

211-50

11/18/2010

10A13

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Richard Kueser
Central Solutions, Inc.
401 Funston Road
Kansas City, KS 66115

NOV 18 2010

SUBJECT: Q5.5-^{5.5}NPB-2.5HW
EPA Registration Number: 211-50
Application Dated: October 18, 2010
Receipt Date: October 19, 2010

Dear Mr Kueser:


This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- Adding Virucidal Performance claims for H1N1 virus.
- Updating nomenclature from Salmonella Choleraesuis to Salmonella Enterica.

Based on a review of the submitted information, this notification is acceptable. Your proposed direction for use will be made part of the record for this file.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2013

Please read instructions on reverse before using form.

Form Approved

OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 211-50	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Q5.5-5NPB-2.5HW 5.5	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) Central Solutions, Inc. 401 Funston Road Kansas City, KS 66115 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. NA Product Name NA	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>FEB 3, 2010</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revising label to change the Storage and Disposal copy as required by PR Notice 2007-4; to add labeling claim against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/2010; and Label Revision - Updating nomenclature used for claimed organism, Salmonella Choleraesuis to currently recognized listing, Salmonella Enterica.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. NA			
3. Location of Net Contents information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4,16,32oz,1,5,5.5gM, 2L, 3L		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other Silk-screened		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Richard Kueser	Title Regulatory Compliance Dir	Telephone No. (Include Area Code) 913-621-5542
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Compliance Dir	
4. Typed Name Richard Kueser	5. Date 10-18-10	

30813



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

FEB 3 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Richard Kueser
Regulatory Compliance Director
Central Solutions, Inc.
401 Funston Road
Kansas City, KS 66115

Subject: Q5.5-5NPB-2.5HW
EPA Registration Number 211-50
Notification Dated December 10, 2009
EPA Received Date January 5, 2010

Dear Mr. Kueser:

This will knowledge receipt of your notification submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09
- Revised Storage and Disposal statement

General Comments:

Based on a review of the material submitted, the following comment apply.

The notification is unacceptable for the following.

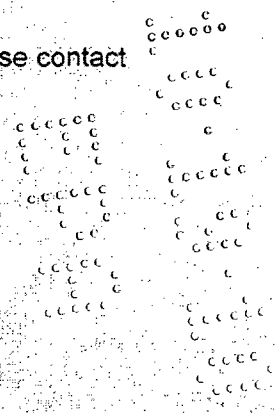
The Storage and Disposal is unacceptable. You must separate the instructions for Pesticide Disposal and Container Disposal.

A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)



4013

(Administrative Note: The following text is required for all labeling, regardless of target market)

Q5.5-5.5NPB-2.5HW

**DISINFECTANT - CLEANER - SANITIZER - FUNGICIDE
MILDEWSTAT - VIRUCIDE* - DEODORIZER**

EFFECTIVE IN HARD WATER UP TO 400 PPM HARDNESS (CALCULATED AS CaCO3)
IN THE PRESENCE OF 5% SERUM CONTAMINATION

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	1.65%
Dioctyl dimethyl ammonium chloride.....	0.825%
Didecyl dimethyl ammonium chloride.....	0.825%
Alkyl (C ₁₄ 50%; C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride.....	2.20%

Inert Ingredients	94.50%
Total:	100.00%

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Keep Out of Reach of Children

DANGER

Central Solutions, Inc.

401 Funston Road
Kansas City, KS 66115

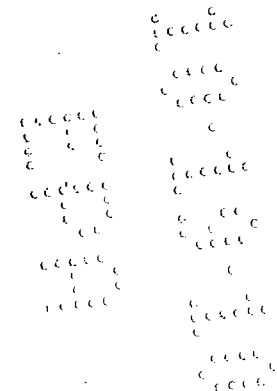
EPA Reg. No. 211-50
EPA Est. No. 211-KS-1

NET CONTENTS: X GALLONS

(Administrative Note: The following text is optional on front panel labeling for the human health care market):

Whirlpool Cleaner Designed for Hospital, Nursing Home, and Institutional Use
Whirlpool Cleaner Designed for Health Care Institutions
Formulated for Whirlpool Bathing Systems
Formulated for Hospitals and Long-Term Care Facilities
Whirlpool Cleaner

