gallon. Use the higher rate when disease is apparent.

Dilution Table:

Amount of water (Gallons)	Amount of Timorex Gold (Fl. Oz.)						
	0.1	0.4	0.6	1	1.6	1.9	3.2
10	1	4	6	10	16	1	32
50	5	20	30	-	-	-	-
100	10	-	-	-	-	-	-
200	20	-	-	-	-	-	-

COMPATABILITY:

Consult specific product labels for additional information or restrictions concerning tank mixing. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures. It is always advisable to conduct a spray compatibility test when you plan to mix this product with other products. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, and then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding products to the spray tank. Use tank-mix combinations on a small number of plants before treating large areas, as crop sensitivity to these mixtures may vary.

Timorex Gold has been evaluated for phytotoxicity on a variety of crops under various normal growing conditions. However, testing all crop varieties, in all mixtures and combinations is not feasible. Prior to treating entire crop, test a small portion of the crop for sensitivity.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container, in a dry, cool place out of direct sunlight and away from heat sources. Keep from overheating or freezing.

Pesticide Disposal: Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

Container Handling:

(For containers ≤ 5 gallons)

Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

(For containers ≥30 gallons)

Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or incineration. Do not burn, unless allowed by state and local ordinances.

NOTICE TO USER: Seller makes no warranty express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with label instructions.

ACCEPTED
FOR REGISTRATION

Nov 30, 2015

New York State Department
of Environmental Conservation
Division of Materials Management
Pesticide Product Registration

Doc id: 543830

TIMOREX GOLD®

A BROAD SPECTRUM BIOFUNGICIDE

Biofungicide for the control of foliar disease in listed vegetables, fruits, grapevines and cereals, in open fields and greenhouses

ACTIVE INGREDIENT:

Tea Tree Oil 23.80%

OTHER INGREDIENTS 76.20%

Total 100.00%

Contains petroleum distillates.

EPA Reg. No.: 86182-1

EPA Establishment No.: 90464-ISR-001

Net Contents: ☐ 32 fl. oz ☐ 1 gallon ☐ 2.5 gallons

GROUP F7 FUNGICIDE

KEEP OUT OF REACH OF CHILDREN

WARNING

See inside for additional precautionary statements. Batch/Lot No.: See on the package

Stockton Group The smart way to grow.

Stockton USA, Inc.
20900 N.E. 30th AVENUE, Suite 607
Aventura, FL. 33180
T. (305) 682-1211 / F. (305) 682-1196 http://www.timorex-gold.com/

FIRST AID	
If on skin or clothing	· Take off contaminated clothing. · Rinse skin immediately with plenty of water for 15 – 20 minutes. · Call a poison control center or doctor for treatment advice.
If in eyes	· Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. · Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. · Call a poison control center or doctor for treatment advice.
If swallowed	· Call poison control center or doctor immediately for treatment advice, · Have person sip a glass of water if able to swallow. · Do not induce vomiting unless told to do so by the poison control center or doctor. · Do not give anything to an unconscious person. · Do not give anything by mouth to an unconscious person.
NOTE TO PHYSICIAN – Contains petroleum distillate. Vomiting may cause aspiration pneumonia. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – WARNING: Causes substantial but temporary eye injury. Causes skin irritation. Harmful if swallowed. Do not get on skin, in eyes or on clothing. Wear goggles or face shield, protective clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Handlers who may be exposed to the dilute through application or other tasks must wear: long-sleeved shirt and long pants, socks, shoes, chemical-resistant gloves and protective eyewear. Follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: This product is toxic to aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. For terrestrial uses: Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean highwater mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL AND CHEMICAL HAZARDS: Combustible. Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the State/Tribal agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is coveralls, waterproof gloves, shoes plus socks, and protective eyewear.

GENERAL INFORMATION:

Timorex Gold is for the prevention and control of plant diseases on horticultural and agricultural crops. Use Timorex Gold to prevent and control powdery mildew, downy mildew, Early and late blight, Botrytis, rusts, sour rot, Sclerotinia, Fusarium, Rhizoctonia, Cladosporium, Colletotrichum, Cercospora, Pyricularia, rice grain complex diseases and Bipolaris oryzae, bacterial spp., and black sigatoka. Use Timorex Gold on the foliage and fruit of the following agricultural commodities and horticultural crops:

Bananas: For control of black sigatoka on bananas, apply Timorex Gold at a concentration of 1.02 – 3.20 fl. oz. per gallon (1.0 – 3.2 fl. oz. / gallon). Apply at any stage of growth to protect foliage and newly developing leaves from black sigatoka infection. Reapply as needed during the growing season for control.

