

47371-104 C 7/11/2013 C i/11

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



Office of Pesticide Programs

Joanna Holcombe
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

JUL -1 2013

Subject: Formulation HS-3328
EPA Registration Number 47371-104
Application Dated February 5, 2013
Submission # 930734

Dear Ms. Holcombe:

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(7)(B) provided that you:

Proposed Amendment:

- Revise the secondary container language
- Add an animal virus claim for Murine Norovirus
- Add disposal instructions for refillable containers

General Comments:

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

A handwritten signature in black ink, appearing to read 'Velma Noble', with a long horizontal flourish extending to the right.

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

Enclosure: stamped label

Note to Reviewer:

[Language in brackets [AAA] is optional or interchangeable]

{Language in braces {AAA} is for informational purposes and will not appear on the final label}

Formulation HS-3328

[DISINFECTANT-SANITIZER-DEODORIZER]

Active Ingredients:

n-Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₈ , 5%; C ₁₂ , 5%) dimethyl benzyl ammonium chloride	7.04%
n-Alkyl (C ₁₂ , 68%; C ₁₄ , 32%) dimethyl ethylbenzyl ammonium chloride	7.04%
Other Ingredients:	85.92%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN**DANGER [PELIGRO]**

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

EPA Reg. No. 47371-104

EPA Est. No. (as indicated on container)

Net Contents (as indicated on container)

[DOT Symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

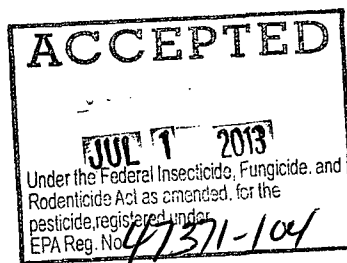
[Barcode]

H&S CHEMICALS DIVISION

c/o Lonza Inc.

90 Boroline Road

Allendale, NJ 07401



Formulation HS-3328

EPA Reg. No. 47371-104

EPA Stamped Label 1-31-12, Draft 2013-02-05

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

DANGER. CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield), protective clothing and protective gloves (rubber or chemical resistant) when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before use.

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.

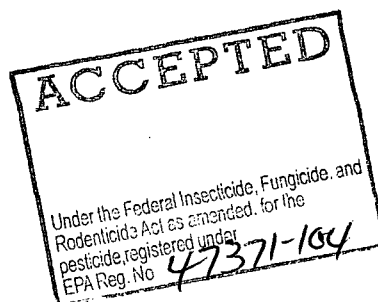
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

{Note to reviewer: If the container size is 5 gallons or greater, the following Environmental Hazards statements will be used:}

ENVIRONMENTAL HAZARDS

This pesticide 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 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.



5711
{Note to reviewer: the following is considered optional marketing language:}

An effective, multi-purpose disinfectant - Staphylocidal, Pseudomonacidal and Salmonellacidal on nonporous, inanimate surfaces.

Formulation HS-3328 is an effective sanitizer for use on food contact surfaces; it also fulfills the criteria of Appendix F, of the Grade "A" Pasteurized Milk Ordinance, recommendation of the U.S. Public Health Service, in hard waters up to [500] [750] ppm hardness [calculated CaCO_3].

Formulation HS-3328 at 1 oz. per 5 1/2 gallons of water [0.18 oz. per gallon of water] [3.64 fl. oz. per 20 gallons of water] [or equivalent dilution] is an effective sanitizer for use on food contact surfaces in 60 seconds at 200 ppm active and 750 ppm hard water against:

Escherichia coli
Staphylococcus aureus

Formulation HS-3328 at 1 oz. per 6 1/4 gallons of water [0.16 oz. per gallon of water] [3.19 fl. oz. per 20 gallons of water] [or equivalent dilution] is an effective sanitizer for use on food contact surfaces in 60 seconds at 175 ppm active and 500 ppm hard water against:

Escherichia coli
Staphylococcus aureus

ACCEPTED

Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 47371-104

Dilution:

DISINFECTANT 1:256.....	[550 ppm active quat]
SANITIZER 1:640	[220 ppm active quat]
SANITIZER 1:704	[200 ppm active quat]
SANITIZER 1:821	[175 ppm active quat]

{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}

[PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.]

