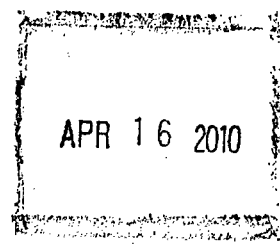


6198-4

L. Charles Landman, Jr., Ph.D., R.S.
National Chemicals, Inc.
105 Liberty Street, P.O. Box 32
Winona, MN 55987-0032



SUBJECT: Q.A. Concentrated Solution
EPA Registration Number: 6198-4
Application Date: November 11, 2009
Receipt Date: November 17, 2009

Dear Dr. Landman:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable subject to the comments listed below.

Proposed Amendment

- Addition of microorganisms, use directions and marketing claims

Conditions

1) As per the last stamped label for this product, the following language must be added verbatim to your label. This language is required for products used in hospitals and other similar sites on unqualified metal surfaces. Delete the incomplete statement in the upper left column of page two.

"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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

CONCURRENCES							
SYMBOL	7510P						
SURNAME	S. J. [Signature]						
DATE	4/16/10						

2) Revise the directions for use "To Sanitize Glasses-Dishes-Utensils in Eating and Drinking Places" to include the contact time in step #4 as follows: "Allow surfaces to remain wet for 1 minute."

3) Add the following statement immediately after the "To Disinfect Food Contact Surfaces" section: "Not for use as a disinfectant on glasses, dishes, utensils or food processing equipment."

4) Delete the claim "Tasteless" found on page one in close proximity to the product name. This product is not for oral consumption and is harmful if swallowed. The term tasteless implies that there are situations in which this product would be ingested.

5) Revise the Storage and Disposal statements to be in agreement with PR Notice 2007-4 as follows. Delete the Product Disposal and Container Disposal statements and add the following:

"Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility."

"Container Handling: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying."

Use the following language for containers 5 gallons and smaller:

"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 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as pesticide waste. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

Use the following language for containers larger than 5 gallons:

"Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 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. Dispose of rinsate as pesticide waste. Repeat this procedure two more times."

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Use this language for all sizes of containers:

“Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.”

- 6) Correct the following microorganism names on page two:
 - Place Staphylococcus aureus Methicillin resistant together on one line
 - Correct Escherichia coli to read Escherichia coli O157:H7
 - Correct Influenza A2 to read Influenza A2 Japan Virus
 - Be advised that any additional information regarding pathogens against which this product is effective must be in agreement with those included on this stamped label.

- 7) Correct the following pathogen names on page three to be in agreement with the supporting data:
 - Revise Proteus mirabilis Clinical Isolate by deleting Clinical Isolate. This occurs in both disinfection sections.
 - Delete the ATCC numbers for Canine Distemper, Hepatitis C Virus, Infectious Bovine Rhinotracheitis virus, Transmissible Gastroenteritis and Vaccinia virus
 - Delete HTLV-IIIB from Human Immunodeficiency Virus Type 1
 - Delete Strain LT-IVAX from Infectious Laryngotracheitis Virus
 - Delete Beaudette IB42 from Infectious Bronchitis Virus
 - Correct Escherichia coli O157:H7 by changing the ATCC number to read 31250

- 8) Revise the Non-Food Contact Surface Sanitizer directions on page three by deleting the statement regarding treatment of food contact surfaces. Delete: “At this dilution food contact surfaces must be rinsed.”

- 9) Delete the following organisms from the Food Contact Sanitizer Directions on page three as you have not provided data to support these claims. Delete
 - Campylobacter jejuni ATCC 29428
 - Listeria monocytogenes ATCC 984
 - Shigella dysenteriae ATCC 9361
 - Yersinia enterocolitica

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

4087

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

7510P:T.Lantz:4/12/2010:6198-4 unacc label amend

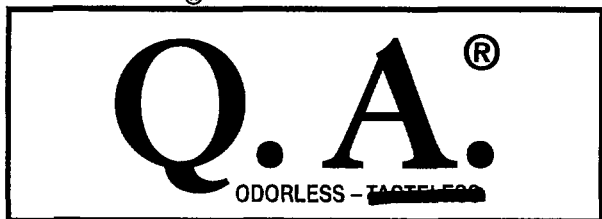
CONCURRENCES							
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(Front Panel 4.5 x 3.5")