Fruiting Vegetables: Eggplant, Groundcherry, Okra, Pepino, Pepper (includes Bell Pepper, Chili Pepper, Cooking Pepper, Pimento, Sweet Pepper), Tomatillo, Tomato, and cultivars, varieties and/or hybrids of these (at a rate of 0.1 – 0.6 fl. oz. / gallon.).

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery, Celtuce, Chervil, Chinese Celery, Chrysanthemum (edible-leaved and garland), Corn Salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach, Spinach (New Zealand and vine) and Swiss Chard (at a rate of 0.1 – 0.6 fl. oz. / gallon.).

Cucurbit Vegetables: Chayote, Chinese Waxgourd, Citron Melon, Cucumber, Gherkin, Edible Gourds (includes Chinese Okra, Cucuzza, Hechima and Hyotan), Momordica spp. (includes Balsam Apple, Balsam Pear, Bitter Melon and Chinese Cucumber), Muskmelon (includes True Cantaloupe, Cantaloupe, Casaba, Crenshaw Melon, Golden Pershaw Melon, Honeydew Melon, Honey Balls, Mango Melon, Persian Melon, Pineapple Melon, Santa Claus Melon, Snake Melon, and hybrids and/or cultivars of Cucumis melo), Pumpkin, Summer Squash (includes Crookneck Squash, Scallop Squash, Straightneck Squash, Vegetable Marrow and Zucchini), Winter Squash (includes Acorn Squash, Butternut Squash, Calabaza, Hubbard Squash, Spaghetti Squash) and Watermelon (includes cultivars, hybrids and/or varieties of Citrullus lanatus) (at a rate of 0.1 – 0.6 fl. oz. / gallon.).

Tropical and Sub-tropical Crops: Avocado, Banana, Mango, Papaya, and Plantain (at a rate of 0.1 – 0.4 fl. oz. / gallon).

Berry Crops: Blackberry (including Bingleberry, Black Satin Berry, Boysenberry, Cherokee Blackberry, Chesterberry, Cheyenne Blackberry, Coryberry, Darrowberry, Dewberry, Dirksen Thornless Berry, Himalayaberry, Hullberry, Lavacaberry, Lowberry, Lucretiaberry, Mammoth Blackberry, Marionberry, Nectarberry, Olallieberry, Oregon Evergreen Berry, Phenomenalberry, Rangeberry, Ravenberry, Rossberry, Shawnee Blackberry, and Youngberry), Blueberry, Cranberry, Currant, Elderberry, Strawberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red) and cultivars, varieties and/or hybrids of these (at a rate of 0.1 – 0.6 fl. oz. / gallon.).

Cereal Grains: Barley, Buckwheat, Corn, Hops, Millet (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum, Teosinte, Triticale, Wheat, and Wild rice. For control of plant diseases on cereal grains, apply Timorex Gold at a rate of 0.16 – 1.92 fl. oz. per gallon (0.2 – 1.9 fl. oz. / gallon). Apply at any stage of growth.

Vine Crops: Grapes (wine, table and raisin), Kiwi and Passion Fruit (at a rate of 0.1 – 0.4 fl. oz. / gallon).

Tree Nut Crops: Almonds, Pecans, Walnuts (at a rate of 0.1 – 0.4 fl. oz. / gallon).

Peanuts: For control of plant disease on peanuts, apply Timorex Gold at a rate of 0.13 – 0.96 fl. oz. per gallon (0.1 – 0.6 fl. oz. / gallon). Apply at any stage of growth.

PREHARVEST INTERVAL:

Do not apply Timorex Gold within 48 hours of harvest.

MIXING DIRECTIONS:

SHAKE WELL BEFORE USE. Fill tank with half the water, then add Timorex Gold and agitate. Add remaining water. When entire volume of water has been added, thoroughly agitate mix before making application. Use solution within 24 hours. It is possible to mix Timorex Gold with other pesticides. Consult specific product labels for additional information or restrictions concerning tank mixing. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

APPLICATION DIRECTIONS:

Do not spray during the warm hours of the day and in hot seasons with temperatures above 95°F (35°C). Do not apply this product through any type of irrigation system.

