



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 3, 2019

Abigail Wacek
Technology Science Group
1150 18th Street, NW Suite 1000
Washington, D.C. 20036

Subject: PRIA Label Amendment – reduce the acute tox categories for the acute oral and acute inhalation
Product Name: BIONIX GA25
EPA Registration Number: 89110-9
Application Date: August 2, 2018
Decision Number: 551553

Dear Ms. Wacek:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Zeno Bain', with a long horizontal stroke extending to the right.

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
DANGER

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Do not breathe vapors or mist. Do not get in eyes, on skin, or on clothing. Wear coveralls over long-sleeved shirt and long pants, socks, chemical-resistant gloves such as butyl rubber or nitrile/butadiene rubber, chemical resistant footwear, goggles, a NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, with NIOSH approval number prefix TC-84A; or a NIOSH approved gas mask with a canister with NIOSH approval number prefix TC-14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC-23C, chemical resistant footwear, and goggles. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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.

USER SAFETY RECOMMENDATIONS

Before handling or using this product, see your employer and read the current safety data sheet. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must wash hands before eating, drinking, chewing gum, or using the toilet. Users must remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or public water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
PESTICIDE STORAGE: This product is incompatible with many commonly used materials or construction such as steel, galvanized iron, aluminum, tin and zinc. The product can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about -6°F(-21°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage time (up to 1 month), temperatures of up to 100°F(37.8°C) can be tolerated but the preferred maximum storage temperature is about 80°F(26.7°C). Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.
PESTICIDE DISPOSAL: Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal or excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple or pressure rinse container (or equivalent) promptly after emptying. For containers 5 gallons or less – Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. For containers larger than 5 gallons – Clean container promptly after emptying. Triple rinse as follows: 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. Follow the Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities.

BIONIX GA25

Active ingredient:
Glutaraldehyde 25.0%
Other ingredients: 75.0%
TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> 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 ON SKIN OR CLOTHING	<ul style="list-style-type: none"> 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 SWALLOWED	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have affected person sip a glass of water if able to swallow. Do not induce vomiting unless told by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

EMERGENCY PHONE NUMBERS

In case of emergency, please call INFOTRAC: (800)-535-5053
 Have product container or label with you when calling a poison control center or doctor or going for treatment.

NOTES TO PHYSICIAN

Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED

Jun 03, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 89110-9

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

A highly effective Microbiocide for use in controlling spoilage, odor causing, corrosion inducing, slime forming and sulfate-reducing Bacteria, Fungi (yeast and molds) and Algae in Air washers and Industrial Scrubbing Systems, Recirculating Cooling and Process Water Systems including those that contain Reverse Osmosis Membranes and Service Water and Auxiliary Systems, Heat Transfer Systems, Wastewater Systems Including Wastewater Sludge and Holding Tanks, Paper Mills and Paper Mills Process Water Systems, Pigments and Filler Slurries for Paper and Paperboard, Water Based Coatings for Paper and Paperboard and Functional Fluids and Lubricants and Aqueous Metalworking Fluids, For use by Manufacturers as a Preservative in Industrial, Institutional and Consumer Processes and Products for use in Preserving Aqueous-Based Solutions, Slurries and Emulsions and in Oil Well Drilling, Oil Field Processing Applications, Oil Field Water Systems, Oil and Gas Production and Transmission Pipelines and Systems, and Gas Storage Fields and Equipment: such as Steam-injection Water, Holding Tanks, Flood Water, Fracturing Fluids, Injection Water, Holding Pond Water, Disposal-Well Water, Water Holding Tanks, Fuel Storage Tanks, and related Refinery and Oil Field Closed, Industrial Recirculating Water Handling Systems.

FOR DETAILED DIRECTIONS FOR USE, PLEASE REFER TO THE ISOMERIC INDUSTRIES LABEL SUPPLEMENT.

Read these entire Directions for Use before using BIONIX GA25.