(Rear Panel 4.5 x 3.5")

507

A B-T-F® DISINFECTANT



Concentrated Solution DISINFECTANT - SANITIZER - DEODORIZER FUNGICIDE - MILDEWSTAT - VIRUCIDE With Organic Soil Tolerance

ACTIVE INGREDIENTS:

- n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chlorides..... 5.0%
- n-Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chlorides..... 5.0%

INERT INGREDIENTS: 90.0%

TOTAL: 100.0%

E.P.A. REG. NO. 6198-4 E.P.A. EST. NO. 6198-MN-1

Approved under the Regulations of the Wisconsin State Board of Health

NET CONTENTS: 1 GALLON (3.79 L.)

DANGER: KEEP OUT OF REACH OF CHILDREN
SEE SIDE & BACK PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED FOR COMMENTS
EPA Letter Dated:

Manufactured by NATIONAL CHEMICALS, INC. Winona, MN 55987
1-800-533-0027 www.nationalchemicals.com

APR 16 2010

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

(Right Panel 4.5 x 3.5") 6198-4 (Left Panel 4.5 x 3.5")

Q.A.® Concentrated Solution

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

SANITIZING FOOD CONTACT SURFACES IN PUBLIC EATING PLACES, DAIRY & FOOD PROCESSING EQUIPMENT & UTENSILS, BEVERAGE DISPENSING EQUIPMENT, BREWING & WINE MAKING EQUIPMENT.

Add 1/4 ounce Q.A.® to each one gallon of water.
Makes 200 ppm active quaternary sanitizing solution.

NO POTABLE WATER RINSE IS ALLOWED AFTER SANITIZING.

DISINFECTING & DEODORIZING: Not for use on Medical device surfaces. FOR GENERAL OR BROAD SPECTRUM, HOSPITAL, MEDICAL, DENTAL OR VETERINARY ENVIRONMENT, VIRUCIDAL, ANIMAL VIRUCIDAL OR FUNGICIDAL USE ON HARD NON-FOOD SURFACES.

Add 4 ounces of Q.A.® to 5 gallons of water. (0.8 oz. per 1 gallon)
Makes 625 ppm active quaternary disinfecting solution.
For HIV use 4.5 ounces to 5 gallons of water (703 ppm) for 2 minutes.
For HBV and HCV use 625 ppm for 10 minutes.

LAUNDRY DEODORIZER: Use 3.5 ounces of Q.A.® per 100 pounds of dry fabric weight diluted in 1 to 2 gallons of water.

TO SANITIZE GLASSES-DISHES-UTENSILS IN EATING & DRINKING PLACES
Wisconsin Five - Step Procedure

- Scrape and prewash utensils and glasses whenever possible.
- Wash with compatible chemical detergents in hot, warm or cold water ... T-D-C®, L-f-D®, TAB-DET®, L-f-D-TAB® or BLU-MAGIK®.
- Rinse with plain ... potable water. Do not add any chemicals to this water.
- Sanitize in solution of 1/4 ounce per 1 gallon of water or 3/4 ounce per 3 gallons of water (200 ppm sanitizing solution). Immerse items for contact time specified by the governing sanitary code. Check with your Health Department as requirements vary.
- Place sanitized items on rack or drainboard to drain & air dry. NEVER TOWEL DRY.

TO DISINFECT FOOD CONTACT SURFACES: Remove or protect food products & packaging. Pre-clean heavy soiled areas. Apply disinfecting solution for 10 min. Remove excess liquid & rinse surfaces with potable water.

Q.A.® Concentrated Solution

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, then continue rinsing eye. Call a Poison Control Center or Physician 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 Physician for treatment advice.

IF SWALLOWED: Call a Poison Control Center or Physician 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 the Poison Control Center or Physician. Do not give anything by mouth to an unconscious person.