**Non-Critical Medical Device Uses



(Side and Back Panels)

(Administrative Note: The following text is required for all labeling, regardless of target market)

PRECAUTIONARY STATEMENTS

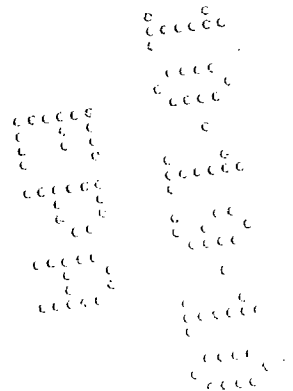
Hazards to Humans and Domestic Animals

DANGER

Keep out of reach of children. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles/face shield, rubber gloves, and protective clothing. Harmful if absorbed through skin. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with plenty of 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 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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to this person. • Do not give anything by mouth to an unconscious person
HOTLINE NUMBER	
For emergency medical advice, call your local poison control center or a doctor Have the product container or label with you when seeking medical advice or treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

(Administrative Note: The First Aid Statement's grid format will be used if market label space permits; otherwise, a paragraph format will be use)



60413

(Administrative Note: The "Environmental Hazards" statement is required only on container sizes of 5 gallons or greater):

ENVIRONMENTAL HAZARDS

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. This product is toxic to fish and aquatic organisms.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE - Store in a securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. Avoid storage at temperature extremes or in sunlight.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or 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.

Offer for recycling, if available.

or

Offer for reconditioning, if appropriate

Less than or equal to 5 gallons:

Clean container promptly after emptying.

or

~~Triple rinse container (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.

Greater than 5 gallons:

Clean container promptly after emptying.

or

~~Triple rinse container (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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

7013

(Administrative Note: The following text is optional for labeling destined for the human health care and/or institutional markets)

Q5.5-5.5NPB-2.5HW

DISINFECTANT-CLEANER-SANITIZER-FUNGICIDE
MILDEWSTAT-VIRUCIDE*-DEODORIZER-WHIRLPOOL CLEANER

Effective in Hard Water up to 400 ppm Hardness (Calculated as CaCO₃) in the Presence of 5% Serum Contamination

- Formulated for Effective Health Care Facility Sanitation
- Formulated for Use in Whirlpool Bathing Systems
- Designed for Hospital, Nursing Home, and Institutional Use
- Formulated for Use in Long-Term Care Facilities
- Formulated for Use on Non-Critical Medical Devices**

Formulation designed to clean and disinfect inanimate hard surfaces on (Administrative Note: Manufacture's Brand Tub Name Inserted Here) fiberglass, stainless steel, chrome plated and/or acrylic bathing and physical therapy equipment such as whirlpools and patient transfer equipment.

PRODUCT COMPOSITION

Q5.5-5.5NPB-2.5HW contains four highly active quaternary ammonium compounds (listed as active ingredients) for bactericidal efficacy. Inert ingredients include a balance of alkaline builders, nonionic surfactants, and odor counteractants to enhance the cleaning and odor control characteristics.

When used as directed, Q5.5-5.5NPB-2.5HW has been found effective for use on fiberglass, stainless steel, and chrome plated exposed surfaces of Central Solutions' bath, therapy and patient transfer equipment.

For cleaning Central Solution's bath and therapy equipment: To remove body oils, dead tissue, hard water and all other buildups of organic matter on inanimate surfaces, apply Q5.5-5.5NPB-2.5HW in a dilution of one part Q5.5-5.5NPB-2.5HW to three parts water. Clean equipment with this dilution according to procedures recommended by Central Solutions and rinse thoroughly with clear water.

Q5.5-5.5NPB-2.5HW is a phosphate free, germicidal-detergent effective in 10 minutes at 20 degrees Celsius, in hard water and in the presence of 5% blood serum, used to simulate organic soil. Q5.5-5.5NPB-2.5HW's multi-chain quaternary formula is designed to clean, disinfect and deodorize any washable, inanimate, non-porous surface in one easy step. When used as directed, Q5.5-5.5NPB-2.5HW is strong enough to kill a broad spectrum of pathogenic bacteria, yet it is mild enough to have no harmful effects on the surface being disinfected, when used as directed.

