

Rebecca L. Mannion  
Senior Registration Specialist  
Diversey, Inc.  
8310 16<sup>th</sup> Street  
Sturtevant, WI 53177

AUG 17 2011

Subject: Render II  
EPA Reg. No. 875-106  
Application Dated: July 13, 2011  
Receipt Date: July 14, 2011

Dear Ms. Mannion:

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

**Proposed Amendment:**

- Label Amendment

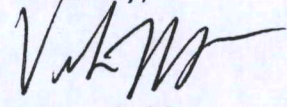
**Conditions:**

Revise the first claim on page 2 to read as follows: "This *product when tested according to AOAC methods* in the presence of 5% blood serum has been shown to be an effective as a disinfectant against the following organisms on hard, non-porous inanimate surfaces (See reference sheet for a complete list of organisms):" Make this same change on page 8.

**General Comments:**

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

Should you have any questions or comments concerning this letter, please contact me at [noble.velma@epa.gov](mailto:noble.velma@epa.gov) or call (703) 308-6233.

Sincerely,  


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

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							



Note to Agency: Text appearing in parenthesis is done to show optional text.

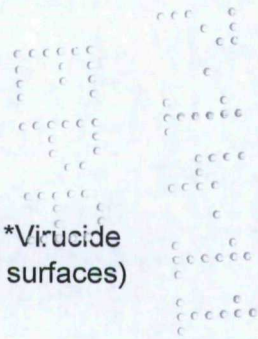


# RENDER® II

## Detergent/Disinfectant

Cleaner • Detergent • Disinfectant • Sanitizer • Deodorizer • \*Virucide  
Fungicide (pathogenic fungi) • Mildewstat (on hard inanimate surfaces)

For Institutional Use

**ACTIVE INGREDIENTS:**

n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> ) dimethyl benzyl ammonium chloride .....	2.25%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chloride.....	2.25%
<b>INERT (OTHER) INGREDIENTS:</b> .....	<b>95.50%</b>
<b>TOTAL:</b> .....	<b>100.00%</b>

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

**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.

**IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.  
XXX-XXX-XXXX**

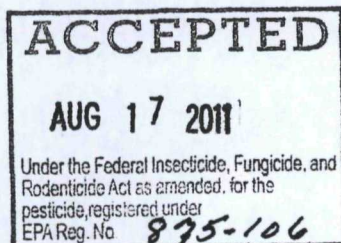
Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

**Note to Physician:** Probable mucosal damage may contraindicate gastric lavage.

See additional precautionary statements on back (side) (left) (right) (panel) (of) (label) (below).

See reference sheet (enclosed in each case) for (a complete list of pathogenic organisms) (additional features, claims, directions for use) (claimed for this product) (eliminated by this product).

Net Contents:



Note to Agency: Text appearing in parenthesis is done to show optional text.

**(MARKETING CLAIMS:)**

**(FEATURES, CLAIMS & USES:)**

This product is a phosphate-free concentrated detergent/disinfectant, which provides effective cleaning, deodorizing, disinfection, and sanitization. It has been designed specifically for hospitals, nursing homes, operating rooms, patient care facilities, restrooms, schools, food processing plants, food service establishments, and other institutions where housekeeping is of prime importance for controlling cross contamination. This product deodorizes areas, which are generally hard to keep fresh smelling, including garbage storage areas, empty garbage bins and cans.

This product is formulated to disinfect the following hard, non-porous, inanimate surfaces: walls, floors, sinks, countertops, toilet bowls, tables, chairs, and telephones.

This product is for use as a sanitizer in restaurants, dairies, food processing plants and bars. For use on: chopping blocks, countertops, tables, glasses, dishes and utensils.

**DIRECTIONS FOR USE:**

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

**(CLAIMS:)**

This product, when diluted at 2 oz. per gallon of water in the presence of 5% blood serum and 10 minute contact time, is an effective disinfectant against the following organisms on hard, non-porous inanimate surfaces (See reference sheet for a complete list of organisms):

**Bacteria:**

- |   |                                  |                               |
|---|----------------------------------|-------------------------------|
| <i>Pseudomonas aeruginosa</i> (PRD-10)  | <i>Brevibacterium ammoniages</i> | <i>Klebsiella pneumoniae</i>  |
| <i>Staphylococcus aureus</i>  | <i>Enterobacter aerogenes</i>    | <i>Shigella dysenteriae</i>   |
| <i>Salmonella enterica</i> (formerly known as<br><i>Salmonella choleraesuis</i> ) | <i>Escherichia coli</i>          | <i>Streptococcus faecalis</i> |