WARRANTIES AND WARRANTY DISCLAIMERS

Conditions of Sale: Isomeric Industries ("ISOMERIC") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to ISOMERIC. To the extent consistent with applicable law, ISOMERIC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. To the extent consistent with applicable law, ISOMERIC SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL, OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, and ISOMERIC's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price. BUYER AND USER ACKNOWLEDGE AND ASSUME ALL RISKS AND LIABILITY RESULTING FROM HANDLING, STORAGE AND USE OF THIS PRODUCT. ISOMERIC DOES NOT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTY, GUARANTEE OR REPRESENTATION CONCERNING THIS PRODUCT.



ISOMERIC INDUSTRIES
 3400 RESEARCH FOREST DR., SUITE B4
 THE WOODLANDS, TX 77381
EPA REG. NO. 89110-9
EPA EST. NO. XXXXXX-XX-XXX

REV 051817

LOT NUMBER

MFG DATE

NET WEIGHT

GROSS WEIGHT

BIONIX GA25

Active ingredient:

Glutaraldehyde	25.0%
Other ingredients:	75.0%
TOTAL:	100.0%

DIRECTIONS FOR USE – LABEL SUPPLEMENT

This document must accompany each shipment.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR USE AS AN INDUSTRIAL BACTERICIDE AND PRESERVATIVE

AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS/RECIRCULATING COOLING AND PROCESS WATER.

Use only in industrial air washer systems, which have mist-eliminating components. Product should be added at a point of uniform mixing such as the basin area. Badly fouled systems can be shock treated by using the highest recommended rate for the product. Under these conditions, blowdown should be discontinued for up to 24 hours. Apply by intermittent or continuous feed methods.

Initial Dose: When the system is noticeably fouled, add 24- 48 fl. oz. (200-400 ppm) of product per 1,000 gal. of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 9.6-24 fl. oz. (80-200 ppm) of product per 1,000 gal. of water in the system per day, or as needed to maintain control.

SERVICE WATER AND AUXILIARY SYSTEMS

Product should be added to the system at a point of uniform mixing such as basin area, sump area, or other reservoir. Product should be used at the same application rates, and in the same manner as described above for Air Washers.

HEAT TRANSFER SYSTEMS

(Evaporative Condensers, Dairy Sweetwater Systems, Hydrostatic Sterilizers and Retorts, Pasteurizers and Warmers)

Product should be used at the same application rates, and in the same manner as described for Air Washer systems. Product should be added to the system at a point of uniform mixing such as a basin area, sump area, or other reservoir or collecting area from which the treated water will be circulated uniformly throughout the system.

INDUSTRIAL WASTEWATER SYSTEMS

For use in aerobic and anaerobic, belt pressed, digested and undigested sludges and holding tanks. Product should be added at a point of uniform mixing, such as the digester. Add 1.0 to 4.6 gal. (900 to 4500 ppm) of product per 1,000 gal. of wastewater or sludge.

BET SUGAR MILLS AND BEET SUGAR MILL PROCESS WATER SYSTEMS

Product should be added to the system at a point of uniform mixing such as the diffuser, transport water pump, weir box, or diffuser feed water pump. Additions may be made intermittently (slug dose) or continuously.

INTERMITTENT (SLUG DOSE) METHOD

Initial Dose: When the system is noticeably contaminated, add 11 to 27 fluid ounces (400 to 1000ppm) of product per ton or 640 to 1600 mL of product per metric ton of sliced beets as a slug dose. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.6 to 16.4 fluid ounces (60 to 600 ppm) of product per ton or 60 to 600 mL of product per metric ton of sliced beets in the system as a slug dose as necessary to maintain control. The total should not exceed 212 gallons per 1,000 tons of beets sliced per day.

CONTINUOUS FEED METHOD

Initial Dose: When the system is noticeably contaminated, add 11 to 27 fluid ounces/minute (400 to 1000 ppm) of product per ton or 640 to 1600 mL/minute of product per metric ton of beets sliced per minute in the system via automatic pump of suitable construction.

