

6836-327

9/5/2012

1/12

SEP -5 2012

Karen E Warkentien
Senior Associate
Lewis & Harrison LLC
122 C Street NW, Suite 740
Washington DC 20001

Subject **Carbosan 50**
EPA Registration Number 6836-327
Application Dated July 23, 2010
EPA Received Date July 26, 2010

Dear Ms Warkentien

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

Proposed Amendment

- label amendment

Labeling Comments

On page 7 under "Waterproof Glove Sanitizing Directions" that reads [0.5 oz of Carbosan 50 per 6 gallons of water] should read [0.5 oz of CARBOSAN 50 per 6.5 of gallons of water] Also, 1 oz of Carbosan 50 per 12 gallons of water should read [1 oz of Carbosan 50 per 13 gallons of water]

General Comments

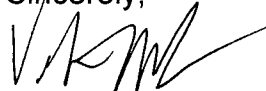
A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2/12

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)

Enclosure stamped label

CARBOSAN 50

Sanitizer – Deodorizer

For Commercial Institutional and Industrial Use

For Farm School Dairy Restaurant Food Handling and Processing Areas Bar and Institutional Kitchen Use

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

Active Ingredients	
Didecyl dimethyl ammonium carbonate and	
Didecyl dimethyl ammonium bicarbonate	50.0%
Other Ingredients	<u>50.0%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

See [left] [side] [right] [back] panel for Precautionary Statements and First Aid

EPA Reg No 6836 327
 EPA Est No (insert EPA Est No here)
 Net Contents (as indicated on container)
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

Manufactured by
 LONZA INC 90 Boroline Road Allendale NJ 07401

ACCEPTED
 with COMMENTS
 in EPA Letter Dated.

SEP 5 2012
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 Fungicide and Rodenticide Act as
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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER Corrosive Causes irreversible eye damage and skin burns Do not get in eyes on skin or on clothing Harmful if swallowed inhaled or absorbed through the skin Wear protective eyewear (goggles face shield or safety glasses) protective clothing and protective gloves (rubber chemical resistant) when handling Avoid breathing spray mist Wash thoroughly with soap and water after handling Remove and wash contaminated clothing before reuse

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

IF ON SKIN OR CLOTHING Take off contaminated clothing Rinse skin immediately with plenty of water for 15 – 20 minutes

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 the 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 by mouth to-mouth if possible

Call a poison control center or doctor for treatment advice Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment

NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage

(If container size is 5 gallons or greater use the following Environmental Hazards statements)

ENVIRONMENTAL HAZARDS

This product is toxic to fish and other aquatic organisms 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

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(Note to reviewer The following is considered optional marketing language)

- Concentrate (Concentrated)
- Deodorizes (Deodorizer)
- [This product] Contains no [phosphates] [phosphorous] [or] [phosphorous compounds]

Carbosan 50

- delivers non-acid performance in an economical concentrate
- is an economical concentrate
- can be diluted for use with a mop and bucket trigger sprayers sponge or by soaking
- improves labor results by effectively controlling odors
- will not leave grit or soap scum
- deodorizes by killing microorganisms that cause offensive odors
- is a complete chemically balanced sanitizer that provides clear use solutions even in the presence of hard water
- meets AOAC Germicidal & Detergent standards for sanitizing previously cleaned food-contact surfaces
- has been cleared by the EPA in 40 CFR §180.940(a) for use on food processing equipment utensils and other food-contact articles [at a concentration of 150 – 400 ppm active]
- is a sanitizer and deodorizer for use in all federally inspected meat and poultry plants institutional and industrial facilities
- can be used on food contact surfaces [in a concentration range of 150 – 400 ppm active]

Cross-contamination is of major [food safety] concern Carbosan 50 has been formulated to aid in the reduction of cross contamination on treated surfaces in schools institutions and industry

Use Carbosan 50

- in kitchens as a sanitizer for all surfaces not always requiring a rinse in official establishments operating under the Federal meat poultry shell egg grading and egg products inspection programs

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(Note to reviewer The following is considered optional marketing language)