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

Division of Materials Management, Bureau of Pest Management
625 Broadway, 9th Floor, Albany, New York 12233-7254
P: (518) 402-8788 I F: (518) 402-9024
www.dec.ny.gov

November 30, 2015

Ms. Zephyr Papin-Tillery
Stockton (Israel) Ltd.
c/o Technology Sciences Group Inc.
712 Fifth St., Suite A
Davis, CA 95616

Dear Ms. Papin-Tillery:

Re: Registration of the New Active Ingredient Tea Tree Oil (Active Ingredient Code 028853) Contained in Timorex Gold

The New York State Department of Environmental Conservation (Department) has evaluated your application materials received in support of registration of Timorex Gold (EPA Reg. No. 86182-1). Timorex Gold contains 23.80% of the active ingredient tea tree oil. It is labeled to control various fungi in many agricultural crops, including major New York crops such as corn, wheat, and grapes. Applications may be made in greenhouses, nurseries or field plantings using spray, fog or drench applications. Application is allowed at 7-14 day intervals throughout the growing season. Chemigation is prohibited on the product label. Aerial application is neither explicitly prohibited nor allowed on the Timorex Gold label. There are no maximum application rates on a “per application” or “per year” basis.

The application package was deemed complete for purposes of technical review on July 17, 2015. Pursuant to the review time frame specified in Environmental Conservation Law §33-0704.2, a registration decision date of December 13, 2015 was established.

Technical reviews of the proposed uses included on the Timorex Gold product label have been performed by the Department and the New York State Department of Health. These reviews encompassed the expected impacts of labeled use of the subject product with respect to human health and ecological effects. The technical reviews are presented in the appendix of this letter. Neither the human health review nor the ecological effects review resulted in objections to registration. However, Pesticide Product Registration Section staff determined registration would not occur until certain label and website corrections were made by Stockton (Israel) Ltd. These corrections have been completed. **As a result, Timorex Gold has been registered in New York State.**

Enclosed for your record are copies of the Certificate of Pesticide Registration and stamped “Accepted for Registration” label. Please note that a proposal by Stockton (Israel) Ltd. or any other registrant to register a product that contains tea tree oil, and whose labeled uses are likely to increase the potential for significant impact on humans, nontarget organisms, or the environment, would constitute a major change in labeling. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of “New York State Pesticide Product Registration Procedures” (November 2014). Such information, as well as forms, can be accessed at our website as listed in our letterhead.

Please contact Shaun Peterson, of our Pesticide Product Registration Section, at 518-402-8768, if you have any questions regarding this letter.

Sincerely,

Scott Menrath

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

Enclosures

Appendix

HUMAN HEALTH ASSESSMENT:

The following assessment was produced by staff within the Bureau of Toxic Substance Assessment at the New York State Department of Health (DOH):

Tea tree oil is a naturally-occurring material (composed of approximately 100 terpene hydrocarbon compounds and their associated alcohols) found in various herbs, spices and fruits and is particularly concentrated in the leaves and terminal branches of the tea tree (*Melaleuca alternifolia*). The major constituents of tea tree oil (terpinen-4-ol, γ-terpinene, 1,8-cineole, and α-terpinene) are approved by the U.S. Food and Drug Administration as substances that may be directly added to food intended for human consumption. The U.S. Environmental Protection Agency (U.S. EPA) classified tea tree oil as a biochemical pesticide and required limited toxicity testing for federal registration of Timorex Gold.

Toxicity Review

Neither the active ingredient, tea tree oil, nor the formulated product, Timorex Gold, were very toxic in acute oral, dermal and inhalation exposure studies in laboratory animals. Tea tree oil was found to be corrosive to the skin. Due to the corrosive nature of tea tree oil, eye irritation and skin sensitization studies were not conducted. In the absence of these studies, it is assumed that tea tree oil is both corrosive to the eyes and a skin sensitizer. Timorex Gold was found to be moderately irritating to skin and eyes, and a skin sensitizer. In a 90-day feeding study in rats, tea tree oil caused testicular toxicity in males and increased liver to body weight ratios in females at 60 milligrams-per-kilogram-per-day (mg/kg/day); the no-observed-effect-level (NOEL) was 30 mg/kg/day. In a developmental toxicity study in rats, tea tree oil caused decreased fetal weights at 120 mg/kg/day; the NOEL was 60 mg/kg/day. Maternal toxicity was characterized by treatment related decreased body weight gain and food intake at 60 mg/kg/day; the maternal NOEL was 30 mg/kg/day. Tea tree oil was also negative in several mutagenicity studies.

