

82972-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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United States
Environmental Protection
Agency

Office of Pesticide Programs

MAR 30 2010

Olivia Laird
Laird's Regulatory Consultants, Inc.
Estates at Shenstone Farm
17804 Braemar Place
Leesburg, VA 20175

Subject: PRIA (D#429844)
Vital Technologies
Vital Oxide
EPA Registration No. 82972-1
Submissions Dated: 11/10/09 and 2/13/10
Receipt Dated: 11/13/09 and 2/13/10

Dear Ms. Laird:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions.

Findings based on submitted data:

1. The proposed label claims that the product, Vital Oxide, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time:

Acinetobacter baumannii
Listeria monocytogenes
Pseudomonas aeruginosa

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the product, Vital Oxide, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time:

HIV Type 1
Respiratory Syncytial Virus
Rotavirus
Influenza A (H1N1) Swine Flu
Hepatitis B
Hepatitis C

3. The proposed label claims that a 1:12 use solution of the product, Vital Oxide, is an effective sanitizing rinse on hard, non-porous, food contact surfaces for a 1-minute contact time. This claim **is acceptable** as it is supported by the submitted data.

Conditions:

The following revisions to the proposed label are required:

- a. You must update the "Storage and Disposal" section of the label per PR-Notice 2007-4 for the container disposal language.
- b. The unacceptable Agency term "grade" has been removed from the label. This product is classified as a "hospital disinfectant" not a "hospital grade disinfectant".
- c. The Ingredient statement must appear as

ACTIVE INGREDIENTS:
 Chlorine Dioxide..... 0.200%
 Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
 dimethyl benzyl ammonium chloride..... 0.125%
 Alkyl (68% C₁₂, 32% C₁₄)
 Dimethyl ehtylbenzyl chloride..... 0.125%
 OTHER INGREDIENTS..... 99.550%
 Total.....100.000%

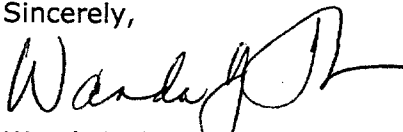
- d. The complete directions for food contact sanitization have been moved to the second page.
- e. Add ATCC numbers for all listed microorganisms. ATCC designation numbers are required in one of the following locations:
 - o on the data matrix;
 - o on the master label (as optional text) with the listing of the organisms claimed; or
 - o As the final page of the master label (as optional text).
- f. Identify types of objects intended for disinfection. The proposed label only I identifies floors.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,



Wanda Y. Henson
 Acting Product Manager - Team 32
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

Disinfects As It Cleans • Eliminates Odors •

Fragrance Free

VITAL OXIDE provides hospital disinfection, sanitization of food contact surfaces, mold & mildew prevention, broad spectrum cleaner & odor elimination.

AREAS OF USE INCLUDE: homes, vehicles, schools & daycare, gyms & locker rooms, sports gear, hospitals, nursing homes, restaurants, boats, ships, federally inspected meat & poultry processing plants, farms, animal pens and poultry houses, egg processing premises, hatcheries, swine premise sanitation. For disinfecting pre-cleaned hard non-porous surfaces such as glass, laminate, chrome, stainless steel, polyurethane coated hardwood floors, glazed ceramic tile, sealed concrete & linoleum floors. Use as a mold & mildewstat on hard non-porous surfaces such as tile, and porous surfaces such as fabric.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before using. Test fabric for color fastness. Contains a dilute oxidizing agent. Do not mix with vinegar or acetic cleaners.

Pre-cleaning Instructions: Remove gross filth and heavy soil by cleaning. Spray VITAL OXIDE straight onto soils, scrub and wipe clean with a dry paper towel or cloth. For cleaning floors add one cup VITAL OXIDE per gallon of water in bucket and clean with sponge, mop or pad.

To Disinfect Hard Non-porous Surfaces: Apply VITAL OXIDE full strength to pre-cleaned hard non-porous surfaces, wetting thoroughly with spray, sponge, mop, or by immersion in solution. Allow surfaces to remain wet for 5 minutes for virus inactivation - 10 minutes for bacteria disinfection. For immersion replace solution daily, or more frequently if it becomes significantly soiled or diluted.

To Prevent Mold or Mildew on Floors, Walls, Ceilings & Fabric: Remove as much surface dirt, old, or mildew as possible by cleaning. Then spray on VITAL OXIDE from a distance of 12 inches until visibly wet and let air dry. To Deodorize: VITAL OXIDE works by oxidation, not by masking of odors. Eliminates odors caused by fire smoke, tobacco smoke, musty odors, stale-cooking odors. Simply spray, fog or wipe on full strength and let air dry to provide long lasting residual deodorizing action. When fogging apply 1 quart per 2000 cubic ft. following fogger manufacturer's directions for use. VITAL OXIDE must come into contact with the cause of the odor to be effective. For pet urine stains in carpet, blot urine as dry as possible then saturate stain with VITAL OXIDE through carpet pad.