Q5.5-5.5NPB-2.5HW is a dilutable, one-step disinfectant cleaner formulated for use in hospitals, nursing homes, medical and dental clinics, laboratories, emergency rooms, ambulances & patient transfer vehicles, and other health care institutions that are dedicated to controlling the hazards of cross contamination in their establishments.

Q5.5-5.5NPB-2.5HW may be used to clean and disinfect non-critical medical devices and equipment such as examination tables and chairs, whirlpool baths, stretchers, patient lifts and scales, walkers, canes, crutches, monitors, stands, carts, cabinets, wheelchairs, patient bed frames, lights, x-ray equipment, therapy tables, and other non-critical medical devices.

Q5.5-5.5NPB-2.5HW is a dilutable one-step disinfectant cleaner for use in laboratories, police vehicles, prisons and jails, funeral homes, schools, hotels, motels, restaurants, day care facilities, offices, veterinary clinics, animal shelters, kennels, restrooms, and other commercial, industrial, and institutional facilities who have a need to control microbial contamination.

Q5.5-5.5NPB-2.5HW may be used to clean and disinfect hard, non-porous, inanimate surfaces such as walls, floors, tables, chairs, counter tops, sinks, tile, porcelain, bed frames, toilets, urinals, tubs, showers, cabinets, door handles, light switch covers, lockers, desks, file cabinets, and other hard, nonporous surfaces that need to be cleaned and disinfected.

Q5.5-5.5NPB-2.5HW is a germicidal detergent formulated for use where broad spectrum disinfection is required in the presence of moderate amounts of organic soil.

Q5.5-5.5NPB-2.5HW is a proven "one-step" disinfectant-cleaner-sanitizer-fungicide-mildewstat-virucide* which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Q5.5-5.5NPB-2.5HW is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal*, fungicidal, and will prevent the growth of mold and mildew and their odors when used as directed.

When used as directed, Q5.5-5.5NPB-2.5HW will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

80213

(Administrative Note: The following text is required for labeling destined for the human health care and/or institutional markets)

DIRECTIONS FOR USE

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

DISINFECTION:

For broad spectrum disinfection of gram negative and gram positive bacteria, including *Pseudomonas aeruginosa* and *Staphylococcus aureus*, add two ounces Q5.5-5.5NPB-2.5HW to one gallon of water. Remove heavy soil or gross filth from the surface to be disinfected, then apply properly diluted solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet the surface thoroughly. Allow to remain wet for 10 minutes and then let air dry. If higher detergency is desired, increase dilution to 4 to 6 ounces per gallon of water. Prepare a fresh solution for each use or when solution becomes visibly dirty.

To disinfect hard, non-porous, inanimate surfaces (such as fiberglass and stainless steel tubs and chair surfaces, chrome plated intakes and lifts, etc.), apply properly diluted Q5.5-5.5NPB-2.5HW detergent/disinfectant so as to wet all surfaces thoroughly. For routine disinfection, proper dilution is 1:64 (2 ounces of product per gallon of water). Allow to remain wet for 10 minutes, then let air dry. For heavily soiled areas, a pre-cleaning step is required and recommended. Prepare a fresh solution for each use as above.

At two ounces to the gallon of water Q5.5-5.5NPB-2.5HW is also fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus) in use areas such as shower room floors, locker room benches, bathmats, or any other hard non-porous, inanimate environmental surfaces.

****Non-Critical Medical Device Uses**

Q5.5-5.5NPB-2.5HW is a general purpose disinfectant that may be used to clean and disinfect hard, non-porous, inanimate, non-critical medical and dental equipment surfaces. Q5.5-5.5NPB-2.5HW may also be used to clean and/or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

(Administrative Note: The following text is required for labeling with sanitization claims):

SANITIZING

To sanitize non-porous, non-food contact surfaces, add 2 ounces of Q5.5-5.5NPB-2.5HW per gallon of water. Remove heavy soil or gross filth from the surface to be disinfected, then apply properly diluted solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet the surface thoroughly. Allow to remain wet for 30 seconds and then let air dry.