For federal registration of tea tree oil, the U.S. EPA additionally reviewed a human dermal exposure study with tea tree and lavender oils from the open literature[1]. This study reported gynecomastia (swelling of the breast tissue) in pre-pubertal boys after repeated dermal exposure to tea tree oil. This observed adverse effect resolved, and did not reoccur, shortly after dermal exposure to the active ingredient ceased. The study authors concluded that tea tree oil has estrogenic and anti-androgenic activities in part because gynecomastia occurs from an imbalance of estrogen and testosterone in the male body. The U.S. EPA did not expect the use of tea tree oil as a fungicide on food crops to result in unreasonable adverse effects to pre-pubertal boys because: 1) the formulated end-use product is not directly applied to the skin, 2) dermal exposure to

[1] Henley DV, Lipson N, Korach KS, Block CA. 2007. Prepubertal gynecomastia linked to lavender and tea tree oils. N Engl J Med.; 356(5): 479-85

workers (assumed not to be pre-pubertal boys) is not anticipated due to adequate personal protective equipment requirements on the label (long-sleeved shirt, long pants, socks, shoes, chemical-resistant gloves, and protective eyewear), and 3) the rapid degradation of tea tree oil in the environment should minimize any additional dietary exposures (above those from its natural presence in plant material). A current search of the toxicological literature did not find any significant other new information regarding the toxicity of tea tree oil.

Dietary Risk Assessment

The U.S. EPA has not established tolerances for tea tree oil on food crops, however U.S. EPA set limitations including a pre-harvest interval (PHI) of 48 hours and a maximum application rate of 1.54 pounds tea tree oil per acre. This determination was based on the high volatility of the active ingredient, rapid degradation of tea tree oil in the environment, and the lack of detectible residues in studies on tomatoes, peppers and bananas. While residue studies were not conducted for all food commodities, the U.S. EPA states that a PHI of 48 hours will provide ample time for dissipation of any residues. In addition, any residues that may be present on edible crops are not likely to be distinguishable from background levels that are found naturally in plants and residues from pesticide use would be further reduced by rain, washing, rinsing, and processing of the food crops. The U.S. EPA did not conduct a dietary risk assessment for use of tea tree oil as a pesticide on food crops.

Occupational Risk Assessment

The U.S. EPA reported the results of an occupational risk assessment for inhalation exposure to tea tree oil from use on field and orchard crops via aerial, groundboom and airblast application methods. For determining margins of exposure (MOEs), the U.S. EPA compared estimated inhalation exposures to a NOEL of 30 mg/kg/day from the 90-day oral toxicity and developmental toxicity studies in rats. Absorption of tea tree oil via inhalation was assumed to be 100%. The MOEs for mixer/loader, applicator and flagger activities ranged from 4,900 to 150,000 depending on the use site and application method. The U.S. EPA considered MOEs of 100-fold or greater in these scenarios to provide adequate worker protection from tea tree oil exposures. Post-application exposures to tea tree oil were not anticipated due to a 24-hour reentry interval label requirement and rapid degradation of the active ingredient in the environment.

Drinking Water/Groundwater Standards

Tea tree oil does not have a chemical-specific federal or New York State drinking water/groundwater standard. Each individual organic chemical in tea tree oil is considered an unspecified organic contaminant, and would have a general New York State drinking water standard of 50 microgram per liter (µg/L) (10 NYCRR Part 5, Public Water Systems). The general NYS DOH drinking water standard for the total of principal organic contaminants and unspecified organic contaminants in public water systems is 100 µg/L.

Summary/Recommendation

The biochemical pesticide tea tree oil is a naturally-occurring compound extracted from the leaves and terminal branches of the tea tree. The available information on the toxicity of tea tree oil and the expectation that residues will not be present on food commodities indicates that the potential for significant risks to public health via dietary exposure is minimal. There is some concern for occupational exposures to Timorex Gold due to the products potential for skin and eye irritation, skin sensitization, and limited evidence in the literature that components of tea tree oil may mimic estrogen. However, this concern should be mitigated by label requirements for personal protective equipment (long-sleeved shirt, long pants, socks, shoes, chemical-resistant gloves and protective eyewear). Given the above, the Department of Health does not object to registration of Timorex Gold in New York State.