To Sanitize Food Contact Surfaces: *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC11229)

Mix 1 part VITAL OXIDE to 12 parts tap water. For glassware, utensils, cookware, and dishware: Scrape and pre-wash, then wash with a good detergent. Rinse with potable water, then

VITAL OXIDE®

HOSPITAL
DISINFECTANT

99.999% SANITIZATION OF FOOD
CONTACT SURFACES



No rinse required sanitizer for food contact surfaces (D-2)

MOLD & MILDEW REMOVER
PREVENTS MOLD & MILDEW
ON HARD SURFACES & FABRIC

HEAVY DUTY ODOR ELIMINATOR

VITAL-OXIDE KILLS:

MRSA, Pseudomonas aeruginosa,
Escherichia coli, Salmonella enterica,
Staphylococcus aureus, Legionella
pneumophila.

Aspergillus niger, Norovirus (Feline
Calicivirus as surrogate) Human

Immunodeficiency virus type 1 (HIV-1),

Enterobacter aerogenes,

Listeria monocytogenes, Acinetobacter
baumannii

Respiratory Syncytial Virus, Rotavirus,
Influenza A (H1N1) Swine Flu, Hepatitis B,
Hepatitis C

ACTIVE INGREDIENTS:

Chlorine Dioxide.....	0.200%	
Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)		
dimethyl benzyl		ammonium
chloride.....	0.125%	
Alkyl (68% C ₁₂ , 32% C ₁₄)		
dimethyl ethylbenzyl		ammonium
chloride.....	0.125%	
OTHER INGREDIENTS.....	99.550%	
Total.....	100.000%	

KEEP OUT OF REACH OF CHILDREN
CAUTION

See side panel for additional

To Sanitize Carpet: For synthetic carpet fibers such nylon, olefin, or polypropylene - not intended for use on wool carpet. Test for color fastness in an inconspicuous area. Carpet should be clean or free of excessive soil before applying. Mix 1 part Vital Oxide to 5 parts water. Apply by sprayer at a rate of 1.7 gallons per 10 sq. yards (approx 22oz per sq. yd). Vital Oxide must come into contact with contaminate to work. Allow to dwell for 10 minutes. Do not rinse, use an extraction wand and dry stroke carpet to remove excess moisture. Carpet can air dry or fans may be used if carpet needs to dry faster.

To Disinfect Farm Premises, Poultry Houses, Animal Pens & Vehicles: Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with VITAL OXIDE for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Allow to air dry. Ventilate buildings, cars, boats, and other closed spaces. Drain any pooled product and/or rinse standing product with potable water. Do not house livestock or employ equipment until treatment has been absorbed, or dried.

KILLS HIV-1, HBV, AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces /objects with blood or body fluids and surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency virus type1 (HIV-1) (associated with AIDS), Human Hepatitis B virus, and Human Hepatitis C virus.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal.

CONTACT TIME: Allow surfaces to remain wet for 5 minutes. This contact time will not control bacteria.

STORAGE AND DISPOSAL: Store in original closed container in a cool, dry place away from heat and open flame. DISPOSAL: Rinse and offer empty

(or longer if specified by government sanitary code) Place on a rack or drain board to air dry. Do not rinse or wipe. Food Contact Immobile Surfaces: (food processing equipment, counter tops, tables, appliances) Remove all gross food particles and soil by cleaning and rinse with potable water. Apply VITAL OXIDE by wetting thoroughly and let stand for 1 minute. (or longer if specified by government sanitary code) Let surfaces drain and air dry. Do not rinse or wipe. Manufactured by: Vital Technologies, Inc. PO Box 9932 W. Palm Bch, FL 33419

Customer Service: 1-800-303-5405

www.vitaltechnologies.com

EPA Reg. No. 82972-1 EPA Est. No. 85804-NC-1: EPA Est. No 29909-CA-1 (See batch code for actual establishment number)

NOTICE: Seller expressly warrants that the product conforms to its chemical description. There are no other warranties associated with sale of the product either express or implied.

128 oz.

NET CONTENTS:

To Sanitize Food Contact Surfaces: Mix 1 part VITAL OXIDE to 12 parts tap water. For glassware, utensils, cookware, and dishware: Scrape and pre-wash, then wash with a good detergent. Rinse with potable water, then sanitize by immersion in VITAL OXIDE for 1 minute (or longer if specified by government sanitary code) Place on a rack or drain board to air dry. Do not rinse or wipe. Food Contact Immobile Surfaces: (food processing equipment, counter tops, tables, appliances) Remove all gross food particles and soil by cleaning and rinse with potable water. Apply VITAL OXIDE by wetting thoroughly and let stand for 1 minute. (or longer if specified by government sanitary code) Let surfaces drain and air dry. Do not rinse or wipe.

available discard container in trash. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Discard excess or used VITAL OXIDE solution in drain with running water.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes

FIRST AID

If	Hold eye open and rinse slowly with water
in	15-20 mins. Remove contact lenses after
Eyes	first 5 mins. and continue rinsing. Call a
	Poison Control Center or doctor for
	treatment advice. Have product container or
	label with you when calling a poison control
	center or doctor, or going for treatment.