

81242-1

3/2/2012

1 of 8



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

MAR - 2 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BioNeutral Group Inc.
211 Warren Street
Newark, NJ 07103

Attention: J. Michael Kelley, PhD
Authorized Representative

Subject: Ygiene 206 – Amendment to add additional marketing claims
EPA Reg. No. 81242-1
Amendment Letter Dated January 12, 2012

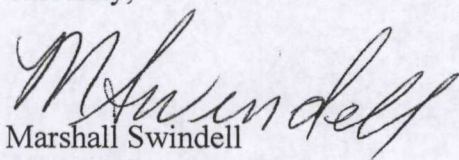
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency approves the following Amendments to the label:

- Addition of additional marketing claims, directions for use, and explanatory language to the front panel and directions for use sections.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,


Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510P)

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{MASTER LABEL}

{All text in brackets [xxx] is optional. xxx may or may not be included on a printed label.}

Ygiene™ 206

Ygiene™ 206 is for use as a detergent cleaner, deodorizer, disinfectant, fungicide, and sporicide/sterilant on non-porous hard surfaces in commercial, hospital, and medical environments.

{This statement is only for use on containers < 1 gallon}

[A Sterilant* is an antimicrobial pesticide that destroys or eliminates all forms of microbial life in the inanimate environment, including bacterial spores.]

{OR}

{This statement is only for use on containers ≥ 1 gallon}

[“A Sterilizer is an antimicrobial pesticide that destroys or eliminates all forms of microbial life in the inanimate environment, including bacterial spores. The term “sporicide” is deemed to be synonymous with “sterilizer”. Since sterilization includes eradication of all living microorganisms, such claims are intrinsically related to protection of human health (EPA DIS/TSS-9).”]

ACTIVE INGREDIENTS:

Hydrogen peroxide	6.14%
Peracetic acid.....	0.60%
Other Ingredients.....	93.26%
Total	100%

ACCEPTED
 MAR - 2 2012
 Under the Federal Insecticide, Fungicide, and Rodenticide Act, registered under EPA Reg. No. 81242-1

DANGER
KEEP OUT OF REACH OF CHILDREN

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 the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice
IF SWALLOWED	Call a poison control center or physician immediately after treatment for advice. Have a 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 physician. Do not give anything by mouth to an unconscious person.
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 physician for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or physician for further treatment advice.
Have the product container with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured by:
BioNeutral Group Inc.
211 Warren Street
Newark, New Jersey 07103

Net Contents:
EPA Reg. No.: 81242-1
EPA Est. No.: 87275-NJ-001

{MASTER LABEL}

{All text in brackets [xxx] is optional. () may or may not be included on a print () .abel.}

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS

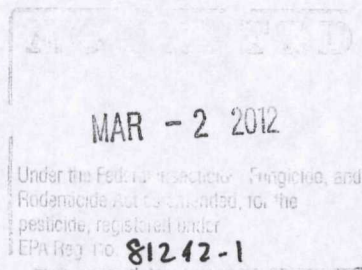
DANGER. CORROSIVE. Causes irreversible eye damage. Do not get in eyes, and avoid contact with skin or on clothing. Harmful if swallowed. Wear protective eyewear (goggles, face shield, or safety glasses), clothing, and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuses.

PHYSICAL AND CHEMICAL HAZARDS

Strong Oxidizing Agent. Corrosive. Never mix or use this product in combination with other sanitizers, cleaners or organic substances.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, 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 (NPEDS) permit and 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 you State Water Board or Regional Office at the EPA.



{MASTER LABEL}

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STORAGE AND DISPOSAL

Pesticide Storage

Do not return Ygiene™ 206 to the original container after it has been removed. Avoid all contaminants, especially dirt, reducing agents and metals. Contamination may reduce shelf life and can induce decomposition. In case of decomposition douse container with cool water and dilute with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight.

Procedure for Leaks or Spills

Stop leak if this can be done without risk. Shut off ignition sources: no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide mixture, or rinsate is in violation of Federal Law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements.

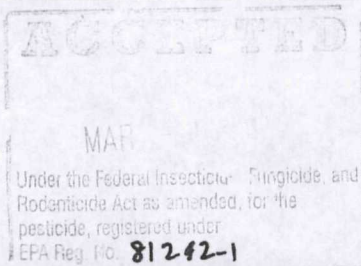
Container Disposal: Nonrefillable container. Do not reuse or refill this container.

[1 gallon or less: If empty, securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions.]

[OR]

[Drums and Totes: 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 if available or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Empty drums and bottles are not returnable to BioNeutral unless special arrangements have been made.]



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{MASTER LABEL}

{All text in brackets [xxx] is optional () may or may not be included on a print () .label.}

DIRECTIONS FOR USE

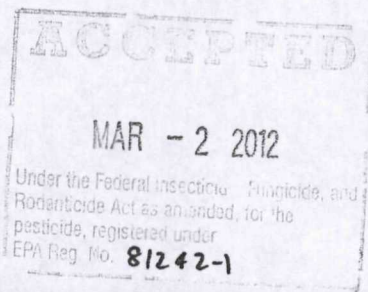
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Suitable for use on most hard, non-porous surfaces in commercial or health care sites including:

Hospitals	Academic Facilities	Airports
Health Care Facilities	University Laboratories	Hotels
Autopsy Facilities	Recreational/Entertainment Facilities	Industrial Facilities
Animal Hospitals and Veterinary Facilities	Sports/Physical Fitness Facilities	Retail and Wholesale Establishments
Farms	Bars/Restaurants/Cafeterias	Spas
Animal Life Science Laboratories	Office Buildings	Salons
Animal Shelters/Care Facilities	Funeral Homes	Dental Facilities

