

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 6, 2021

Kathryn Rosiaro Regulatory Assurance Specialist Lonza Solutions AG 412 Mt. Kemble Ave. Suite 200S 07960 Morristown, NJ 07960

Subject: PRIA Label Amendment – Adding of SARS CoV-2 Organisms Product Name: LONZA Formulation HWS-64 EPA Registration Number: 47371-131 Application Date: November 6, 2020 Case Number: 00217308

Dear Ms. Rosiaro:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one 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 its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2 EPA Reg. No. 47371-131 Action Case No. 00217308

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Stacey Grigsby by phone at 703-305-6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

Jacqueline Hardy

Jacqueline Hardy, Branch Chief Regulatory Management Branch 2 Antimicrobials Division (7510P)

Enclosure: Approved label

Note to Reviewer: [Items in brackets [AAA] are optional and may/may not be included on final label] {Items in braces {AAA} are for information purposes and will not appear on final label}

FORMULATION HWS-64

ONE-STEP DISINFECTANT GERMICIDAL DETERGENT AND DEODORANT



$$\label{eq:linear} \begin{split} \text{Disinfectant} &- \text{Pseudomonacidal}^4 - \text{Staphylocidal}^5 - \text{Salmonellacidal}^6 - \text{Bactericidal} - \text{Fungicidal} - \text{Mildewstatic} \\ &- \text{*Virucidal} - \text{Sanitizer} \end{split}$$

FLORAL / CITRUS / FRESH / CLEAN / LEMON / PINE / MINT [scent] [fragrance] [odor] [scented]

Active Ingredients:	
Didecyl dimethyl ammonium chloride	2.54%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride	1.69%
Inert Ingredients:	<u>95.77%</u>
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

{**Note to Reviewer**: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the label.}

See [right] [left] [side] [back] panel for Precautionary Statements

EPA Reg. No. 47371-131 EPA Est. No. (insert Est. No. here) NET CONTENTS (insert container size here)

[DOT Symbols] [Country of origin (*insert country*)] [Manufactured in (*insert country*)] [Barcode]

H&S CHEMICALS Division of Lonza, LLC 412 Mount Kemble Avenue, Suite 200S Morristown, NJ 07960

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if inhaled. Avoid breathing vapor or spray mist. 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.

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 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.

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

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

{Note to reviewer: Pages 3-8 are considered optional marketing language.}

- Concentrate [Concentrated]
- Disinfects [Disinfectant]
- Cleans [Cleaner]
- Deodorizes [Deodorizer]
- Sanitizes [Sanitizer]

A multi-purpose, germicidal detergent and deodorant effective in hard water up to 200 ppm [calculated as CaCO₃] in the presence of a moderate amount of soil, 5% organic serum, tested according to the AOAC Usedilution Test. Disinfects, cleans and deodorizes in one labor-saving step.⁷

For use in hospitals and nursing homes as a disinfectant. Use in schools, colleges, universities, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, zoos, federally inspected meat and poultry plants, equine farms, tack shops, pet shops, airports, kennels, hotels, motels, poultry farms, turkey farms, dairy farms, hog farms, breeding establishments, grooming establishments, funeral homes, and households. Use to clean and disinfect non-medical [i.e. industrial and fire-fighting] respirators in industrial, commercial and institutional premises.

Disinfects, cleans, sanitizes and deodorizes the following hard, nonporous, inanimate surfaces: floors, walls, *[non-medical]* metal surfaces, *[non-medical]* stainless steel surfaces, glazed porcelain, plastic surfaces [such as polypropylene, polystyrene, acrylic, etc.].

Use [on] [to clean and disinfect] [clean and sanitize] hard, nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.

Use [on] [to clean and disinfect] [clean and sanitize] hard, nonporous personal protective safety equipment, wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse. [Notice: Cleaning at 120°F. temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.]

- for Poultry Premise Sanitation [Hatcheries]: Egg Receiving Area, Egg Holding Area, Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers, and all other Poultry House related Equipment, and other hard nonporous surfaces in the Hatchery Environment.
- for Swine Premise Sanitation: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and Areas, Nursery, Blocks, Creep Area, Chutes.
- for Farm Premise Sanitation: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

For use in (insert name of automated dilution system here) [automated] [dilution system].