Subsequent Dose: When microbial control is evident, add 1.68 to 16.4 fluid ounces/minute (60 to 600ppm) of product per ton or 60 to 600 mL/minute of product per metric ton of beets sliced per minute in the system, or as necessary to maintain control. The total should not exceed 212 gallons per 1,000 tons of beets sliced per day.

PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS

Apply by intermittent or continuous feed methods. Product should be added at a point of uniform mixing such as beaters, broke chest pump, save-all tank, or white-water tank.

Initial Dose: When the water is noticeably contaminated, add 1.6-6.0 lbs. of product per ton of pulp or paper (dry basis). Repeat until control is achieved.

Subsequent Dose: When microbial control is evident add 0.6-4.0 lbs. of product per ton of pulp or paper (dry basis) necessary to maintain control.

PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD

To inhibit the growth of spoilage microorganisms during manufacture, storage and distribution of pigments and filler slurries such as kaolin, calcium carbonate and titanium dioxide. Add product to produce a concentration of 200-1200 ppm by weight of the formulation slurry (2.0-12.0 lbs. of product per 10,000 lbs. of slurry).

WATER BASED COATINGS FOR PAPER AND PAPERBOARD

To inhibit the growth of spoilage microorganisms during manufacture, storage and distribution of water-based coatings for use on non-food-contact paper and paperboard. Add product at 200-1200ppm by weight of the formulation slurry (2.0-12.0 lbs. of product per 10,000 lbs. of slurry).

AQUEOUS METALWORKING FLUIDS

Product should be added to a metalworking fluid system at a point of uniform mixing such as the fluid collection tank. Additions can be made intermittently at intervals of one week or less.

Initial Dose: When the system is noticeably fouled apply 0.4 to 1.2 gal. of product per 1,000 gal. of metalworking fluid to the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 0.16 to 0.8 gal. of product per 1,000 gal. of metalworking fluid to the system weekly, or as needed to maintain control. Badly fouled systems should be cleaned before treatment begins.

WATER BASED CONVEYOR LUBRICANTS

(Brewery, Juice, Dairy, Beverage, and Food Processing Systems)

Avoid contamination of food in application of product. Thoroughly clean all tracks and conveyors to remove gross soil. Rinse well. Use an automatic feed system to provide 2.4 to 14.4 fluid ounces (50 to 300 ppm) of product per 100 gallons of diluted lubricant.

GENERAL PRESERVATIVE USE

Non-food contact: For use by manufacturers for in-can preservation of aqueous industrial, institutional and consumer non-food contact products that require the control of bacteria and fungi for example, mineral slurries used in paints and plastics, pigments, lattices, printing inks, paint, laundry detergents, and cleaning products. Add the product to the product formulation at a rate of 5.6 to 56 fluid ounces (400 to 4000 ppm) per 100 gal. of the water content of the product. Mix uniformly.

Food contact: For use by manufacturers that require the control of bacteria or fungi in the preservation of food-contact adhesives and mineral slurries used in papermaking. Add the product to the product formulation at a rate of 5.6 to 56 fluid ounces (400 to 4000 ppm) per 100 gal. of the water content of the product. Mix uniformly.

PRESERVATIVE FOR CONCENTRATES

Use in concentrates where effective preservation is needed after dilution. Add product at a rate such that the diluted end-use product will contain 400 to 4,000 ppm (0.04% to 0.4%) of product.

REVERSE OSMOSIS MEMBRANES

Use only where approved for compatibility by the membrane manufacturer. Immerse membrane in a tank containing 4,000 to 40,000 ppm of product for 6 to 24 hours. Product can also be added to inline recirculating systems of installed out-of-service osmosis equipment. Add 400 to 4,000 ppm product to the tank on the circulating system and maintain this concentration by periodic addition to counteract any system leakage. Flush the system through with clean water before returning to service.