(AREAS OF USE)

Use **Carbosan 50** in

Bathrooms
Homes [households]
Kitchens

Day care centers
Nurseries

Bars
Beverage Plants
Cafeterias
Convenience stores
Egg Processing plants
Food processing plants
Food preparation areas
Food storage areas
Institutional kitchens
Restaurants
USDA inspected food processing facilities

Colleges
Correctional facilities
Factories
Hotels
Institutional facilities
Institutions
Motels
Prisons
Public facilities
Schools

Camp grounds

Airplanes
Airports
Boats
Buses
Campers
Mobile homes
Ships
Trains

(TYPES OF SURFACES)

Use **Carbosan 50** on washable hard nonporous surfaces of

Appliances
Counters [countertops]
Countertop laminates
Highchairs
Microwave ovens
Refrigerators
Refrigerated storage and display equipment

Stoves [stovetops]

Tables (Non wooden picnic tables)

Tiles glazed

Beer fermentation and holding tanks

Blenders
Bottling or premix dispensing equipment

Chopping blocks plastic and other nonporous

Cooking utensils
Coolers

Cutlery
Cutting Boards plastic and other nonporous

Dishes
Eating Utensils
Food processors
Glassware
Ice Chests
Kitchen equipment
Silverware
Slurpy Machines

Other hard nonporous surfaces made of

Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Metal

Plastic (such as polystyrene or polypropylene)

Sealed granite
Sealed limestone
Sealed marble
Sealed slate
Sealed stone
Sealed terra cotta
Sealed terrazzo
Stainless steel
Upholstery vinyl and plastic
Woodwork finished

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Under the Federal Insecticide
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(Note to reviewer The following is considered optional marketing language)

Use Carbosan 50

- as a sanitizer for all surfaces not always requiring a rinse in official establishments operating under the Federal meat poultry shell egg grading and egg products inspection programs
- as a sanitizer on dishes glassware and utensils
- as a sanitizer in bottling and beverage dispensing equipment
- as a sanitizer in sanitary filling of bottles and cans
- in sanitizing bottles or cans in the final rinse application and for external spraying of filler and closing machines
- as a sanitizer in beer fermentation and holding tanks
- as a Food-Grade Shell-Egg sanitizer with best results achieved in water temperatures ranging from 78°F – 110°F **Carbosan 50** may be applied through automatic washing systems immersion tanks foaming apparatus and low pressure sprayers
- in federally inspected meat and poultry facilities (as a sanitizer for all surfaces not always requiring a rinse)

Carbosan 50 is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm active and 500 ppm hard water against
Escherichia coli
Staphylococcus aureus

Carbosan 50 is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm – 400 active and 500 ppm hard water against
Escherichia coli
Staphylococcus aureus

Regular effective cleaning and sanitizing of equipment utensils and work or dining surfaces which could harbor food poisoning microorganisms minimizes the probability of contaminating food during preparation storage or service Effective cleaning will remove soil and prevent the accumulation of food residues which may decompose or support the rapid development of food poisoning organisms or toxins Application of effective sanitizing procedures reduces the number of those disease organisms which may be present on equipment and utensils after cleaning and reduces the potential for the transfer either directly through tableware such as glasses cups and flatware or indirectly through food

To prevent cross-contamination on treated surfaces kitchenware and food-contact surfaces of equipment must be washed rinsed with potable water and sanitized after each use and following any interruption of operation during which time contamination may have occurred

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis utensils and the food-contact surfaces of equipment must be washed rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature type of food and amount of food particle accumulation

Articles that can be immersed in solution must remain in solution for 60 seconds

Articles or surfaces too large for immersing should be thoroughly wetted or flooded by rinsing spraying or swabbing

Allow all sanitized surfaces to drain [and air dry]

Carbosan 50 fulfills the criteria of Appendix F of the Grade A Pasteurized Milk Ordinances 1999 Recommendations of the U S Public Health Services in waters up to 500 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method