For use in:

- Federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas and/or exterior areas. All surfaces must be thoroughly rinsed with potable water.
- Federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging material must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.
- Federally inspected meat and poultry plants, as a disinfectant agent for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. Use product in accordance with its label. All surfaces must be thoroughly rinsed with potable water.

For use in tanning salons. For use on [tanning beds], [and] [tanning equipment].

- Disinfects surfaces by killing [99.9%] SARS-CoV-2 [USA-WA1/2020] [in one step⁷]⁸
- Effective against SARS-CoV-2 [USA-WA1/2020] [in 1 minute]⁸
- [Effective against] [Disinfects] [Kills 99.9%] SARS-CoV-2 [virus]⁸
- [Effective against] [Disinfects] [Kills 99.9%] SARS-CoV-2 virus, the cause of COVID-19⁸
- [Kills 99.9% of] [Effective against] Influenza A virus associated with the flu.
- [Kills] [Effective against] the virus1¹ that may cause COVID-19⁸
- Kills 99.9% of SARS-CoV-2 [USA-WA1/2020] [the virus that may cause COVID-19]⁸
- Kills coronavirus¹ that may cause COVID-19⁸
- Kills the coronavirus¹ that may cause COVID-19⁸
- Kills the virus¹ that may cause COVID-19⁸
- Kills 99.9% of SARS-CoV-2, which may cause COVID-198
- [Proven to] kill[s] coronavirus¹, ⁸
- [Proven to] kill[s] the virus¹ that may cause COVID-19⁸

{Note to reviewer: If additional labeling /reference sheets are used, the following statement will appear on the container label:}

See [additional labeling] [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].

See [Reference Sheet] [insert] [product insert] for additional [product information] [and] [directions for use].

Formulation HWS-64 is effective at controlling mold and mildew odor on mattresses, pillows and shower curtains. **{Not for Use in California}**

Use **Formulation HWS-64** in the laundry to control odors on musty bedding and linens. Test on a small inconspicuous area before using.

Use Formulation HWS-64 on mildew stains.

Use **Formulation HWS-64** on mildew stains in damp areas such as bathrooms, showers, kitchens, basements and laundry rooms. **{Not for Use in California}**

Use **Formulation HWS-64** in work areas such as tool rooms and garages for odor control and light duty cleaning.

Use Formulation HWS-64 to remove odors caused by flooding and smoke from fires.

Formulation HWS-64 leaves a clean fresh scent.

Formulation HWS-64 provides long lasting freshness against tough [pet] odors from litter boxes and pet accidents.

Formulation HWS-64 [Kills 99.9% of] [Eliminates 99.9% of] [Removes] [Destroys] avian influenza A (H5N1) virus on pre-cleaned hard non-porous environmental surfaces

Formulation HWS-64 [Kills 99.9% of] [Eliminates 99.9% of] [Removes] [Destroys] (*Insert pathogen or pathogens from lists on pages 7 and 8*) on [pre-cleaned] hard non-porous environmental surfaces

Formulation HWS-64 [Kills 99.9% of] [Eliminates 99.9% of] [Removes] [Destroys] [Germs] [Bacteria] [Viruses*] [on [pre-cleaned] hard non-porous environmental surfaces]

Formulation HWS-64 is a sanitizer for hard nonporous non-food contact surfaces] according to the method for Sanitizers - Non-Food Contact Surfaces, modified in the presence of 400 ppm hard water plus 5% organic serum in 60 seconds against:

Klebsiella aerogenes Staphylococcus aureus

Formulation HWS-64 is effective against:

- Enterobacter cloacae NDM-1 positive
- Escherichia coli NDM-1 positive
- Klebsiella pneumoniae NDM-1 positive

[AREAS OF USE:] Use Formulation HWS-64 in:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}

- Bathrooms Homes [households] Kitchens
- Clinics Dental offices Health Care Facilities Hospitals Medical Offices Medical Related Facilities Nursing homes Sick Rooms

Day care centers Nurseries

Bars

- Cafeterias Convenience stores Food processing plants Food storage areas Institutional kitchens Restaurants USDA inspected food processing facilities
- Athletic facilities Barber shops Business and office buildings Colleges Correctional facilities Dressing rooms Exercise facilities Factories Hotels Institutional facilities Institutions Locker rooms Morgues Mortuaries

Motels Prisons Public facilities Public rest rooms Schools Shower and bath areas Salons [Beauty] Spas Tanning Salons Tattoo Parlors Universities