ECOLOGICAL EFFECTS ASSESSMENT:

The following assessment was produced by staff within the Department's Division of Fish, Wildlife & Marine Resources' Bureau of Habitat (BOH):

I. CHEMICAL BACKGROUND

Tea tree oil is extracted from the leaves and terminal branches of the tea tree, *Melaleuca alternifolia,* a Myrtle, which is native to Australia, New Zealand, and Southeast Asia. The oil consists of approximately 100 different compounds, primarily terpene hydrocarbons, mainly monoterpene, sesquiterpenes, and their associated alcohols. These aromatic terpene hydrocarbons are characterized by high volatility, low water solubility, and are the major component of the essential oils of many plants.

The composition of tea tree oil used in commerce is regulated by an international standard, ISO 4730 (International Organization for Standardization), which sets maximum and minimum limits for 14 of its components. Of several varieties or chemotypes of tea tree oil, the one used as the active ingredient in Timorex Gold is the terpinen-4-ol type. It is 30-48% terpinen-4-ol and diminishing amounts of 4 other compounds.

Use Profile

Timorex Gold, 23.8% tea tree oil, is labeled for control of fungal and bacterial diseases in numerous agricultural crops. Many of the labeled sites are significant New York State crops, including cereal grains, fruiting vegetables, leafy vegetables, cucurbits, berry crops, and grapes.

Timorex Gold is applied using water as the carrier at a rate of 0.1-1.9 fluid ounces of formulation per gallon of water. The label states that thorough coverage of all plant parts is recommended and to apply to the point of runoff. It later suggests that, while the amount of spray solution needed will vary by crop type, most field-grown crops will require up to 100 gallons of spray solution per acre. Using the 100 gal/acre value, single

applications will equal 0.15-2.76 pounds of active ingredient per acre. Repeat applications are made at 1-2 week intervals. No seasonal maximum application limits are given.

Timorex Gold may not be applied through any type of irrigation equipment. Aerial applications are not mentioned on the label. Timorex Gold may not be applied within 48 hours of harvest.

Physical/Chemical Properties
Tea tree oil is a clear to pale yellow liquid with a characteristic odor. Chemical properties for the five tea tree oil main constituents as defined by ISO 4730 for this chemotype are given in Table 1.

Table 1.

Compound	Water solubility mg/L	Octanol/water partition coefficient, log K_{OW}	Vapor pressure mmHg	ISO 4730 limits min-max %
Terpinen-4-ol	1767	2.64	0.39	30-48
γ-Terpinine	8.72	4.47	0.7	10-28
α-Terpinine	5.92	4.75	0.8	5-13
p-Cymene	5.0	4.44	1.5	0.5-8
1,8-Cineole	552	3.13	1.9	Trace-15

Mode of Action
The tea tree oil mode of action is not well understood but it has been shown to affect cell respiration and alter cell membrane structure in yeast.

II. TOXICITY

As a biopesticide with active ingredients common to many plants utilized as food by wildlife, tea tree oil is not particularly toxic to most non-target organisms. Only a bare minimum of ecotoxicity studies were submitted to U.S. EPA, due to the relatively low toxicity found in Tier I studies and the expected rapid dissipation of tea tree oil post-application. Study results for works submitted in support of tea tree oil are given in Table 2.

Table 2. **Mammalian Toxicity**

Study Type	Result	Study ID (EPA MRID No.)	Comments
Rat Acute Oral	LD_{50} = 1773 mg/kg	47730404	Technical TEA TREE OIL
Rat Acute Oral	LD_{50} > 2000 mg/kg	47730507	Timorex Gold formulation
Rabbit Acute Dermal	LD_{50} > 2000 mg/kg	47730404	Technical TEA TREE OIL

Study Type	Result	Study ID (EPA MRID No.)	Comments
Rat Formulation Acute Dermal	LD_{50} > 2000 mg/kg	47730508	Timorex Gold formulation
Rat Acute Inhalation	LC_{50} > 3.1 mg/L	47730509	
Rat Subchronic Oral, 90-day	LOAEL = 60mg/kg/day NOAEL = 30 mg/kg/day	48598702 48878202	Testicular toxicity, increased liver to body weight ratios in females
Rat Developmental Toxicity, Gavage Doses Gestation Days 5-19	LOAEL = 60 mg/kg/day NOAEL = 30 mg/kg/day LOAEL = 120 mg/kg/day NOAEL = 60 mg/kg/day	49166401 Reduced fetal weights	Maternal systemic toxicity at 600 ppm and 300 ppm in diet equivalents Developmental toxicity at 1200 ppm and 600 ppm diet equivalents