Suitable for Use as a Disinfectant and Fungicide on most hard, non-porous surfaces (e.g., linoleum, vinyl, sealed asphalt, sealed nonporous concrete, sealed nonporous brick and stone, glazed porcelain and ceramic tile, plastic (vinyl, polyethylene, and polypropylene), and glass). This product is compatible with stainless steel and aluminum surfaces. If this product is intended to be used on other metal surfaces it is recommended that you apply this product to a small test area to determine compatibility before proceeding with its use. Areas of appropriate use as a disinfectant and/or fungicide include:

Appliances	Crutches	Tables
Attics	Desks	Tires
Banisters/Hand railings	Devices and equipment – non-electrical and non-critical health care related	Toys
Bathrooms/Restrooms – fixtures/appliances	Doors – handles/knobs	Walls
Benches – bench tops	Fans	Wheels
Bottles	Faucets/Spickets	Windows – frames/sills
Cabinets/Shelves	Fences/Gates/Partitions	Window glass
Cages	Floors	Seats
Cans	Garbage/Trash/Refuse/Waste – cans/bins/chutes/carriers/compactors	Remote Controllers
Carts	Kitchens – appliances/fixtures	Phones
Chairs/Wheelchairs	Light – switches/covers	Railings
Containers	Lockers	Ceilings
Coolers	Poles/Posts	
Countertops	Stairs/Steps	



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{All text in brackets [xxx] is optional () ay or may not be included on a print () abel.}

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Suitable for Use as a Disinfectant and Fungicide on most hard, non-porous surfaces in transportation applications, including:

Cars
Ambulances/Patient transfer vehicles
Trucks/Fire trucks
Taxis/Buses/Subways
Other public transportation and mass transit
Trains/Planes/Ships/Boats/Cruise Ships
Bicycles

Suitable for Use as a detergent cleaner on most hard non-porous surfaces, including:

Suitable Materials	Stains	
Floors	Grape juice	Pen
Table tops	Cranberry juice	Marker
White boards	Grass stain	Wine
Counter tops	Ketchup	Blood
Walls	Ice cream	Grease
Vinyl tile floor	Chocolate	
Tea	Jellies and Jams	
Coffee	Pen	

{Optional Cleaning Claims include:}

Cleaning examples include:

Removing Permanent markers such as Sharpie, Stanley Industrial Grade, Just Basics, and Bic Permanent markers off of floors, table tops and white boards.

Ygiene 206 Sterilant easily removes pen, marker, and crayon marks, black heel scuff marks, grease, and tar.;

Ygiene 206 Sterilant removes black heel scuff marks off a vinyl tile floor;

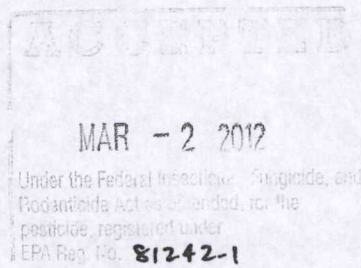
Ygiene 206 Sterilant removes soap scum in bathtub and sink with hardly any effort;

Ygiene 206 Sterilant removes dirt from small cracks around sink drain;

Ygiene 206 Sterilant removes old/dried red children's sun tan lotion from vinyl tile;

Also an excellent laundry presoak for a variety of known and unidentified stains –

- Tea
- Coffee
- Grape juice
- Cranberry juice
- Grass stain
- Ketchup
- Ice cream
- Chocolate
- Jellies and Jams



{MASTER LABEL}

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Sterilization by Immersion: Immersion may be used to treat immersible non-electrical articles, tools, and devices that are not related to critical/semi-critical health care (e.g., jewelry, keys, eyewear, small containers, coins, toys, etc.). Remove any obvious debris or organic material from the surface or object to be sterilized. Dismantle devices prior to pre-cleaning, if necessary. Pour appropriate amount of Ygiene™ 206 into a tray or receptacle that will hold the items to be treated and allow for their complete immersion in, and surface contact with, the solution. Immerse articles for a minimum of 20 minutes. Transfer the treated articles to a water rinse bath to remove the treatment solution. Dry the Ygiene™ 206 treated articles prior to reassembly or use.

Note: Ygiene™ 206 may cause bleaching of treated surfaces; test item if unsure. Before using Ygiene™ 206 on metal surfaces other than stainless steel and aluminum, it is recommended that the product be tested on a small area to determine compatibility.

This product must not result in direct or indirect contamination of food products.

WARRANTY

BioNeutral Group Inc. warrants that this product complies with the specifications expressed on the label. To the extent consistent with applicable law, **BioNeutral Group Inc.** makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose.

{The following statement and its corresponding table is optional language}

{This product has been demonstrated efficacy against the following specific organisms:}

Organism	ATCC No.	Contact Time
<i>Pseudomonas aeruginosa</i>	15442	2 minutes
<i>Salmonella enterica</i>	10708	90 seconds
<i>Staphylococcus aureus</i>	6538	90 seconds
Methicillin Resistant <i>S. aureus</i> (MRSA)	33592	90 seconds
<i>Bacillus subtilis</i>	19659	20 minutes
<i>Clostridium sporogenes</i>	3584	20 minutes
<i>Trichophyton metagrophytes</i>	9533	2 minutes
<i>Aspergillus niger</i>	16404	2 minutes