DIRECTIONS FOR USE

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

DIRECTIONS FOR DISINFECTING: For use in hospitals and nursing homes, federally inspected meat and poultry plants, restaurants and bars, beverage plants, barber shops, schools and colleges.

For use on hard, nonporous surfaces such as floors, walls, metal surfaces, glazed porcelain, and plastic surfaces [such as polypropylene, polystyrene, etc.].

Remove gross filth and heavy soils. Pre-clean all surfaces then thoroughly wet surfaces with **Formulation HS-3328**. Use 1/2 oz. per gallon of water for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. The recommended use solution is prepared fresh for each use, then discarded. Rinsing is not necessary, unless floors are to be waxed or polished. Rinse food contact surfaces such as counter tops, tables, picnic tables, appliances and / or stove tops with potable water prior to reuse. Do not use on glasses, dishes or utensils as a disinfectant.

DISINFECTION OF BARBER TOOLS:

Preclean barber tools. Mix 1/2 oz. per gallon of water to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, razors and scissors for 10 minutes. Rinse thoroughly and dry before reuse. Prepare a fresh solution daily or more often if solution becomes visibly soiled, cloudy or diluted.

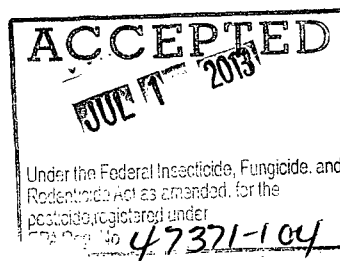
Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

{Note to reviewer: Only One of the following two statements will be used:}

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.

{or}

This product is not for use on medical device surfaces.



{Note to reviewer: On a final printed label, only one of the dilution rates below will be used in the sanitizing direction sections.}

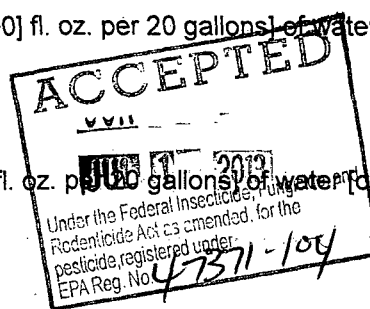
[1 oz. per 5 [- 5 ½] gallons [0.18 [- 0.20] oz. per gallon] [[3.64 [- 4.00] fl. oz. per 20 gallons] of water [or equivalent dilution] [200 [- 220] ppm active quat]

or

[1 oz. per 5 - 6 ¼ gallons [0.16 - 0.20 oz. per gallon] [3.19 - 4.00 fl. oz. per 20 gallons] of water [or equivalent dilution] [175 - 220 ppm active quat]]

or

[1 oz. per 5 ½ gallons] [0.73 oz. per 4 gallons] [2.73 fl. oz. oz. per 15 gallons] [the contents of this packet] [3.64 fl. oz. per 20 gallons] [or equivalent dilution] [200 ppm quat]



DIRECTIONS FOR SANITIZING: For use on hard, nonporous surfaces such as eating utensils and drinking glasses.

Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Then, use (*insert appropriate dilution rate here from box*) for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. Apply by soaking to dishes, glasses and eating utensils. For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not rinse.

Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware, cooking utensils, Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Immerse in a solution of (*insert appropriate dilution rate here from box*) for at least 1 minute. Do not rinse. Allow to air Dry. Prepare a fresh solution at least daily or when use solution becomes visibly dirty.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Fill equipment with solution of [*insert appropriate dilution rate here from box*]. Allow the solution to remain in contact with equipment for at least 1 minute or until operations resume at which time the sanitizing solution should be drained from the system.

To insure the removal of flavors, it is suggested that during change over between products, the system should be cleaned, rinsed, and flushed with the sanitizing solution for 1 minute. Allow to drain completely before using.

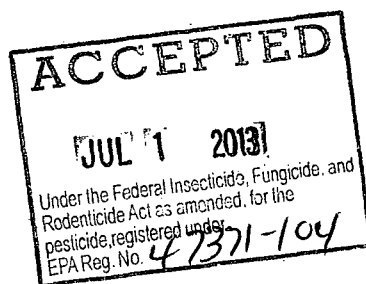
SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. **Formulation HS-3328** is to be proportioned into the final rinse water line of the container washer or rinser in concentration of [*insert appropriate dilution rate here from box*]. A sanitizing solution of (*insert appropriate dilution rate here from box*) should be used for the filler and closing machine.

STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. A solution of (*insert appropriate dilution rate here from box*) should be applied by spraying or used in combination with automated cleaning systems. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Drain thoroughly. Do not rinse. For mechanical operations or automated systems, the used sanitizing solution may not be reused for sanitizing, but may be reused for other purposes such as cleaning.

DIRECTIONS FOR SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS:

1. Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment.
2. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and
3. Rinse with potable water prior to sanitizing.
4. Immerse in a solution of (*insert appropriate dilution rate here from box*). Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drainboard to air dry.
6. Prepare a fresh solution at least daily or when use solution becomes visibly dirty.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code [reference 40 CFR 180.940(a)].



9/11
{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products}

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 $\frac{1}{4}$ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{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.

{Note to reviewer: Several packaging options are designed for use dilution systems with sealed containers or bottles 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:}

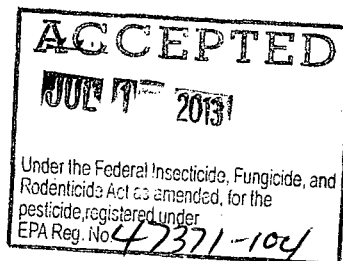
STORAGE AND DISPOSAL

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. Wrap empty container and discard in trash [or offer for recycling].



{Note to reviewer: Language for packets.}

TEAR HERE

FORMULATION HS-3328

Active Ingredients:

n-Alkyl (C14 60%, C16 30%, C18 5%, C12 5%) dimethyl benzyl ammonium chloride 7.04%
n-Alkyl (C12 68%, C14 32%) dimethyl ethylbenzyl ammonium chloride..... 7.04%
Other Ingredients 85.92%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See box label for Precautionary Statements and First Aid.

EPA Reg. No. 47371-104

EPA Est. No. (insert Establishment number here)

{Note to reviewer: The following Directions for Use may or may not appear on the packet, depending on whether space allows. It is not required text for small containers. Other similar sanitizing directions from pages 5 or 6 may be substituted.}

DIRECTIONS FOR USE:

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

This product is not for use on medical device surfaces.

DIRECTIONS FOR SANITIZING: For use on hard, nonporous surfaces such as eating utensils and drinking glasses. Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment. Thoroughly preclean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Then use [0.73 oz. [the contents of this packet] per 4 gallons] [2.73 fl. oz. [the contents of this packet] per 15 gallons of water] [200 ppm quat] for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. Apply by soaking to dishes, glasses and eating utensils. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from the surface; rub with a brush, cloth or sponge. Do not breathe spray. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not rinse.]

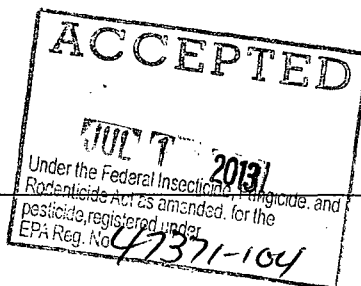
Refer to box label for complete directions for use.

Net Contents 0.73 fl. oz. [21.59 ml.]

Net Contents 2.73 fl. oz. [80.73 ml.]

SOLD BY:

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401



{Note to reviewer: Additional language for outside box.}

- Do not open box with knife
- Tear off panel at perforation
- Remove packets through opening
- Packets can be opened by tearing across pouring spout where indicated
- It is not safe or healthy to open [packet] by using your teeth or a knife.

{SECONDARY CONTAINER LABEL}

{Note to reviewer: This secondary container label will be used only when the product is diluted at 2 oz. or less per gallon of water. Other dilutions must use concentrate signal word and precautionary statements from page 1 and 2.}

FORMULATION HS-3328

Active Ingredients:

n-Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₈ , 5%; C ₁₂ , 5%) dimethyl benzyl ammonium chloride.....	7.04%
n-Alkyl (C ₁₂ , 68%; C ₁₄ , 32%) dimethyl ethylbenzyl ammonium chloride	7.04%
Other Ingredients:	85.92%
Total	100.00%

The product in this container must be diluted at the use rate of 2 oz. or less per gallon of water as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN

CAUTION [PRECAUCIÓN]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Follow the directions for use on the pesticide label when applying this product.

EPA Reg. No. 47371-104