Camp grounds Play ground equipment

Animal laboratories Dairy farms Farms Hog Farms Kennels Poultry farms Pet animal quarters Pet shops Turkey farms Zoos Airplanes Airports Ambulances **Boats Buses** Campers Cars Emergency [Police] [EMS] [Fire] [Rescue] vehicles Mobile homes Ships Taxis Trailers Trains Transportation terminals Trucks [Box Trucks]

[TYPES OF SURFACES:]

Use **Formulation HWS-64** on washable hard, nonporous surfaces of: {Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal, or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

Appliances, exteriors of Bathroom fixtures Bathtubs [Fiberglass] Cabinets Cages Chairs Coils and drain pans of air conditioning and refrigeration equipment and heat pumps ⁹ Conductive flooring Counters [countertops] Counters [countertops] Countertop laminates Desks Doorknobs Floors Garbage cans Highchairs Kennel runs Microwave ovens, exteriors of Outdoor furniture except cushions and wood frames Refrigerators, exteriors of ⁹ Refrigerated storage and display equipment ⁹ Telephones Other hard nonporous surfaces made of: Glazed ceramic Glazed enameled surfaces Glazed porcelain Laminated Surfaces Metal	Sealed granite Sealed limestone Sealed marble Sealed slate Sealed stone Sealed terra cotta Sealed terrazzo Stainless steel Upholstery, vinyl and plastic Woodwork, finished Non-critical medical device surfaces: Beds [Medical] [Hospital] Bed frames Bed rails Crutches Defibrillators Gurneys Non-critical [hospital] [medical] equipment surfaces [Medical] Examining tables [Medical] [Hospital] Lamps [Medical] [Hospital] Scales Resuscitators Stands Stretchers Stethoscopes Walkers
Plastic [such as polystyrene or polypropylene]	Wheel chairs

Formulation HWS-64 is effective at eliminating odors on porous surfaces such as drapes, carpets, bedding, shower curtains and non-porous surfaces such as walls and floors. Excellent for fire restoration.

Other suggested Uses: Homes, Veterinary Clinics, Fish Markets, Kennels, Trash Compactors, Offices, Beauty Salons, Locker Rooms, Health Spas, Conference rooms, Elevators, Smoking Areas, Lounges, Day Care Centers, Dry Cleaners, Theaters, Farms, Auditoriums and Churches.

Effective against the following pathogens:

[Bacteria:] Pseudomonas aeruginosa² Staphylococcus aureus² Salmonella enterica Acinetobacter baumannii Acinetobacter calcoaceticus Bordetella bronchiseptica Chlamydia psittaci Enterobacter cloacae Enterobacter cloacae - NDM-1 Enterococcus faecalis - Vancomycin Resistant [VRE] Escherichia coli² Escherichia coli - NDM-1 Fusobacterium necrophorum Klebsiella aerogenes Klebsiella pneumoniae² Klebsiella pneumoniae - NDM-1 Legionella pneumophila Listeria monocytogenes Pasteurella multocida Proteus mirabilis Proteus vulgaris Salmonella enteritidis Salmonella typhi Serratia marcescens Shigella flexneri Shigella sonnei Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300] Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400] Staphylococcus aureus - Methicillin resistant - [MRSA] Staphylococcus aureus - Vancomycin Intermediate Resistant - [VISA] Staphylococcus epidermidis³ Streptococcus faecalis² Streptococcus pyogenes [Strep]

[Fungi:] Aspergillus niger Candida albicans Trichophyton interdigitale [Athlete's Foot Fungus] [may cause Ringworm] [may cause Ringworm of the foot]] [Viruses:] *Adenovirus Type 7 - at 8 oz. per gallon {Note for Reviewer: 8 oz. per gallon dilution disinfection directions must be used if Adenovirus Type 7 is listed on the label} *Hepatitis B Virus [HBV] *Hepatitis C Virus [HCV] *Herpes Simplex Virus Type 1 *Herpes Simplex Virus Type 2 *Human coronavirus *HIV-1 [AIDS virus] *Influenza A Virus {Note to supplemental registrant: if one of the following pathogens with ** are used must include statement "in association with the organism Influenza A Virus"} [Influenza Virus** associated with Influenza] [Flu Virus** associated with the flu] [**in association with the organism Influenza A] *Respiratory Syncytial Virus [RSV] *Rotavirus [WA] *Rubella virus *SARS Associated Coronavirus [SARS] [may cause Severe Acute Respiratory Syndrome] *SARS-Related Coronavirus 2 [SARS-CoV-2] [may cause COVID-19] *Vaccinia virus [Animal viruses:] *Avian Influenza virus (H5N1) *Avian polyomavirus *Canine distemper virus *Feline leukemia virus *Feline picornavirus *Infectious bovine rhinotracheitis virus *Infectious bronchitis virus [Avian IBV] *Newcastle Disease virus *Pseudorabies virus [PRV] *Rabies virus