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Dilution

- Sanitizer (1 1248) 1 0 oz per 9 77 gallons of water (400 ppm active quat)
- Sanitizer (1 1536) 0 5 oz per 6 5 gallons of water (300 ppm active quat)
- Sanitizer (1 2080) 0 6 oz per 9 3/4 gallons of water (240 ppm active quat)
- Sanitizer (1 2496) 0 5 oz per 9 3/4 gallons of water (200 ppm active quat)
- Sanitizer (1 3328) 0 5 oz per 13 gallons of water (150 ppm active quat)

DIRECTIONS FOR USE

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

(Note to reviewer On a final printed label only one of the following dilution rates will be used in the sanitization sections below

- [1 oz of CARBOSAN 50 per 19-1/2 - 26 gallons of water (3/4 - 1 oz of Carbosan 50 per 19 1/2 gallons of water) (150 - 200 ppm active quat)]
- or
- [1 oz of CARBOSAN 50 per 19-1/2 gallons of water [2 oz of Carbosan 50 per 39 gallons of water] [200 ppm active quat]]
- or
- [1 oz of CARBOSAN 50 per 16-1/4 - 26 gallons of water [3/4 - 1 2 oz of Carbosan 50 per 19 1/2 gallons of water] [150 - 240 ppm active quat]]
- Or
- [0 5 oz of CARBOSAN 50 per 6 5 gallons of water [1 oz of Carbosan 50 per 13 gallons of water] (300 ppm active quat)]
- or
- [1 0 oz of CARBOSAN 50 per 9 77 gallons of water [2 oz of Carbosan 50 per 19 54 gallons of water] (400 ppm active quat)]

TO SANITIZE FOOD CONTACT SURFACES

or

TO SANITIZE [FOOD PROCESSING EQUIPMENT] [AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS], [DAIRIES], [RESTAURANTS] [AND] [BARS]

For sanitizing food processing equipment dairy equipment food utensils dishes silverware glasses sink tops countertops refrigerated storage and display equipment and other hard surfaces

Prior to application remove gross food particles and soil by a pre-flush or pre-scrape and when necessary pre-soak Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution

Apply a use solution of [insert appropriate dilution from box here] [or equivalent dilution] to the pre-cleaned hard surface with a cloth mop sponge coarse sprayer or by immersion thoroughly wetting surfaces Surfaces must remain wet for at least [one minute] [60 seconds] followed by adequate draining [and air drying] Do not rinse

Prepare fresh solution daily or more often if the use solution becomes diluted or soiled For mechanical applications use-solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning

Apply to sink tops counter tops refrigerated storage and display equipment and other stationary surfaces by cloth sponge [or] brush [or coarse spray]

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Immerse pre-cleaned glassware dishes silverware cooking utensils and other similar size food processing equipment in a solution of [insert appropriate dilution here] [or equivalent dilution] for at least [one minute] [60 seconds] Drain thoroughly [and allow to air dry] before reuse Do not rinse

TO SANITIZE FOOD PROCESSING EQUIPMENT, UTENSILS, AND OTHER FOOD CONTACT ARTICLES REGULATED BY 40 CFR § 180.940 (a)

- 1 Scrape flush or presoak articles (whether mobile or stationary) to remove gross food particles and soil
- 2 Thoroughly wash articles with an appropriate detergent or cleaner
- 3 Rinse articles thoroughly with clean water
- 4 Sanitize by immersing articles in a use-solution of [insert appropriate dilution from box here] (or equivalent dilution) for at least [60 seconds] [one minute] Articles too large for immersing must be thoroughly wetted by rinsing spraying or swabbing
- 5 Remove immersed items from solution to drain and then air dry Non-immersed items should also be allowed to air dry

TO SANITIZE [SOFT SERVE] [FOOD] [AND] [BEVERAGE] DISPENSING EQUIPMENT

- 1 Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing
- 2 Fill equipment with a solution of [insert appropriate dilution from box here] [or equivalent dilution]
- 3 Allow solution to remain in equipment for at least [60 seconds] [one minute]
- 4 Drain thoroughly [and allow to air dry] before reuse Do not rinse