(Administrative Note: The following text is optional for labeling destined for the human health care and/or institutional markets)

FOR CLEANING (Administrative Note: Manufacture's Brand Tub Name Inserted Here) BATH AND THERAPY EQUIPMENT: After using the whirlpool unit, drain the water and refill with fresh water to just cover the intake valve. Add two ounces of Q5.5-5.5NPB-2.5HW for each gallon of water in the unit at this point. Briefly start the pump to circulate the solutions. Turn off pump. Wash down the unit sides, seat of the chairlift, and any/all related equipment with a clean swab or sponge. After the unit has been thoroughly cleaned, drain solutions from the unit and rinse any/all cleaned surfaces with fresh water. The unit is ready for re-use.

(Administrative Note: The following text is required for labeling on products used to clean and/or disinfect toilet bowls and/or urinals):

To clean and disinfect toilet bowl and urinal surfaces, flush toilet or urinal, add 2 ounces of Q5.5-5.5NPB-2.5HW directly to the bowl or urinal tap water. Swab the bowl and/or urinal surface completely using a bowl swab or brush, making certain to get under and rims. Let stand for 10 minutes and flush.

(Administrative Note: The following text is required for labeling destined for the human health care and/or institutional markets)

EFFICACY PERFORMANCE

The broad spectrum efficacy of Q5.5-5.5NPB-2.5HW has been confirmed using A.O.A.C. protocol testing, as is required by the EPA, at a use-dilution of 1:64 in water up to 400 ppm hardness in the presence of 5% blood serum (used to simulate organic soil load), at 20 degrees Celsius with an exposure time of 10 minutes.

GERMICIDAL

Q5.5-5.5NPB-2.5HW is effective against a broad spectrum of Gram positive and Gram negative pathogens as confirmed against *Salmonella enterica*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* by the AOAC Use Dilution Confirmation test.

At a 2 oz. per gallon use-level, the broad spectrum activity of Q5.5-5.5NPB-2.5HW has been evaluated and found to be effective against the following organisms by the A.O.A.C. Use-Dilution test: *Pseudomonas aeruginosa*, *Enterobacter aerogenes*, *Staphylococcus aureus*, *Streptococcus faecalis*, *Salmonella enterica*, *Shigella dysenteriae*, *Escherichia coli*, *Brevibacterium ammoniagenes*, *Streptococcus pyogenes*, *Salmonella typhi*, *Klebsiella pneumoniae*, *Serratia marcescens*, *Methicillin resistant Staphylococcus aureus (MRSA)*

FUNGICIDAL

When used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities, Q5.5-5.5HPB-2.5HW's fungicidal efficacy has been confirmed, at 2 oz. per gallon use-level, through testing using the AOAC Fungicidal Test against the following pathogenic fungi: *Trichophyton mentagrophytes* (the athlete's foot fungus)

MOLD AND MILDEW CONTROL

At 2 oz. per gallon use level, Q5.5-5.5NPB-2.5HW will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

***VIRUCIDAL PERFORMANCE**

At 2 oz. per gallon use-level, Q5.5-5.5HPB-2.5HW was evaluated and found to be effective against the following viruses on inanimate environmental surfaces: *Influenza A2 / Brazil*, *HIV-1 (AIDS Virus)*

(Optional copy for claim against H1N1 Virus – Swine Flu)

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. Q5.5-5.5HPB-2.5HW is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic H1N1 (formerly called swine flu).

or

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

or

This product has demonstrated effectiveness against (influenza A virus and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called Swine flu)

or

Kills Pandemic 2009 H1N1 influenza A virus (formerly known as swine flu)

or

Kills Pandemic 2009 H1N1 influenza A virus.

***KILLS HIV 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 in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES / OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Disposable gloves must be worn when cleaning blood, body fluids or contaminated items. Hands must be washed immediately and thoroughly after gloves are removed, or if hands are contaminated with blood or body fluids. Masks and protective eyewear or face shields must be worn during cleaning procedures involving blood or body fluids. Gowns or aprons must be worn during cleaning procedures for protection against splashes of blood or other body fluids.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant. After cleaning is complete, follow disinfection directions described previously.

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

CONTACT TIME: Leave surface wet for ten minutes.