*Transmissible gastroenteritis virus [TGE]

{Note to Reviewer: These statements for claims against enveloped emerging viral pathogens shall not appear on marketed (final print) product labels.} EMERGING VIRAL PATHOGENS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

- Enveloped Viruses

For an emerging viral	follow the direction for use for the following
pathogen that is a/an	organisms on the label:
Enveloped virus	Adenovirus type 7 ATCC VR-7

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **non-porous surfaces**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Adenovirus type 7**, **ATCC VR-7** on **hard**, **non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging virus]. [Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Adenovirus type 7, ATCC VR-7** on **hard, non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

DISINFECTION		
DILUTION: 1:64	2 ounces per gallon of water	
[660 ppm quat]	4 ounces per 2 gallons of water	
	8 ounces per 4 gallons of water	
	10 ounces per 5 gallons of water	
	12 ounces per 6 gallons of water	
SANITIZATION		
DILUTION: 1:64	2 ounces per gallon of water	
[660 ppm quat]	4 ounces per 2 gallons of water	
	8 ounces per 4 gallons of water	
	10 ounces per 5 gallons of water	
	12 ounces per 6 gallons of water	

DIRECTIONS FOR USE

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

[To [remove] [insert] [the] [dispenser system name] container place hand securely under the container, slide release lever to the right and pull the container out]

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must 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 pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection. *{or}*

This product is not for use on medical device surfaces.

DISINFECTION / CLEANING / DEODORIZING DIRECTIONS: Remove visible soil deposits from surface, then visibly wet surface with a use-solution of 2 ounces of the concentrate per gallon of water. [Use 8 oz per gallon of water to kill Adenovirus Type 7]. The use-solution can be applied with a cloth, mop, sponge, or coarse spray or by soaking. 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. Let solution remain visibly wet on surface for a minimum of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished. *[Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:]* [For SARS-CoV-2, treated surfaces⁸ must remain visibly wet for 1 minute.]

{Note for reviewer: One of the following statements must be used:}

Food contact surfaces must be thoroughly rinsed with potable water. This product must not be used to clean the following food contact surfaces: utensils, glassware and dishes.

{or}

This product is not for use on food contact surfaces.

For Human Coronavirus, treated surfaces must remain visibly wet for 1 minute. Wipe dry with a clean cloth, sponge or mop or allow to air dry.

For Influenza Virus Type A, treated surfaces must remain visibly wet for 2 minutes. Wipe dry with a clean cloth, sponge or mop or allow to air dry.

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

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that **Formulation HWS-64**, when diluted in 200 ppm hard water [via use of automatic dispensing devices], remains effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella enterica for [up to 7 days] [for up to one week] [for up to one month] [for up to 2 months] [for up to 3 months] [up to 4 months] [up to 5 months] [up to 6 months] [up to 7 months] [up to 8 months] [up to 9 months] [up to 10 months] [up to 11 months] [up to 12 months] [up to one year] when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

{or}

Prepare a fresh use-solution daily or more often if the solution becomes visibly dirty or diluted.

TOILET BOWLS [/ URINALS]: Swab bowl with brush to remove visible soil prior to cleaning or disinfecting. Clean by applying use-solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first preclean to remove visible soil, then remove or expel over the inner trap the residual bowl water. Pour in three ounces of the diluted solution. Allow surface to remain visibly wet for a contact time of 10 minutes, then flush.

FUNGICIDAL DIRECTIONS:

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

MILDEWSTATIC INSTRUCTIONS: Will effectively control the growth of mold and mildew, plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors and table tops. Apply use-solution of 2 ounces per gallon of water with a cloth, mop, sponge or coarse spray. Make sure to visibly wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

To control the growth of mold and mildew on large inflatable non-porous plastic and rubber structures [animals, promotional items, moonwalks, obstacle course play and exercise equipment]: Visibly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 2 ounces per gallon of water with a cloth, mop, sponge, or coarse spray. Make sure to visibly wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears. Ventilate buildings and enclosed spaces. Do not use equipment until treatment has been absorbed, set or dried.