TO SANITIZE SANITARY FILLING EQUIPMENT

Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing Prepare a use-solution of [insert appropriate dilution from box here] [or equivalent dilution] for final washer and rinser applications Allow surfaces to remain wet for at least [60 seconds] [one minute] Drain thoroughly [and allow to air dry] before reuse Do not rinse

TO SANITIZE BEER FERMENTATION AND STORAGE TANKS

Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing Prepare a use-solution of [insert appropriate dilution from box here] [or equivalent dilution] for mechanical or automated systems Allow surfaces to remain wet for at least [60 seconds] [one minute] Drain thoroughly [and allow to air dry] before reuse Do not rinse

WATERPROOF GLOVE SANITIZING DIRECTIONS

To prevent cross contamination into processing areas of food plants waterproof gloves must be sanitized prior to entering or re-entering those areas Remove gross contamination from gloves before sanitizing Then place gloved hand in a use-solution of [1 oz of Carbosan 50 per 19 1/2 gallons of water] [2 oz of Carbosan 50 per 39 gallons of water] [200 ppm active quat] or [1 oz of CARBOSAN 50 per 9 3/4 – 19 1/2 gallons of water (1 – 1 2 oz of Carbosan 50 per 19 1/2 gallons of water) [200 – 240 ppm active quat] or [0.5 oz of CARBOSAN 50 per 6 gallons of water] [1 oz of Carbosan 50 per 12 gallons of water) (300 ppm active quat)] [1.0 oz of CARBOSAN 50 per 9 3/4 gallons of water] [2 oz of Carbosan 50 per 19 1/2 gallons of water) (400 ppm active quat)] for at least [sixty seconds] [one minute] Change the solution in the bath at least daily or more often if the solution appears visibly diluted or soiled

TO SANITIZE EGG SHELLS INTENDED FOR FOOD

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants spray with a use-solution of [insert appropriate dilution here] [or equivalent dilution] The solution must be equal to or warmer than the eggs but not to exceed 130°F Wet eggs thoroughly and allow to drain Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products Eggs must be reasonably dry before casing or breaking The solution must not be re-used for sanitizing eggs

Note Only clean whole eggs can be sanitized Dirty cracked or punctured eggs cannot be sanitized

Carbosan 50 can be used in accordance with the U.S. Public Health Service food sanitization recommendations

ACCEPTED with COMMENTS in EPA Letter Dated

SEP 5 2012

**U S PUBLIC HEALTH SERVICE
FOOD SERVICE SANITIZATION RECOMMENDATIONS**

CLEANING AND SANITIZING Equipment and utensils must be thoroughly pre-flushed or pre-scraped and when necessary pre-soaked to remove gross food particles and soil

- 1 Thoroughly wash equipment and utensils in hot detergent solution
- 2 Rinse utensils and equipment thoroughly with clean water
- 3 Sanitize equipment and utensils by immersion in a use solution of [*insert appropriate dilution from box here*] [or equivalent dilution] for at least [60 seconds] [one minute] at a temperature of 75°F
- 4 For equipment and utensils too large to sanitize by immersion apply a use-solution of [*insert appropriate dilution here*] (or equivalent dilution) by rinsing spraying or swabbing until thoroughly wet
- 5 Allow sanitized surface to drain [and air dry] Do not rinse

**WISCONSIN STATE BOARD OF HEALTH
DIRECTIONS FOR EATING ESTABLISHMENTS**

- 1) Scrape and pre-wash utensils and glasses whenever possible
- 2) Wash with a good detergent or compatible cleaner
- 3) Rinse with clean water
- 4) Sanitize in a solution of [1 oz of CARBOSAN 50 per 19 1/2 gallons of water [2 oz of Carbosan 50 per 39 gallons of water] [200 ppm active quat]] or [1 oz of CARBOSAN 50 per 9 3/4 – 19 1/2 gallons of water (1 – 1 2 oz of Carbosan 50 per 19 1/2 gallons of water) [200 – 240 ppm active quat]] [0 5 oz of CARBOSAN 50 per 6 5 gallons of water [1 oz of Carbosan 50 per 13 gallons of water) (300 ppm active quat)] or [1 0 oz of CARBOSAN 50 per 9 77 gallons of water [2 oz of Carbosan 50 per 19 54 gallons of water) (400 ppm active quat)] [or equivalent dilution] Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code