NOTE: Have a product container or label with you when contacting the Poison Control Center or Physician or going for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. For information on product, usage, etc. call 1-800-533-0027. Product labels, Material Safety Data Sheets, etc. can be found on the internet at our website www.nationalchemicals.com. For information on health concerns, medical emergencies, or pesticide incidents, call the National Pesticide Information Center at 1-800-858-7378.

HAZARDS TO HUMANS and DOMESTIC ANIMALS

DANGER: CORROSIVE: Keep out of reach of children. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL and CHEMICAL HAZARDS: Do not mix with oxidizers, anionic soaps & detergents.
ENVIRONMENTAL HAZARD: (5 gallon container of Q.A.® or greater): Toxic to fish. Do not discharge effluent containing Q.A.® 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 into sewer systems without previously notifying the local sewage treatment authority. For guidance, contact your State Water Board or Regional EPA Office.

To The User:

If this product fails to satisfy, return unused portion to the dealer and entire purchase price will be refunded.

Q.A.® Concentrated Solution

TO DISINFECT HARD, NON-POROUS SURFACES

(Walls, Floors, Counters, Tables, Chairs, Bathing Areas, Lavatories, Sinks, Bed Frames, Garbage Pails, Tile, Cages, Crates, Litter Boxes, Barber & Salon Tools such as Combs, Brushes, Razors & other Hard Non-porous Surfaces) In Hospitals, Dental Offices, Nursing Homes, Veterinary Clinics, Zoos, Agricultural and Farm Premise, Dairy and Food Processing Equipment, Mushroom Farms, Florists, Pet Shops/Kennels, Home, Schools, Barber Shop/Salon Tools, Hotel, Motels, Dormitories and Day Care.

- CLEANSE** - thoroughly wash with compatible synthetic detergent or cleaner. See CHEMICAL HAZARDS for compatible detergents.
- RINSE** - thoroughly rinse with plain water.
- DISINFECT** - immerse items or apply Q.A.® disinfecting solution with a clean cloth, sponge, mop or coarse (mist) spray (mist spray not allowed in California). Allow at least ten (10) minutes wet contact time. Health Codes may vary so check government codes.
NOTE: With spray application do not breath spray, cover or remove food products. Prepare a fresh solution at least daily.
- DRAIN - RINSE** thoroughly with potable water (if permitted by code). Allow to air dry.

STORAGE AND DISPOSAL

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

STORAGE: Gallon containers or less:

Store in original container in areas inaccessible to small children or persons unfamiliar with its proper use. Do not reuse empty container.

Containers greater than one gallon:

Store in original container in areas inaccessible to small children or persons unfamiliar with its proper use. Open dumping is prohibited. Do not reuse empty container.

PRODUCT DISPOSAL: Improper disposal of excess product, spray mixture or rinsate is a violation of Federal law. Waste cannot be disposed according to label instructions, contact state or Federal pesticide or environmental control representative for guidance.

CONTAINER DISPOSAL: Triple Rinse, Wrap, puncture & discard in trash (or offer for recycling or reconditioning). Dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

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(Right Auxiliary Panel 4.5 x 3.5")

(Left Auxiliary Panel 4.5 x 3.5")

Q.A.® Concentrated Solution

Q.A.® Concentrated Solution

TO DISINFECT IN
Hospitals, Nursing Homes, Dental Facilities

TO DISINFECT IN
Veterinary Clinics, Zoos, Agricultural & Farm Premises, Pet Shops & Kennels

1. Q.A.® is not a terminal sterilant or high level disinfectant for any surface or instrument that
 - a. is introduced directly into the human body.
 - b. is into or in contact with the bloodstream or normally sterile areas of the body.
 - c. is in contact with intact mucous membranes.
2. Q.A.® may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

1. Remove all animals and feed from premises, vehicles and enclosures.
2. Remove all litter & manure from floors, walls & surfaces of barns, pens, chutes and other facilities & fixtures occupied or traversed by animals.
3. Empty all troughs, racks, feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Disinfect by saturating all surfaces with 0.8 oz Q.A.® per gallon of water.
6. Treated surfaces must remain wet for 10 minutes.
7. Disinfect halters, ropes and other handling equipment by immersion in a solution with 0.8 oz Q.A.® per gallon of water.
8. Disinfect items for removing litter and manure (forks, shovels, rakes, etc.) by immersion with 0.8 oz Q.A.® per gallon of water.
9. Ventilate buildings, vehicles, boats and other closed spaces.
10. Do not house animals or employ equipment until treatment has set, dried or absorbed into the surface.
11. **IMPORTANT.** Thoroughly wash all treated feed racks, mangers, troughs, feeders, fountains and water containers with soap or detergent, and rinse with potable water before use.