CLEANING AND DISINFECTING HARD NONPOROUS SURFACES ON PERSONAL PROTECTIVE EQUIPMENT [RESPIRATORS]:

Preclean equipment if visibly soiled to ensure proper surface contact. Add 2 oz. of **Formulation HWS-64** to one gallon of water. [Use 8 oz. per gallon of water to kill Adenovirus Type 7]. Gently mix for a uniform solution. Apply solution to hard, nonporous surfaces of the respirator with a brush, coarse spray device, sponge, or by immersion. Visibly wet all surfaces to be disinfected. Treated surfaces must remain visibly wet for 10 minutes. Remove excess solution from equipment prior to storage. Comply with all OSHA regulations for cleaning respiratory protection equipment (29 CFR §1910.134).

*KILLS HIV-1 [AIDS VIRUS] AND HBV [HEPATITIS B VIRUS] AND HCV [HEPATITIS C VIRUS] ON PRECLEANED, HARD NON-POROUS ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type I [HIV-1] [associated with AIDS] or Hepatitis B Virus [HBV] or Hepatitis C Virus [HCV].

Special Instructions for Disinfection, Cleaning and Decontamination against HIV-1 [AIDS Virus] or HBV or HCV on Surfaces / Objects Soiled with Blood / Body Fluids:

Personal Protection: Disposable protective gloves, gowns, face masks and eye coverings, [as appropriate,] must be worn during all cleaning of blood / body fluids and during decontamination procedures. **Cleaning Procedures**: Blood / body fluids must be visibly cleaned from surfaces / objects before application of disinfectant.

Contact Time: Mix 2 oz. of **Formulation HWS-64** per gallon of water [or equivalent dilution]. HIV-1 [AIDS virus] is inactivated after a contact time of 4 minutes at 25°C [77°F] [room temperature]. HBV and HCV are inactivated after a 10 minute contact time. Use appropriate contact time as listed on label for all other viruses[,] [and] bacteria [and fungi] claimed.

Disposal of Infectious Materials: Blood / body fluids must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

[DISINFECTANT] [FOR] [NAIL] [MANICURE] SALON [BARBER] [SHOPS] [TANNING SALONS] [HAIR SALONS] [TATTOO PARLORS] [HEALTH CLUBS] [SPA SURFACES] INSTRUMENTS AND TOOLS DISINFECTION [BACTERICIDE] / * VIRUCIDE / FUNGICIDE DIRECTIONS:

Mix 2 oz. of **Formulation HWS-64** per gallon of water [or equivalent dilution] to disinfect hard, nonporous instruments and tools. [Use 8 oz. per gallon of water to kill Adenovirus Type 7]. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For visibly soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled. **Note:** Plastics may [can] remain immersed until ready to use. 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.

DISINFECTION OF HARD, NON-POROUS SURFACES IN FOOTBATHS

To remove body oils, dead tissue, soil and all other buildups or organic matter on inanimate surfaces after using the footbath, drain the water and visibly clean all hard, non-porous surfaces with soap or detergent, then rinse with water. Saturate surfaces with a use solution of 2 oz. per gallon of water [or equivalent use dilution] to exposed surfaces with a cloth, mop, sponge or sprayer. [Use 8 oz. per gallon of water to kill Adenovirus Type 7]. For spray applications, use a coarse spray device. Do not breathe spray. Allow surface to remain visibly wet for 10 minutes. After the unit has been thoroughly disinfected, rinse all surfaces with fresh water. Do not use equipment until treatment has been absorbed, set or dried.

CLEANSING OF BODY SURFACES AND BODY ORIFICES OF HUMAN REMAINS: This product removes body secretions, soil, and blood, along with their accompanying malodor, from the surfaces and orifices of human remains. Using a sponge or washcloth, bathe the entire body with a use-solution of 2 ounces per gallon of water. [Use 8 oz. per gallon of water to kill Adenovirus Type 7]. A soft handbrush may be employed on surfaces other than the face. Use fresh solution for each [cadaver] remains or when solution becomes visibly dirty or diluted.

FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT

DILUTION: 1:64 2 ounces per gallon of water

[Use 8 oz. per gallon of water to kill Adenovirus Type 7].

- 1. Remove all animals and feeds from premises, trucks, coops, crates and enclosures.
- 2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, and other facilities and fixtures occupied or traversed by animals.
- 3. Empty all troughs, racks, and other feeding and watering appliances.
- 4. Visibly clean all surfaces with soap or detergent, then rinse with water.
- 5. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure.
- 6. Saturate all hard non-porous surfaces with the disinfecting solution. Allow surfaces to remain visibly wet for a period of 10 minutes.
- 7. Ventilate buildings, coops, cars, trucks, boats and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
- 8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, then rinse with potable water before reuse.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Visibly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. of **Formulation HWS-64** per gallon of water [or equivalent dilution]. Allow surfaces to remain visibly wet for a period of 10 minutes. [Use 8 oz. per gallon of water to kill Adenovirus Type 7]. Immerse all animal handling and restraining equipment as well as forks, shovels and scrapers used to remove litter and manure. Wipe or allow to air dry. Ventilate buildings and other closed spaces. Thoroughly scrub all treated surfaces that come into contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FOR HEAVY DUTY CLEANING AND / OR ODOR CONTROL: When greater cleaning is desired, use 4 - 8 oz. of **Formulation HWS-64** per gallon of water. Visibly soiled areas may require repeated cleaning before treatment.

CITRUS CANKER DISEASE CONTROL

For prevention of Citrus Canker Disease through treatment of equipment. Effective against Xanthomonas axonopodis pv. citri [Citrus Canker Disease] at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, and field equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous equipment taken into infested areas.

Visibly wet surfaces with a 1:21 use-dilution [24¼ oz. per 4 gallons of deionized water] [or equivalent dilution] [2000 ppm active quat]. Allow surfaces to remain visibly wet for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Thoroughly rinse or launder clothing before reuse. Rinse footwear before reuse.

TO SANITIZE NON-FOOD CONTACT HARD NON-POROUS SURFACES:

[Add] [mix] 2 oz. of **Formulation HWS-64** per gallon of water to sanitize hard nonporous surfaces. Treated surfaces must remain visibly wet for 60 seconds. Wipe dry with a sponge, mop, or cloth or allow to air dry. Do not use in food preparation, food handling and food storage areas. This product is not to be used on glassware, dishware, cookware or utensils.

TO SANITIZE BARBER [SHOP] / SALON [TANNING SALON] [HEALTH CLUB] [SPA SURFACES]

INSTRUMENTS [EQUIPMENT] AND TOOLS: {Not For Use in California} Immerse precleaned [barber / salon] instruments, [and] tools] [or personal protective equipment] such as combs, brushes, [rollers], razors, scissors, blades and manicure instruments [eye protection] in a use-solution [dilution] of 2 oz. of [this product] **Formulation HWS-64** per gallon of water [or equivalent dilution] for at least [60 seconds] [one minute]. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if [the use] solution becomes visibly diluted, cloudy or soiled.

NOTE: Plastics may remain immersed until ready to use. 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.

SANITIZATION OF [WHIRLPOOL [BATH[S] [UNITS]]:

After using the [whirlpool [unit] [bath]], drain and refill with fresh water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet]. Add 2 oz. of **Formulation HWS-64** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the sides, [[deck,] [seat of chair lift,] [any related equipment,]] and any uncovered hard non-porous surfaces on the [bath] [unit] with a clean swab, brush or sponge. Treated surfaces must remain visibly wet for at least [60 seconds] [one minute]. After the [unit] [bath] has been thoroughly sanitized, drain the solution from the [unit] [bath]. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for visibly soiled units.

Deodorizing directions:

Nursing Homes, Hospitals, Hotels, Schools, Restaurants: Using 2 oz. in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals, commodes and air conditioner pans will eliminate odors.

Mopping Solutions, Automatic Scrubbers: Use 2 oz. per gallon of cleaning solution to eliminate undesirable odors.

Laundry: 2 oz. per load added during the final rinse cycle deodorizes all offensive odors.

Air Freshener/Automotive Uses: 8 oz. per gallon of water will effectively neutralize damp musty odors caused by mildew in storage areas, basements, closets and bathrooms. Effective on smoking and cooking odors [garlic, fish, onions, etc.]. Automobile odors from tobacco, musty carpet smell and beverage smells will be eliminated.