100 of 13

(Administrative Note: The following text is required for labeling with sanitization claims):

SANITIZING NON-FOOD CONTACT SURFACES (such as floors, walls, tables, etc.)

At 1 ounce per 2 $\frac{3}{4}$ gallon use-level, Q5.5-5.5NPB-2.5HW is an effective sanitizer on non-porous, non-food environmental surfaces against the following organisms: *Staphylococcus aureus*, *Klebsiella pneumonia*

(or)

When diluted at 2 ounces per one gallon of water in the presence of 400 ppm hard water for a contact time of 30 seconds at room temperature, Q5.5-5.5NPB-2.5HW is an effective sanitizer on non-porous, non-food environmental surfaces against the following organisms: *Staphylococcus aureus*, *Enterobacter aerogenes*

(Administrative Note: The following text is required for labeling destined for mushroom farm markets)

Q5.5-5.5NPB-2.5HW
GERMICIDAL-DETERGENT WITH ORGANIC SOIL TOLERANCE.
FORMULATED FOR MUSHROOM FARM SANITATION

Q5.5-5.5NPB-2.5HW effectively kills fungi and bacteria which prove dangerous to mushroom crops.

DO NOT APPLY TO MUSHROOM CROP. DO NOT APPLY TO COMPOST OR CASING.
USE ONLY AS DIRECTED

EFFICACY PERFORMANCE

The broad spectrum efficacy of *Q5.5-5.5NPB-2.5HW* has been confirmed using A.O.A.C. protocol testing, as is required by the EPA, at a use dilution of 1:64 (two ounces per gallon of water) in water up to 400 ppm hardness in the presence of 5% blood serum (used to simulate organic soil load) at 20 degrees Celsius with an exposure time of 10 minutes.

GERMICIDAL: *Q5.5-5.5NPB-2.5HW* has been tested and found effective against bacteria detrimental to the mushroom crop including:

Pseudomonas fluorescens (Biotype G)...(Bacterial Blotch Disease)
Pseudomonas aeruginosa.....(Mummy Disease)

In addition, *Q5.5-5.5NPB-2.5HW* is effective against the broad spectrum of Gram positive and Gram negative pathogens as confirmed against *Salmonella enterica*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* by the AOAC Use Dilution Confirmation Test in water up to 400 ppm hardness and in the presence of 5% organic soil load at 20 degrees Celsius with an exposure time of 10 minutes.

FUNGICIDAL: Fungi specific to the mushroom industry which *Q5.5-5.5NPB-2.5HW* has been tested against and found effective include:

Verticillium fungicola.....(Verticillium disease, Brown spot or Fungus spot)
Mycogone pernicioso.....(Mycogone disease or Wet bubble)
Tricoderma viride.....(Tricoderma spot, Tricoderma blotch, Tricoderma mildew, Green mold)
Dactylium dendroides...(Hypomyces mildew, Cobweb, Soft decay)

Q5.5-5.5NPB-2.5HW's fungicidal efficacy has also been confirmed through testing using the AOAC Fungicidal Test against the pathogenic fungi *Trichophyton mentagrophytes*.

General Information

Q5.5-5.5NPB-2.5HW is a phosphate free, germicidal detergent effective in hard water in the presence of moderate amounts of organic soil on a variety of surfaces found at mushroom farms. *Q5.5-5.5NPB-2.5HW's* four chain quaternary based formula is designed for one-step cleaning and disinfecting of hard inanimate non-porous environmental surfaces. *Q5.5-5.5NPB-2.5HW* is strong enough to kill a broad spectrum of microbial mushroom pests, yet mild enough to have no harmful effects on the surfaces being treated when used as directed.

Areas of Use

Q5.5-5.5NPB-2.5HW has been designed for use between crops on surfaces that do not come in contact with the crop. Areas of intended use include tools, breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds, spawning machines, tampers and casing rings. Use of *Q5.5-5.5NPB-2.5HW* must be limited to areas where compost and mushrooms are not present.

DIRECTIONS FOR USE

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

SITE PREPARATION:

The first step in any on-going sanitation program must be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter.

