

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

92513-16

EPA Reg. Number:

Date of Issuance:

4/15/25

NOTICE OF PESTICIDE:

X Registration

___ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

BioSuiteG25x

Name and Address of Registrant (include ZIP Code):

Michael Gurecki BioSuite, LLC

Electronic Transmittal: michael.gurecki@biosuitegroup.com

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

A/15/25

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510M)

Office of Pesticide Programs

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- 2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Gluteraldehyde GDCI-043901-1668

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Reevaluation Team Leader (Team 36): https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division

- 3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 92513-16."
- 5. Submit one copy of the final printed label for the record before you release the product for shipment.

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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF and Alternate CSF 1 dated, 09/25/2023

If you have any questions, please contact Linda Amar via email at amar.linda@epa.gov.

Enclosure: Final Stamped Label

BioSuite G25x

ACTIVE INGREDIENTS

Glutaraldehyde	25.00%
INERT INGREDIENTS	
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER / PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

SEE [{SIDE} {BACK}] PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

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 SWALLOWED: Call a 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: 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 advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Aspiration may cause lung damage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday - Friday, 8:00 am - 12:00 pm Pacific Time; email: npic@ace.orst.edu; or website: http://npic.orst.edu/. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

You may contact 800-262-8200 for chemical, medical, or environmental emergencies.

ACCEPTED

04/15/2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 92513-16

EPA REG. NO. 92513-RA EPA EST. NO. {producing establishment's number}



Net Contents: {net contents in gallons or lbs}

{Batch/Lot #: {batch or lot #} }

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Not to be used as an aerosol. Wear protective eyewear such as goggles, face shield, or safety glasses. Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Coveralls worn over long-sleeve shirt and long pants, socks, chemical-resistant footwear, chemical-resistant gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Polyethylene, or Polyvinyl Chloride (PVC), or Viton, selection Category A), and chemical-resistant apron. 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 use.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper-reactive individuals. Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and a combination N, R, or P filter; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air-purifying respirator with OV cartridges and combination HE filters.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear: goggles or face shield, coveralls worn over long-sleeve shirt, long pants, chemical-resistant footwear, socks, chemical-resistant gloves (such as butyl rubber) and chemical resistant apron.

USER SAFETY REQUIREMENTS

Follow manufacturers' instructions for cleaning & maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Users must wash hands before eating, drinking, chewing gum, or using the toilet. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must 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.

The open pouring of glutaraldehyde solutions must be limited to low volume applications where the amount of concentrate handled is less than five gallons per day.

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Automatic addition systems that minimize operator exposure to the concentrated product must be used when handling larger amounts of glutaraldehyde. If this is not feasible then local exhaust ventilation must be used to reduce glutaraldehyde exposure.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters 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 local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

{MARKETING CLAIMS}

- This product is a microbiocide for use in controlling sulfate-reducing bacteria (SRB) and slime forming bacteria in oil well drilling, oil field processing applications, oil field water systems, oil and gas productions and transmission pipelines and systems, and gas storage fields and equipment; such as steam-injection water holding tanks, flood water, injection water, holding pond water, disposal-well water, water holding tanks, fuel storage tanks and related refinery and oil field closed systems, industrial recirculating water handling systems.
- This product reduces bacterial contamination and degradation of fracturing fluids and gels used in oil and gas well stimulations.
- To control algae and bacterial slimes, use this water treatment microbiocide as directed.
- Effective against the growth of algae in non-public health uses.
- Has been designed specifically for control of sulfate-reducing bacteria that contribute to souring, the
 production of sulfide, and abiotic corrosion in oil field systems, gas production and transmission
 pipelines and systems.
- Helps inhibit the growth of unsightly algae.
- Kills and prevents algae when used in accordance with use directions.
- The residual effectiveness of this algaecide tends to stabilize the total chemical treatment system.
- This product is effective for the control of odor-forming and slime-forming bacterial, fungi and algae in auxiliary service water systems such as fire protection systems and pump or screen bays, waste water systems such as storage tanks, storage piles, associated piping, setting ponds or lagoons, transport spillways or canals and disposal wells.