5) Place sanitized utensils on a rack or drain board to air-dry

NOTE A clean potable water rinse following sanitization is not permitted under Section HFS 196 13 of the Wisconsin Administrative Code

FOGGING DEVICE HATCHERY ROOM SANITIZER DIRECTIONS

Remove all animals and feed from premises vehicles and enclosures Remove all litter and manure from floors walls and surfaces of the room to be treated Empty all troughs racks and other feeding and watering appliances Thoroughly clean all surfaces with soap or detergent and rinse with water Close room off so fog is confined to room to be treated Mix 1 gal of Carbosan 50 per 20 gal of water Insert the nozzle of the fogger through a suitable opening into the room With the setting in maximum output for one minute for each 4000 cubic feet of space in the room Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed)

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(Note to reviewer For Nonrefillable Containers, Container is five gallons or less, Label has institutional/industrial/commercial uses)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children

Nonrefillable container Do not reuse or refill this container Clean container promptly after emptying Triple rinse as follows Fill container 1/4 full with water and reclose the container Agitate vigorously and dispose of rinsate Repeat two more times Wrap [container] and put in trash or offer for recycling if available

(or)

Nonrefillable container Do not reuse or refill this container Clean container promptly after emptying Triple rinse as follows Fill container 1/4 full with water and reclose the container Agitate vigorously and dispose of rinsate Repeat two more times Wrap [container] and put in trash or offer for reconditioning if appropriate

(Note to reviewer For Nonrefillable Containers, Container is over 5 gallons, Label has commercial, industrial, and institutional uses)

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal

Pesticide Storage

Open dumping is prohibited Store in original container in areas inaccessible to children

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 Clean container promptly after emptying (Plastic and Metal Containers) Triple rinse as follows Fill container 1/4 full with water and reclose the container 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 Follow Pesticide Disposal instructions for rinsate disposal Repeat two more times Then offer for recycling or reconditioning If not available puncture and dispose in sanitary landfill (For metal containers only DO NOT cut or weld metal containers)

(Bag in Box Containers) Completely empty bag into application equipment Then offer for recycling if available or dispose of in a sanitary landfill or by incineration or by other procedures allowed by state and local authorities

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(For Bag in Box Containers)

For Bag - In - Box Containers

How to use this package

This package is designed to be used with dilution control systems only Open package and connect to dispense according to directions on box top

Trigger Sprayers

Fill bottle from dispenser

Apply to surfaces as specified in directions above

Mop Buckets

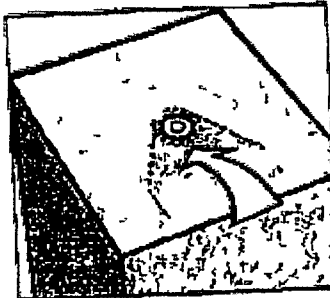
Fill bucket from dispenser

Set up Wet Floor signs

Mop floor surface as specified in directions above

OPENING INSTRUCTIONS

- 1 Position box with perforation up
- 2 Press in circle
- 3 Lift flap near along perforation
- 4 Remove fitting on bag
- 5 Remove clear dust-cap from bag fitting
- 6 Twist dispenser connector onto bag fitting
- 7 Place bag-in-box into position on dispenser shelf
- 8 Close dispenser (if applicable)



INSTRUCCIONES PARA ABRIR

- 1 Ponga la caja con la perforación hacia arriba.
- 2 Empuje el círculo hacia adentro
- 3 Levante la pestaña atravesada de la caja a lo largo de la perforación
- 4 Saque el adaptador que está en la bolsa
- 5 Quite la tapa transparente contra el polvo que tiene el adaptador de la bolsa
- 6 Enrosque el conector dispensador al adaptador.
- 7 Ponga la "bag-in-box" (bolsa en caja) en posición en el mostrador de despacho
- 8 Cierre el dispensador (si corresponde)

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