CLEANING AND DISINFECTION

For all general cleaning and disinfection, use two ounces of *Q5.5-5.5NPB-2.5HW* per gallon of water (1:64 dilution). Apply *Q5.5-5.5NPB-2.5HW* as a spray, wetting surfaces thoroughly. Treated surfaces must be allowed to remain wet for 10 minutes and let air dry. For heavily soiled areas, a precleaning step is required. Prepare a fresh solution for each use. When greater detergent action is desired, dilute *Q5.5-5.5NPB-2.5HW* four ounces of concentrate to each gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

Apply *Q5.5-5.5NPB-2.5HW* only on surfaces that DO NOT come in contact with the crop. USE AS A PREMISES SPRAY, DO NOT APPLY TO THE CROP, COMPOST, OR CASING. Rinse treated surfaces with potable water before they contact the crop, compost or casing.

(Administrative Note: The following text is for labeling destined for poultry, cattle, or swine premise use)

Formulated for Effective Poultry & Swine Premise Sanitation

DIRECTIONS FOR USE

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

SITE PREPARATION

The first step in any ongoing sanitation program must be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum, depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, disinfection can be accomplished in a single step.

CLEANING AND DISINFECTION

For all general cleaning and disinfection, use 2 ounces of *Q5.5-5.5NPB-2.5HW* per gallon of water (1:64 dilution). Apply *Q5.5-5.5NPB-2.5HW* using a cloth, mop, or pressure sprayer so as to thoroughly wet surface to be disinfected. Do not apply this product in a way that will contact workers or other persons, either directly or by drift. Only protected handlers may be in the area during application. Allow to remain wet for 10 minutes and then let air dry. Following application as a low or high pressure spray, do not enter or allow others to enter the treated area until sprays have dried. For heavily soiled areas, a precleaning step is required.

EFFICACY PERFORMANCE

The broad spectrum efficacy of *Q5.5-5.5NPB-2.5HW* has been confirmed using A.O.A.C. protocol testing at a use-dilution of 1:64 in hard water up to 400 ppm, in the presence of 5% blood serum (used to simulate organic soil load), at 20°C with an exposure time of 10 minutes.

GERMICIDAL: *Q5.5-5.5NPB-2.5HW* is effective against the broad spectrum of Gram positive and Gram negative pathogens as confirmed against *Salmonella enterica*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* by the AOAC Use Dilution Confirmation test.

FUNGICIDAL: *Q5.5-5.5NPB-2.5HW*'s fungicidal efficacy has been confirmed through testing using the AOAC Fungicidal Test against the pathogenic fungi, *Trichophyton mentagrophytes*.

***VIRUCIDAL:** Virucidal testing using prescribed E.P.A. testing procedures has verified *Q5.5-5.5NPB-2.5HW*'s effectiveness against the following viruses commonly associated with poultry and swine areas including: *Avian Influenza Virus*, *Avian Herpes Virus 2* (Mareks Disease), *Avian Bronchitis Virus*, *Hog Cholera Virus*, *Avian Laryngotracheitis*, *Pseudorabies Virus*

AREAS OF USE

POULTRY PREMISE SANITATION (HATCHERIES)

- | | | | |
|---------------------|-----------------------------|-------------------|------------------------|
| -Egg Receiving Area | -Tray Dumping Area | -Egg Holding Area | -Chick Procession Area |
| -Setter Room | -Chick Holding Room or Area | -Hatchery Room | -Chick Loading Area |
| -Poultry Buildings | -Hauling Equipment | | |

APPLICATION AND USE DILUTIONS

POULTRY HOUSES:

1. Remove all poultry and feeds from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water.
2. Use 2 ounces of *Q5.5-5.5NPB-2.5HW* per gallon of water (1:64 dilution). Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals or poultry, as well as cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solution. Ventilate buildings, cars, boats, coops, and other closed spaces in which the product has been used. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

HATCHERIES:

1. Use 2 ounces of *Q5.5-5.5NPB-2.5HW* per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.

EQUIPMENT:

1. Empty all troughs, rack, feeding and watering bins, buckets and fountains.
2. Use 2 ounces of *Q5.5-5.5NPB-2.5HW* per gallon of water to treat all equipment.
3. Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.

VEHICLES:

1. Clean all vehicles including mats, crates, cabs and wheels with high pressure water and *Q5.5-5.5NPB-2.5HW* disinfectant. Use 2 ounces per gallon of water to treat all vehicles.
2. Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.