This product is for use in (insert location) For use {in} {on} (insert location).

{LOCATIONS}

- Air Washers and Industrial Scrubbing Systems/ Recirculating Cooling and Process Water Systems
- Aqueous Metalworking Fluids
- Beet Sugar Mills and Beet Sugar Mill Process Water Systems
- Concrete Admixtures
- Drilling, Completion and Workover Fluids Systems
- Frac Fluids (Not a use registered by California)
- Gas Production and Transmission Pipelines and Systems

- Gas Storage Wells and Systems
- General Preservative Use
- Heat Transfer Systems
- Hydrotesting Facilities
- Industrial Wastewater Systems
- Oil Field Water Flood Systems {and Fracturing Fluid Systems}
- Oil Production and Transmission Pipelines and Systems (Not a use registered by California)
- Packer Fluid Systems
- Paper Mills and Paper Mill Process Water Systems
- Pipeline Pigging and Scraping Operations
- Reverse Osmosis Membranes
- Service Water and Auxiliary Systems
- Non-Food Contact Water Based Coatings for Paper and Paperboard
- Water Based Conveyor Lubricants
- Oil Well Water Floods

DIRECTIONS FOR USE

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

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

Use only in industrial air washer systems, which have mist-eliminating components. 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 23.0-46.0 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 9.2-23.0 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 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. It 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. Add 1.0 to 4.6 gal. (900 to 4,500 ppm) of product per 1,000 gal. of wastewater or sludge.

BEET 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 1,000 ppm) of product per ton or 640 to 1,600 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 27.2 fluid ounces/minute (400 to 1,000 ppm) of product per ton or 640 to 1,600 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 1.6 to 16.4 fluid ounces/minute (60 to 600 ppm) 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.

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.

WATER BASED COATINGS FOR NON-FOOD CONTACT 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 200-1,200 ppm 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.

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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 plastics, lattices, 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 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.

OIL WELL 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 (0.18 to 9.0 gallons product per 1,000 gallons flood water). Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 100 to 500 ppm of the product (0.1 to 0.5 gallons of the product per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

FRAC FLUIDS (Not a use registered by 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

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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

Add product at 0.42 to 5.0 gals (100 - 1,200 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 wall between the casing and production tube.

OIL PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS (Note a use registered by 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 1,000 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 400 to 4,000 ppm product when diluted by the water present in the drip. Injections should be repeated yearly, or as needed to maintain control.

HYDROTESTING

For use in pipelines, valve systems, boilers and vessels. Water used to hydrotest pipelines or vessels should contain 200 to 8,000 ppm (0.2 to 8.0 gal. per 1,000 gal. water) of this product, depending on water quality, pH, environmental conditions and the length of time the equipment will remain idle. At neutral pH and below, treated water can remain in the system for more than 1 year.

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.

STORAGE AND DISPOSAL

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

STORAGE AND HANDLING: Store only in original container. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

This product is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc.

These solutions can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment.

The preferred storage temperature is about 20°C.

A stainless steel centrifugal pump is suggested for transfer service. Spiral wound stainless steel with TEFLON® is suitable for gaskets and packing.

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

Wastes resulting from the use of this product may be disposed of on site or any approved waste disposal facility.

CONTAINER HANDLING:

Note to Reviewer: One or more of the following paragraphs for Container Handling will be selected, depending on packaging use/type.

{For non-refillable containers equal to or less than 5 gal.}

Non-Refillable Container. Do not reuse or refill this container. Triple rinse container {(or equivalent)} promptly after emptying. Triple rinse as follows: Fill the 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 this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

{For non-refillable containers greater than 5 gal.}

Non-Refillable Container. Do not reuse or refill this container. Triple rinse container {(or equivalent)} 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 back and forth several times. Turn the container over onto its other end and tip back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

{DOT UN number}
{DOT proper shipping name}

Note to Reviewer: Optional DOT UN number and proper shipping name may be placed on the label.

Note to Reviewer: Text within braces {} is optional. Marketing text is optional. Brackets [] indicate that at least one option within the brackets must be used on the final label. Parentheses () are meant to appear on the final label. "This product" can be substituted with actual product name in the marketing and directions for use.