CONCRETE ADMIXTURES

For effective preservation of concrete admixtures, add the product to the product formulation at a rate of 4,000 to 16,000 ppm based on the weight of the admixture (4.0 to 16.0 lbs. product per 1,000 lbs. concrete admixture). Mix uniformly.

WATER FLOODS

The product should be added to a water flood system at a point of uniform mixing.

Initial Treatment: When the system is noticeably contaminated, add 200 to 10,000 ppm of the product to the system (0.2 to 9.4 gallons product per 1,000 gallons flood water). Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 40 to 10,000 ppm of the product (0.04 to 9.4 gallons of the product per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

FRAC FLUIDS

(Not approved for this use in the state of California)

Product reduces bacterial contamination and degradation of fracturing fluids and gels used in oil and gas well stimulations. Add product to the frac water storage tanks or directly into the well head injection pipeline as the water is being pumped down-hole.

Dose Range: Product should be added at a rate of 1.9 - 94 gals. (200 to 10,000 ppm) of product per 10,000 gallons of fluid, depending on the degree of contamination in the source water.

DRILLING, COMPLETION, AND WORKOVER FLUIDS

Product should be added to a drilling fluid system at a point of uniform mixing such as the circulating mud tank.

Initial treatment: Add 0.4 to 7.9 gallons (100 - 2,000 ppm) of product per 100 barrels of fluid to a freshly prepared fluid depending on the severity of contamination.

Maintenance dosage: Maintain a concentration of 100 to 2,000 ppm product by adding 0.4 to 7.9 gallons of product per 100 barrels of additional fluid, or as needed, depending on the severity of contamination.

PACKER FLUIDS

Product should be added at a point of uniform mixing such as circulating holding tank.

Add product at 0.42 to 5 gals (100 - 1200 ppm) of product per 100 barrels of fluid to a freshly prepared fluid, depending on the severity of contamination. Apply once before sealing the treated packer fluid in the well between the casing and production tube.

OIL PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS

(Not approved for this use in the state of California)

Product should be added to an oil production or transmission line via direct injection. The application should be conducted to ensure maximum distribution of product throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect/measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in bacterial counts and/or reduced corrosion rates. To facilitate application, it may be desirable to dilute the product with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5,000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly, or as needed to maintain control.

GAS PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS

Product should be added to a gas production or transmission pipeline via direct injection. The application should be conducted to ensure maximum distribution of product throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect/measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in bacterial counts and/or reduced corrosion rates. To facilitate application, it may be desirable to dilute the product with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5,000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly, or as needed to maintain control.

GAS STORAGE WELLS AND SYSTEMS

Individual injection wells should be treated with a sufficient quantity of product to produce a concentration of 1000 to 10,000 ppm of product when diluted by the water present in the formation. Injection should take place before gas is injected (during the summer). Injections should be repeated yearly, or as needed to maintain control. Individual drips should be treated with a sufficient quantity of product to produce a concentration of 200 to 2000 ppm product when diluted by the water present in the drip. Injections should be repeated yearly, or as needed to maintain control.

HYDROTESTING

Water used to hydrotest pipelines or vessels should contain 200 to 8,000 ppm product (0.2 to 7.5 gallons product per 1,000 gallons water), depending on water quality and length of time the equipment will remain idle.

PIPELINE PIGGING AND SCRAPING OPERATIONS

Add product to a slug of water immediately following the scraper (ideally this water volume can be kept to a minimum and contained between the scraper and a trailing pig). Sufficient product should be added to produce a concentration of 0.2 to 2% (0.2 to 1.9 gallons product per 100 gallons water), depending on the length of the pipeline and the severity of biofouling.

INJECTION WASTE FLUIDS

(Not approved for this use in the state of California)

Add 100 to 5,000 ppm product to the waste fluid prior to or at injection into an approved disposal well.



3400 RESEARCH FOREST DR., SUITE B4
THE WOODLANDS, TX 77381
EPA REG. NO. 89110-9
EPA EST. NO. XXXXXX-XX-XXX
REV 080218