Carpets: 2 oz. per gallon of shampoo solution eliminates odors associated with urine, vomit, smoke, and mildew. Reapply after cleaning for freshening effects. Allow to dry.

RV Holding Tanks: Toilet waste: cover bottom of holding tank with water and add 2 oz. If odors return before time to empty, simply add 2 oz. to the tank. Kitchen waste: 2 oz. of **Formulation HWS-64** to gray water tank as needed to control malodors created by dirty dish water.

Pet Odors: Use 8 - 12 oz. per gallon of water for urine, feces, and vomit, in carpet and upholstery. Clean prior to application then spray onto affected areas. Test hidden area for colorfastness. Allow to remain visibly wet for a contact time of 10 minutes. Then blot with clean cloth. Allow to dry. Also effective on pet bedding and litter boxes.

Sewage Backup, Water, Smoke Damage: Use 2 - 4 oz. per gallon of water. Spray over affected areas before and after cleaning and extraction. Allow to remain visibly wet for a contact time of ten minutes. Use proper ventilation; open windows.

Cleaning Solution: Dilute 2 oz. per gallon of water for cleaning of kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications.

{This whole page is Not for Use in California}

WATER, SMOKE DAMAGE RESTORATION AGAINST ODOR-CAUSING BACTERIA AND FUNGI FOR HOME, INSTITUTIONAL¹⁰, AND INDUSTRIAL USE:

This product is particularly suitable for use in water damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushions, subfloors, drywall, concrete, brick, trim and frame lumber, tackless strip and paneling. Using appropriate dilution, saturate the affected materials with enough product to remain visibly wet for at least 10 minutes.

Sewer Backup and River Flooding: During mitigation procedures, dilute 2 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove visible filth or visible soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction. Allow areas to remain visibly wet for a contact time of 10 minutes.

Carpets, Carpet Cushions and Other Porous Materials such as Subfloors, Drywall, Concrete, Brick, Trim and Frame Lumber, Tackless Strip and Paneling: For water damage from a clean source, extract excess water. Test hidden area for colorfastness. Dilute 2 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove visible filth or visible soil. Saturate all affected areas with a coarse spray device. Roll, brush or agitate into the materials and allow materials to remain visibly wet for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table C3 of the Label Review Manual's statements about burning are labeled as "Not required;" therefore, no incineration language is provided for plastic containers.}

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 Handling: {For containers >5 gallons or 50 lbs net weight}

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. 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: For Nonrefillable Sealed Containers: Packaging options can be in sealed containers or bottles designed for use dilution systems 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 Handling: {For containers < 5 gallons}:

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

{Note to reviewer: For Refillable Containers – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table C3 of the Label Review Manual's statements about burning are labeled as "Not required;" therefore, no incineration language is provided for plastic containers.}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

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 Handling: {Refillable containers, all sizes}

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container.

(Plastic or Metal Containers:) To clean the container before 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, and dispose of rinsate consistent with pesticide disposal instructions. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill. 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.

²ATCC & antibiotic-resistant strain

³antibiotic-resistant strain only

⁴ Pseudomonas aeruginosa

⁵ Staphylococcus aureus

Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300] Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]

Staphylococcus aureus - Methicillin resistant [MRSA]

Staphylococcus aureus - Vancomycin Intermediate Resistant [VISA]

Staphylococcus epidermidis

⁶ Salmonella enterica

⁷ When used according to disinfection directions.

⁸ hard, non-porous surfaces

⁹ surfaces must be brought to room temperature (approximately 20°C) before application of the product for disinfection

¹⁰ not for use in medical facilities

¹SARS-Related Coronavirus 2

{SECONDARY CONTAINER LABEL}

{Note to reviewer: This secondary container label will be used only when the product is diluted at 2 oz. per gallon of water or equivalent}

FORMULATION HWS-64

Active Ingredients:	
Didecyl dimethyl ammonium chloride	2.54%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chlo	ride1.69%
Inert Ingredients:	
Total:	

The product in this container is diluted as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN

DANGER

{**Note to Reviewer**: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the label.}

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Harmful if inhaled. Avoid breathing vapor or spray mist. Remove and wash contaminated clothing before reuse.

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

EPA Reg. No. 47371-131

This container is not for the sale or distribution of the diluted product.