DISINFECTION PERFORMANCE

TO DISINFECT IN
Barber Shops and Beauty Salon Instruments

Q.A.® is bactericidal according to the AOAC Use Dilution Test Method on hard inanimate surfaces modified in the presence of 5% organic serum. It is virucidal in the presence of 5% organic serum. This product kills the following bacteria, viruses and fungi:

1. Pre-clean hard, nonporous instruments and tools.
2. Completely immerse combs, brushes, rollers, manicure and other salon and barber instruments in a solution of 0.8 oz Q.A.® per gallon of water for 10 minutes.
3. Plastic instruments may remain immersed until ready for use.
4. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.
5. Rinse thoroughly and dry before use.
6. Prepare a fresh solution daily.
7. Do not re-use solutions.
8. Discard solutions when they become visibly soiled or diluted.

Pseudomonas aeruginosa *Staphylococcus aureus* *Klebsiella pneumonia* *Hepatitis B Virus*
Listeria monocytogenes *Salmonella typhi* *Escherichia coli* *Hepatitis C Virus*
Proteus mirabilis *Staph. aureus Methicillin* *Salmonella enterica* *HIV-1*
Campylobacter jejuni *Resistant (MRSA)* *Shigella sonnei* *Influenza A2*
Botrytis cinerea *Burkholderia cepacia* *Yersinia enterocolitica* *Vaccinia Virus*
Corynebacterium ammoniagenes *Enterococcus faecium* *Vancomycin Resistant (VRE)*
Herpes Simplex Type 1 and Type 2 Virus *Human Coronavirus* *Infectious Bronchitis Virus*
Avian Influenza A H5N1 *Avian Reovirus* *Bovine Viral Diarrhea* *Canine Coronavirus*
Canine Distemper Virus *Newcastle Disease Virus* *Porcine Rotavirus* *Pseudorabies Virus*
Trichophyton mentagrophytes *Aspergillus niger* A detailed list of susceptible bacteria, viruses and fungi is available from NATIONAL CHEMICALS, INC.

7087



105 Liberty Street Phone 507-454-5640
PO Box 32 800-533-0027
Winona, MN 55987 Fax 507-454-5641
USA 877-858-4141

updated 9/2009

BTF Q.A.® Concentrated Solution Sanitizer / Disinfectant

EPA Reg. No. 6198-4
EPA Est. No. 6198-MN-1

Use Dilutions

Hospital Disinfectant	4.0 oz per 5 gal of water	625 ppm
Non-medical Disinfectant	3.0 oz per 5 gal of water	469 ppm
Virucidal	4.0 oz per 5 gal of water	625 ppm
Sanitization Non-food contact	1.0 oz per 4 gal of water	200 ppm
Sanitization Food contact	1.0 – 2.0 oz per 4 gallons	200 – 500 ppm

Efficacy

Hospital Disinfectant: AOAC Use Dilution Test method on hard inanimate surfaces modified in the presence of 5% organic serum at 4 ounces of this product per 5 gallons of water (625 ppm active) Treated surfaces must remain wet for 10 minutes.