**\*Viruses:**

- \*HIV-1 (Human Immunodeficiency Virus Type 1) (AIDS virus)
- \*Adenovirus Type 2 (causative agent of upper respiratory infections)
- \*Herpes Simplex Virus Type 1 (causative agent of fever blisters)
- \*Influenza A<sub>2</sub>/Asian Virus (representative of the common flu virus)
- \*Vaccinia Virus (representative of the pox virus group)

**Fungi:** *Trichophyton mentagrophytes*

**Mold/Mildew (Mildewstatic Activity)** – controls and prevents (inhibits) the growth of mold and mildew: *Aspergillus niger* (and the odors caused by them) when applied to hard, non-porous inanimate surfaces.



Note to Agency: Text appearing in parenthesis is done to show optional text.

(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

\*Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A<sub>2</sub>, and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

\*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.

\*This product has demonstrated effectiveness against Influenza Type A<sub>2</sub>, and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

\*Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).

\*Kills Pandemic 2009 H1N1 Influenza A virus.

**(Modes of Application:)**

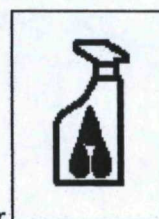
This product can be applied by mop, sponge, cloth, paper towel or (hand pump) coarse trigger sprayer.



**To Prepare (Disinfectant) Use Solution:**

Add the product at 2 oz. per gallon water (703 ppm) (1:64). Prepare fresh solution daily or more frequently if soil is apparent.



*(Note to EPA: The directions that appear for specific container sizes will be substituted for the sentence above only on that container size.)*

**RTD™ SYSTEMS** (1.5 or 5 L containers) - Using the RTD unit, dispense product into a (trigger sprayer), (auto scrubber, ) (or) bucket.



For Cleaning (and Disinfection) set the control knob to the (  or  ) setting which provides 2 oz. per gallon dilution (1:64).



For Sanitization (and Cleaning) set the control knob to the (  or  ) setting which provides 2 ½ oz. per 3 gallon dilution (1:224).

**To Disinfect:** Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous inanimate surfaces. To disinfect, all surfaces must remain wet for 10 minutes. Allow to air dry.

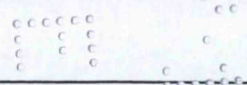
**To Control Mold and Mildew:** Apply Use Solution to hard, non-porous environmental surfaces. Allow to air dry. Repeat application weekly or when growth reappears.



Note to Agency: Text appearing in parenthesis is done to show optional text.

**To Disinfect Toilet Bowls:** Pre-clean heavily soiled areas. Flush toilet. Add 2 oz. of this product directly to bowl water. Swab bowl completely using toilet brush or mop, making sure to get under the rim. Let stand for 10 minutes. Flush.

**For Use as a Fungicide:** Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous environmental surfaces in areas such as locker rooms, dressing rooms, shower and bath areas. Allow surface to remain wet for ten (10) minutes. (Wipe surfaces (and let air dry).)



**\*Kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids** in health care settings (Hospitals, Nursing Homes) 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-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

**Cleaning Procedures:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**Contact Time:** Allow surface to remain wet for 10 minutes.

**Disposal of Infectious Material:** Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

**To Sanitize Hard, Non-Porous Food Contact Surfaces and Equipment:**

1. Prior to sanitization, remove gross particulate matter with a warm water flush, presoak or scrape, then wash equipment with detergent or cleaning solution and follow with a potable water rinse.
2. Prepare the sanitizing use solution by adding 2 oz. of this product per 3-1/2 gallons water (200 ppm active quat), (or equivalent dilution).
3. Apply sanitizing solution by immersion, coarse spray, mop, wipe, flood techniques or circulation techniques as appropriate to the equipment or surface to be treated. Allow a contact time of at least one (1) minute.
4. Allow surfaces to drain thoroughly and air dry before resuming operation. Do not rinse.

**To Sanitize Hard, Non-Porous Food Contact Surfaces and Equipment in Restaurants, Bars, Institutions, and Other Food Service Establishments:**

1. Scrape, flush or presoak (articles) (utensils, dishes and glasses) (whether mobile or stationary) to remove gross soil.
2. Thoroughly wash articles with detergent.
3. Rinse articles thoroughly with clean (potable) water.
4. Sanitize in a solution containing (2 oz. of this product per 3-1/2 gallons water (or equivalent dilution) (200 ppm active quat). Immerse all articles or utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.

Note: NO POTABLE WATER RINSING of equipment is allowed. Prepare a fresh solution daily or more frequently if soil is apparent.