ADDITIONAL LABELING / INSERTS / REFERENCE SHEETS

{Note to reviewer: If additional labeling / insert / reference sheets are used, the following statements may appear on the additional labeling /insert / reference sheet:}

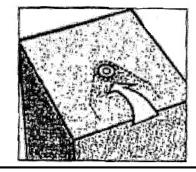
- Product name
- EPA Reg. No.
- Direction for use; It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- Read the label affixed to the container for [this product] [product name] before applying.
- Use of [this product] [product name] according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for [product name].

{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/tear along perforation.
- 4. Retrieve fitting on bag.
- 5. Remove clear dust-cap from bag fitting.
- Twist dispanser connector onto bag fitting.
- Place bag-in-box into position on dispenser shelf.
- 8. Close dispensor (If applicable).



INSTRUCTIONES PARA ABRIR

- 1. Ponge la caje can la perforación hecia arriba.
- 2. Empuje el creulo hecla adentro.
- Levente le pessone arrancandola de la caja a lo largo de la perforación.
- Saque el adaptedor que este en la bolse.
 Guite la tapa transparente contra el polyo
- que tierre el sospisión de la bolsa. 6. Enrosque el conectador despaciador al
- e. Encoque el conscient despacifique al adaptador.
- Ponya la "bag-its-box" (botsa en caja) en posición en el mostrador de despacho.
- 6. Cierre al despaciador (si corresponda),

{Note to reviewer. The following may be used only if the supplemental registrant has obtained UL Classification.}



FLOOR COATING AND FINISHING MATERIAL AS TO SLIP RESISTANCE ONLY (Control No.)

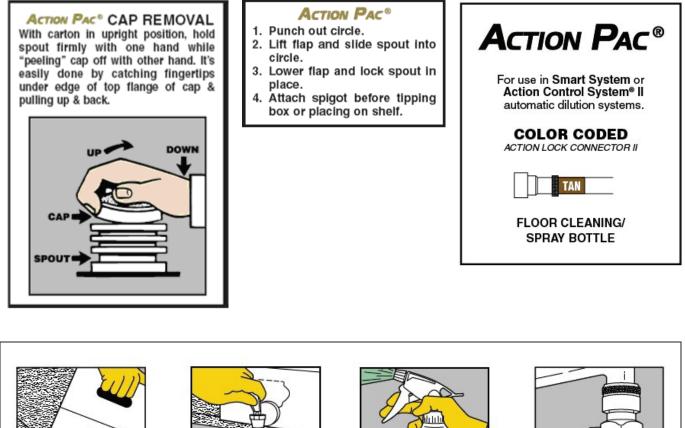
{Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.}

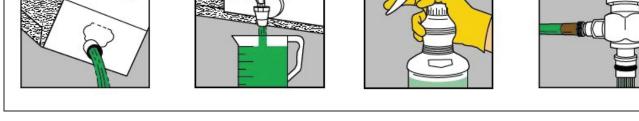


{Any Kosher Symbol such as:} [Kosher]

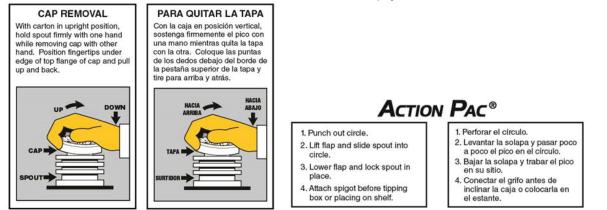
THE FOLLOWING SECTIONS CONTAIN PROPRIETARY LANGUAGE AND GRAPHICS.

LANGUAGE AND GRAPHICS IN THE FOLLOWING SECTIONS CAN ONLY BE UTILIZED WITH LONZA APPROVAL AND BY THE SUPPLEMENTAL REGISTRANTS APPROVED FOR ITS USE. {Note to reviewer: Optional proprietary graphics} {Section 1}





THIS END UP TO ATTACH Quick-Draw® SPIGOT Note: Do not remove liner from Action Pac® until empty.



{Note to reviewer: Optional proprietary graphics} {Section 2}



{Note to reviewer: Optional proprietary graphics} {Section 3}













{Note to reviewer: Optional proprietary graphics} {Section 4}





Formulation HWS-64 EPA Reg. No. 47371-131 EPA Notification 2018-07-09 EPA Submission 2020-11-06