- Botrytis cinerea ATCC #12481
- Burkholderia cepacia ATCC 25416
- Campylobacter jejuni ATCC 29428
- Corynebacterium ammoniagenes ATCC 6871
- Escherichia coli 0157:H7 ATCC 35150
- Enterococcus faecium Vancomycin Resistant (VRE)
- Klebsiella pneumoniae ATCC 13883
- Listeria monocytogenes ATCC 984
- Proteus mirabilis ~~Clinical Isolate~~
- Pseudomonas aeruginosa ATCC #15442
- Salmonella typhi ATCC 6539
- Salmonella enterica ATCC #10708
- Shigella sonnei ATCC 9290
- Staphylococcus aureus ATCC #6538
- Staphylococcus aureus (Methicillin Resistant) (MRSA) ATCC 33591
- Staphylococcus aureus (Community Associated Methicillin Resistant) (CA-MRSA) (NRS 123) (Genotype USA400) ATCC 33591
- Yersinia enterocolitica ATCC 23715

Virucidal: 4 ounces per 5 gallons use level (625 ppm quat active), in the presence of 5% serum with a 10 minute contact time and found to be effective against the following viruses on hard nonporous environmental surfaces.

- Avian influenza A H5N1 virus
- Avian influenza /Turkey/Wisconsin ATCC VR-798
- Avian Reovirus ATCC VR-2449
- Bovine Viral Diarrhea ATCC VR-534
- Canine Coronavirus ATCC VR-809
- Canine Distemper ~~ATCC VR-108~~
- Equine Arteritis virus ATCC VR-796
- Hepatitis B Virus
- Hepatitis C Virus ~~ATCC CCL-99~~
- Herpes Simplex Type 1 ATCC VR-260
- Herpes Simplex Type 2 ATCC VR-734
- Human Coronavirus ATCC VR-740
- Human Immunodeficiency Virus type 1 (HIV 1) ~~ATCC VR-117~~
- Infectious Laryngotracheitis Virus (LT) ~~Clinical Isolate~~
- Influenza A2/Japan ATCC VR-100
- Infectious Bovine Rhinotracheitis virus (IBR) ~~ATCC VR-108~~
- Infectious Bronchitis Virus ~~ATCC VR-102~~
- Newcastle disease virus
- Porcine Respiratory & Reproductive (PRRSV)
- Porcine Rotavirus ATCC VR-893
- Pseudorabies virus ATCC VR-135
- Transmissible Gastroenteritis (TGE) ~~ATCC VR-142~~
- Vaccinia virus ~~ATCC VR-142~~

General Disinfection: AOAC Use Dilution Test method on hard inanimate surfaces modified in the presence of 5% organic serum at 3 ounces of this product to 5 gallons of water (469 ppm active) Treated surfaces must remain wet for 10 minutes.

- Salmonella enterica ATCC #10708
- Staphylococcus aureus ATCC #6538
- Campylobacter jejuni ATCC 29428
- Escherichia coli 0157:H7 ATCC ~~35150~~
- Listeria monocytogenes ATCC 984
- Proteus mirabilis ~~Clinical Isolate~~
- Staphylococcus aureus (Methicillin Resistant) (MRSA) ATCC 33591
- Yersinia enterocolitica ATCC 23715

Non-Food Contact Surface Sanitizer: Add 0.25 ounce of this product to 1 gallon of water to sanitize hard porous and non-porous non-food contact surfaces. Treated surfaces must remain wet for 3 minutes. Then wipe with sponge, mop or cloth or allow to air dry. ~~At this point, the food contact surface must be rinsed.~~

- Enterobacter aerogenes ATCC 13048
- Staphylococcus aureus ATCC #6538

Food Contact Sanitizer (No Rinse): At 0.25 ounce per gallon (1 ounce per 4 gallons) (200 ppm) this product is an effective food-contact surface sanitizer eliminating 99.999% of the of the following bacteria in 60 seconds in 500 ppm hard water (calculated as CaCO3) according to the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants test.

- Escherichia coli ATCC #11229
- Staphylococcus aureus ATCC #6538
- Aeromonas hydrophila ATCC 23213
- ~~Campylobacter jejuni ATCC #29428~~
- Enterococcus faecalis Vancomycin Resistant (VRE) ATCC 51299
- Enterobacter sakazakii ATCC 29544
- Escherichia coli O111:H8 ATCC BAA-184
- Escherichia coli O157:H7 ATCC #43888
- ~~Listeria monocytogenes ATCC 984~~
- Salmonella typhi ATCC 6539
- ~~Clinical Isolate~~
- Streptococcus pyogenes ATCC 12344
- ~~Staphylococcus aureus ATCC #6538~~