Table 2 continued. **Ecotoxicity**

Study Type	Result	Study ID	Comments
Japanese Quail Acute Oral with Formulation	LD_{50} > 2000 mg/kg	47730513	LD_{50} > 476 mg/kg TEA TREE OIL content
Rainbow Trout Acute with Formulation	LC_{50} = 5.7 ppm NOEC = 0.5 ppm	47730514	LC_{50} = 1.3 ppm TEA TREE OIL NOEC = 0.12 ppm TEA TREE OIL
Zebra Fish Acute with TEA TREE OIL	LD_{50} > 100 ppm	47730408	No NOEC reported
Daphnia Acute with Formulation	EC_{50} = 1.45 ppm NOEC = 0.63 ppm	47730515	EC_{50} = 0.35 ppm TEA TREE OIL NOEC = 0.15 ppm TEA TREE OIL
Fresh Water Green Algae *S. subspicatus*	EC_{50} = 1.7 ppm TEA TREE OIL	47730516	No NOEC reported
Honey Bee Acute	Contact LD_{50} =331 µg/bee Oral LD_{50} > 98.5 µg/bee	47730520	Practically Non-toxic
Bumblebee Acute	Contact LD_{50} > 105.5 µg/bee	47730519	Practically Non-toxic

	Oral LD_{50} > 100 µg/bee		
Predatory Mite	LR_{50} > 0.86 lb TEA TREE OIL/acre	47730517	Delayed development & reduced reproduction at > 0.214 lb TEA TREE OIL/acre
Aphid Parasitoid Wasp	ER_{50} > 0.21 lb TEA TREE OIL/acre	47730518	

III. EXPOSURE

The active ingredient in Timorex Gold dissipates rapidly enough that except for a brief period immediately post-application, non-target exposure to tea tree oil is expected to be minimal.

Environmental Fate

Tea tree oil is expected to dissipate rapidly post-application, primarily through volatilization. Any material that isn't lost to the atmosphere will be microbially degraded. None of the standard EPA suite of environmental fate studies were conducted.

In indoor residue trials conducted on tomatoes and green peppers in The Netherlands and Spain, respectively, no measurable tea tree oil constituents were found on the harvested fruits after 48 hours post treatment. Up to 90% of the applied tea tree oil volatilized within the first 24 hours.

In a 28-day Ready Biodegradability assay (OECD Guideline 310), biodegradation of tea tree oil was 10% after 2 days, 60% after 5 days, 87% by day 7, and was 106% at study termination.

Exposure Modeling

BOH standard screening level terrestrial and aquatic exposure modeling was performed as part of this review.

In both compartments, a single application was simulated at the highest label rate given for a New York crop. The terrestrial food item residues in AVTOX and MAMTOX modules are for upper limit residues, i.e. residues immediately following application. The PONDTOX runoff module parameters are set to produce the maximum runoff immediately following application.

The avian modeling output indicated the possibility of toxicity occurring when the Japanese quail toxicity values are used. The AVTOX modeling system, however, does not account for the fact that the Quail values are actually "greater than" results. The

Quail study result is that the LD_{50} > 476 mg/kg, i.e. the LD_{50} is unknown. There were no mortalities or adverse clinical signs at the highest dose tested in the study so it's not clear that the model predicted toxicity would occur in the field. One point that may be a mitigating factor is that tea tree oil is a highly volatile substance. A concentrated plume of volatile aromatic hydrocarbons might serve as a deterrent to feeding in recently treated areas.

The exceeded toxicity values in the MAMTOX output are for chronic studies. Exposures that might occur in the field will be very brief, therefore chronic exposure is not a concern.

The label doesn't specifically prohibit aerial applications so the Direct Application to surface waters module results aren't beyond the realm of possibility. The only labeled use that results in tea tree oil concentrations lethal to fish from a direct misapplication to a surface water is the upper limit given for cereal grains. Given that the label doesn't even include aerial application directions, it's not clear to this reviewer that potential impacts from the highest application rate for one of six allowed crop groups rises to the level of warranting a label change.

Even at exaggerated screening level runoff rates, the Runoff module results show little reason for concern.

IV. SUMMARY AND RISK ASSESSMENT

The tea tree oil rapid post-application dissipation and relatively low toxicity make adverse impacts to non-target resources unlikely. As a result, the Bureau of Habitat has no objection to registration of Timorex Gold in New York State.