Note to Agency: Text appearing in parenthesis is done to show optional text.

**(Wisconsin Sanitizer Instructions)**

**Sanitizing Food Contact Surfaces:**

1. Pre-flush, scrape or pre-soak articles to be washed.
2. Wash areas or items to be sanitized with clean water and a recommended detergent.
3. Rinse with potable water.
4. Sanitize in a solution prepared by diluting 2 oz. of this product per 3-1/2 gallon water to 200 ppm quaternary level. Immerse or wet all surfaces for at least 60 seconds (1 minute) or as required by local sanitation regulations. When solution depreciates or becomes soiled, discard. Test sanitizer solution periodically with a Quaternary Test Kit to ensure 200 ppm active quaternary.
5. Drain and allow equipment or utensils to air dry.

Note: NO POTABLE WATER RINSING of equipment is required. Prepare a fresh solution daily or more frequently if soil is apparent.

**For Use as a (General) Cleaner (and/or Deodorizer):**

Apply Use Solution to surfaces. Wipe surfaces (and let air dry).

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE:** Do not reuse empty container. Store in a dry place at 50° F to 120° F.

**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:** (Note to Reviewer: we will choose one of the following statements, depending on product container type:)

**NONREFILLABLE SEALED CONTAINERS:** *Note to reviewer: Several of our packaging options are sealed containers or bottles designed to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

**NONREFILLABLE NON-RIGID CONTAINERS:** *Note to reviewer: Several of our packaging options are Bag-in-Box containers (a plastic bag liner supported inside a box) or are flexible bag-type containers. These flexible containers are exempt from the triple rinsing requirements. The following text will be used on these container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

**SMALL NONREFILLABLE CONTAINERS:** *Note to reviewer: The following text will be used on rigid, nonrefillable containers small enough to shake (5 gallons or smaller):*

Nonrefillable container. Do not reuse or refill this container. Clean container 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 and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available.



Note to Agency: Text appearing in parenthesis is done to show optional text.

**LARGE NONREFILLABLE CONTAINERS:** *Note to reviewer: One of the following paragraphs will be used on labels for rigid, nonrefillable containers too large to shake (larger than 5 gallons):*

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate. Repeat this procedure two more times. Offer for reconditioning, if appropriate.

OR

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.

**REFILLABLE CONTAINERS:** *Note to reviewer: One of the following paragraphs will be used on labels for refillable containers:*

Refillable container. Refill this container with (this brand or brand name pesticide) only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

OR

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Repeat this rinsing procedure two more times.

**ENVIRONMENTAL HAZARDS**

*(If container is equal to or smaller than 5 gallons, use the following statement:)*

This product is toxic to fish.

*(If container is 5 gallons or greater in size, use the following statement:)*

This product is toxic to 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 (NPDES) permit and the permitting agency 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.

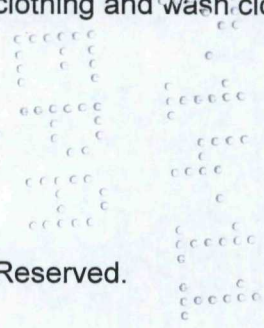


Note to Agency: Text appearing in parenthesis is done to show optional text.

**PRECAUTIONARY STATEMENTS  
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

**DANGER: Corrosive.** Causes irreversible eye damage and skin burns. Harmful if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear chemical splash-proof goggles or face shield, rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

EPA Reg. No. 875-106  
EPA Est. No.  
(Lot code letters indicate manufacturing location)  
(MSDS Ref. No. XXXXXXXXXXXX)



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Optional Kosher Symbol such as the following:



Optional NSF logo:





Note to Agency: Text appearing in parenthesis is done to show optional text.



### RENDER® II REFERENCE SHEET

This product, when diluted at 2 oz. per gallon of water in the presence of 5% blood serum and 10 minute contact time, is an effective disinfectant against the following organisms on hard, non-porous inanimate surfaces:

**Bacteria:**

- |   |                                  |                               |
|---|----------------------------------|-------------------------------|
| <i>Pseudomonas aeruginosa</i> (PRD-10)  | <i>Brevibacterium ammoniages</i> | <i>Klebsiella pneumoniae</i>  |
| <i>Staphylococcus aureus</i>  | <i>Enterobacter aerogenes</i>    | <i>Shigella dysenteriae</i>   |
| <i>Salmonella enterica</i> (formerly known as<br><i>Salmonella choleraesuis</i> ) | <i>Escherichia coli</i>          | <i>Streptococcus faecalis</i> |

**\*Viruses:**

- \*HIV-1 (Human Immunodeficiency Virus Type 1) (AIDS virus)
- \*Adenovirus Type 2 (causative agent of upper respiratory infections)
- \*Herpes Simplex Virus Type 1 (causative agent of fever blisters)
- \*Influenza A<sub>2</sub>/Asian Virus (representative of the common flu virus)
- \*Vaccinia Virus (representative of the pox virus group)

**Fungi:** *Trichophyton mentagrophytes*

**Mold/Mildew (Mildewstatic Activity)** – controls and prevents (inhibits) the growth of mold and mildew: *Aspergillus niger* (and the odors caused by them) when applied to hard, non-porous inanimate surfaces.