SHOEBATHS SANITIZER:

Shoebaths sanitizer containing one inch of freshly made disinfectant solution must be placed at all entrances to buildings and hatcheries. Change the disinfectant solution in the bath daily or when solution appears dirty

130413

(Administrative Note: The following text is required for labeling destined for farm premise use)

FOR CLEANING AND DISINFECTION OF:

EQUIPMENT including feeders, waterers, fans, racks, troughs, bins and buckets. VEHICLES including live haul poultry delivery truck, feed trucks, service person cars, tractors, and all other vehicles.

HATCHERIES including floors, walls, equipment, incubators, hatchers, tray and buggies. SHOEBATHS including all entrances to buildings and hatcheries.

AREAS OF USE

SWINE AND CATTLE SANITATION

-Farrowing Barns and Areas -Waterer & Feeder -Blocks -Nursery -Creep Area -Hauling Equipment

MISCELLANEOUS

-Horse Stables -Sales Barn Stalls -Dressing Plants -Chutes/Loading Equipment
-Sick Pens -Veterinary Hospitals -Cat and Dog Kennels

General Disinfection Uses:

Can be used in the routine disinfection of hog houses, farrowing houses, finishing houses, growers, feeders and other equipment; horse stables and sick pens at race tracks or sale barns, hospital pens, calf pens and equipment. Disinfecting houses used for poultry, turkeys, ducks and game birds and for equipment used in brooding growing and laying quarters. Disinfecting dog and cat kennels as well as laboratory animal facilities, at veterinary hospitals, research laboratories and medical institutions. Spraying cattle pens, chutes loading equipment trucks and animal manure pits for the control of odor and ammonia.

Dressing Plant Use:

Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Equipment and utensils must be thoroughly rinsed with potable water before operations are resumed. Disinfect offal rooms, exterior walls and loading platforms of dressing plants.

APPLICATION AND USE DILUTIONS

Do not apply this product in a way that will contact workers or other persons, either directly or by drift. Only protected handlers may be in the area during application. Following application as a low or high pressure spray, do not enter or allow others to enter the treated area until sprays have dried.

FARM PREMISE:

DO NOT USE IN MILKING STALLS, MILKING PARLORS OR MILK HOUSES.

1. 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 or poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean surfaces with soap or detergent and rinse with water.
2. Use 2 ounces of Q5.5-5.5NPB-2.5HW per gallon of water (1:64 dilution). Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.
3. Use 25-50 gallons of disinfectant solution per 1000 square feet of floor space. Totally immerse equipment to be treated in disinfectant solution. Ventilate buildings, cars, boats, and other closed spaces in which the product has been used. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, troughs, mangers, automatic feeder, fountains, and waterers with soap or detergent and rinse with potable water before reuse.

EQUIPMENT:

1. Empty all troughs, racks, feeding and watering bins, buckets and fountains.
2. Use 2 ounces of Q5.5-5.5NPB-2.5HW per gallon of water (1:64 dilution) to saturate all equipment. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals or poultry, as well as cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solution.
3. Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.

VEHICLES:

1. Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and PHENO-CEN solution.
2. Use 2 ounces of Q5.5-5.5NPB-2.5HW per gallon of water (1:64 dilution) to treat all vehicles. Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.

HATCHERIES:

1. In the absence of eggs or chicks, clean all surfaces with soap and detergent, and rinse with potable water. Treat all surfaces thoroughly with Q5.5-5.5NPB-2.5HW solution by scrubbing with brush under high water pressure with emphasis on cracks and molding where fungus and mold are usually located.
2. Use 2 ounces of Q5.5-5.5NPB-2.5HW per gallon of water (1:64 dilution) to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to the disinfectant solution for 10 minutes or more.
3. Do not introduce eggs or chicks until disinfectant solution has been absorbed, set, or dried.
4. Thoroughly scrub treated surfaces with soap or detergent, and rinse with potable water before reuse.

SHOEBATHS SANITIZER:

1. Shoebaths containing one inch of freshly made disinfectant solution should be placed at all entrances to buildings and hatcheries. Change the disinfectant solution in the bath daily or when solution appears dirty