(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

\*Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A<sub>2</sub>, and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

\*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.

\*This product has demonstrated effectiveness against Influenza Type A<sub>2</sub>, and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

\*Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).

\*Kills Pandemic 2009 H1N1 Influenza A virus.



Note to Agency: Text appearing in parenthesis is done to show optional text.

**DIRECTIONS FOR USE:**

This product can be applied by mop, sponge, cloth, paper towel or (hand pump) coarse trigger sprayer.

**To Prepare (Disinfectant) Use Solution:**

Add the product at 2 oz. per gallon water. Prepare fresh solution daily or more frequently if soil is apparent.

**To Disinfect:** Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous inanimate surfaces. To disinfect, all surfaces must remain wet for 10 minutes. Allow to air dry.

**For Use as a (General) Cleaner (and/or Deodorizer):**

Apply Use Solution to surfaces. Wipe surfaces (and let air dry).

**To Control Mold and Mildew:** Apply Use Solution to hard, non-porous environmental surfaces. Allow to air dry. Repeat application weekly or when growth reappears.

**To Disinfect Toilet Bowls:** Pre-clean heavily soiled areas. Flush toilet, add 2 oz. Render II directly to bowl water. Swab bowl completely using toilet brush or mop, making sure to get under the rim. Let stand for 10 minutes. Flush.

**For Use as a Fungicide:** Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous environmental surfaces in areas such as locker rooms, dressing rooms, shower and bath areas. Allow surface to remain wet for ten (10) minutes. (Wipe surfaces (and let air dry).)

**\*Kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids** in health care settings (Hospitals, Nursing Homes) 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-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

**Cleaning Procedures:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**Contact Time:** Allow surface to remain wet for 10 minutes.

**Disposal of Infectious Material:** Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.



Note to Agency: Text appearing in parenthesis is done to show optional text.

**To Sanitize Hard, Non-Porous Food Contact Surfaces and Equipment:**

1. Prior to sanitization, remove gross particulate matter with a warm water flush, presoak or scrape, then wash equipment with detergent or cleaning solution and follow with a potable water rinse.
2. Prepare the sanitizing use solution by adding (2 oz. of this product per 3-1/2 gallons water (200 ppm active quat) (or equivalent dilution).
3. Apply sanitizing solution by immersion, coarse spray, mop, wipe, flood techniques or circulation techniques as appropriate to the equipment or surface to be treated. Allow a contact time of at least one (1) minute.
4. Allow surfaces to drain thoroughly and air dry before resuming operation. Do not rinse.

**To Sanitize Hard, Non-Porous Food Contact Surfaces and Equipment in Restaurants, Bars, Institutions, and Other Food Serving Establishments:**

1. Scrape and pre-wash utensils, dishes and glasses to remove gross soil.
2. Wash with detergent.
3. Rinse with clean (potable) water.
4. Sanitize in a solution containing (2 oz. of this product per 3-1/2 gallons water (or equivalent dilution) (200 ppm active quat). Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.

(Wisconsin Sanitizer Instructions)

**Sanitizing Food Contact Surfaces:**

1. Pre-flush, scrape or pre-soak articles to be washed.
2. Wash areas or items to be sanitized with clean water and a recommended detergent.
3. Rinse with potable water.
4. Sanitize in a solution prepared by diluting 2 oz. Render II per 3-1/2 gallon water to 200 ppm quaternary level. Immerse or wet all surfaces for at least 60 seconds (1 minute) or as required by local sanitation regulations. When solution depreciates or becomes soiled, discard. Test sanitizer solution periodically with a Quaternary Test Kit to ensure 200 ppm active quaternary.
5. Drain and allow equipment or utensils to air dry.

Note: NO POTABLE WATER RINSING of equipment is required. Prepare a fresh solution daily or more frequently if soil is apparent.

See container label for First Aid, Precautionary Statements and complete Directions for Use.

EPA Reg. No. 875-106

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