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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 1 4 2008

Ms. April Zasmbelli-Weiner Sterilex Corporation 11409 Cronhill Drive Suite L Owings Mills, MD 21117

Subject:

Sterilex Ultra Powder

EPA Registration No.: 63761-5

Amendment Date: November 6, 2007 EPA Receipt Date November 11, 2007

Dear Ms. Weiner,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

• One-Step Disinfection Claim

Conditions

Revise the label as follows:

- 1) Since a protocol and data were not sent to support a biofilm claim on hard nonporous surfaces, you must revise the 3rd bullet on page 1 to read "Kills biofilm bacteria in dental unit water lines."
- 2) Revise the nomenclature for Salmonella choleraesuis (ATCC 10708) to reflect the new designation of "Salmonella enterica."
- 3) Revise the "Barber and Salon Instruments and Tools" directions on page 6 by qualifying rollers as hard nonporous by stating "plastic" rollers. Also, revise step 5 by deleting "should" and stating "must" so that the directions are incompliance with PR Notice 2000-5, Mandatory Labeling.
- 4) Revise the "Precleaning Whirlpool Bathtubs" directions to by stating:

After using the whirlpool unit, drain and refill with fresh water to just cover the intake valve. Add 50 g Ultra Powder per Liter of hot tap water. Briefly start the pump to circulate the solution. Turn off

	the pump.	Wash down the sides, seat of the charge any all related equipment with a sponge of						
SYMBOL							4	
SURNAME							·	
DATE		,		·				

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brush. Drain solution from the unit and rinse cleaned surfaces and equipment with fresh water.

Acceptable Data

Data Requirement	Means of Support	Status
AOAC Use Dilution Method–S. aureus, P. aeruginosa, S. enterica	MRID No. 472803-01	Acceptable, 50 gm in 1L of water for 10 min in 5% soil and 400 ppm
		hard water

General Comments

The Confidential Statement of Formula dated November 2, 2007 is acceptable. It is incompliance with PR Notice 91-2 and in agreement with the label.

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosures: Stamped Label

Efficacy Data Evaluation Concurrences

SYMBOL SURNAME DATE

Sterilex Ultra Powder

Think Pink Once A Week®

- Removes* biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Kille biefilm besterie
- Maintains dental unit water line effluent water <500 cfu/ml
 - * Laboratory studies have shown >90% removal

KEEP OUT OF THE REACH OF CHILDREN

DANGER

(See back panel for additional precautionary and first aid statements)

STERILEX CORPORATION
Owings Mills, MD 21117
Phone: 1-800-511-1659 Fax: 410-581-8864
www.sterilex.com

EPA Reg. No. 63761-5 EPA Est. No. 21737-MN-01

Net Contents:

RCCEPTED

With COMMENTS

in EPA Letter Dated:

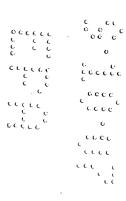
JUL 1 4 2008

Finder the Federal Insecticide,

Pungicide, and Rodonticide Act as

registered under EPA Rec. 50 6.3761-5

registered under EPA Rec. 50



AMENDED LABEL PAGE 2 - REVISES MASTER LABEL Lated 08/12/



DIRECTIONS FOR USE

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

TREATMENT OF DENTAL UNIT WATER LINES

Important Notice:

Before using Sterilex Ultra please read the following information.

- 1. This product is to be used in conjunction with regular testing of dental unit water.
- 2. The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra with the dental unit.
- 1. Initial Start-Up Treatment: Treat the Dental Unit Water Lines (DUWL) for three consecutive nights.
- 2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Startup treatment.

How To Apply Sterilex Ultra Powder:

- 1.At the end of the workday, add eight (8) ounces of HOT water to a Sterilex measuring cup or other empty container.
- 2.Add one packet of Sterilex Ultra to the hot water. Use stirrer to mix or swirl to dissolve. Be sure all powder is dissolved. Pour pink liquid into an empty external dental unit water bottle. Do not use PET Bottles (See note for bottle requirements). Use within 24 hours after powder has been dissolved in water.
- 3.Run Sterilex Ultra mixture through the system until the pink mixture appears at the end of the AW Syringe and Handpiece Line. Always remove the Handpiece.
- 4. Allow the mixture to sit in the unit overnight (Place the ends of waterlines into a sink or cuspidor in case any pink mixture drips overnight).
- 5. At the beginning of the next workday, discard any remaining mixture in external water bottle. Rinse the external water bottle with hot water.
- 6. Fill the external water bottle with hot water. Flush each line (A/W Syringe, Handpiece) until the bottle is empty.

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PETE) Bottles. We Recommend Either A High Density Polyethylene Bottle With A Minimum Thickness Of 0.08 Inches Or A High/Low Density Polyethylene Blend With A Minimum Thickness Of 0.14 Inches.

DISINEFCTION of HARD NON-POROUS SURFACES

One-Step Disinfectant - Cleaner

Staphylocidal - Pseudomonacidal - Salmonellacidal

Sterilex Ultra Powder is a hospital-use disinfectant at 50 grams per liter, Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum against:

(Bacteria:)

Pseudomonas aeruginosa (Pseudomonas)(ATCC# 15442) Staphylococcus aureus (Staph)(ATCC# 6538) Salmonella ehelerastato (Salmonella)(ATCC# 10708)

Sterilex Ultra Powder is for use on washable hard, nonporous surfaces in: hospitals, medical and dental offices, nursing homes, health care facilities, ultrasonic baths (ultrasonic cleaning units); federally inspected food processing facilities, federally inspected meat and poultry plants, wineries, breweries, beverage manufacturing facilities, dairy farms, swine farms, poultry and turkey farms, farm premises,

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hatcheries, refrigerated trucks, kennels, pet animal quarters, zoos, pet shops, animal laboratories, veterinary facilities, animal care facilities, transportation terminals, hotels and motels, factories, business and office buildings, barber shops, salons, boats, ships, campers, trailers, mobile homes, homes, kitchens, bathrooms, household areas, cars, buses, trains, taxis, airplanes, restaurants, bars, cafeterias, institutional kitchens, food preparation and storage areas, convenience stores, food storage areas, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, and exercise equipment.

Sterilex Ultra Powder is for use on the following washable hard, nonporous surfaces:

Medical machines (x-ray, MRIs, CAT scanners), noncritical medical devices and equipment surfaces (that do not penetrate the body or contact the human bloodstream or mucous membranes);

Steam sterilizer water reservoirs, steam sterilizer water reservoir tubing;

Water reservoir tanks, water reservoir pipes, tanks, and piping systems used in food processing;

Floors, walls, countertops, stovetops, sinks, appliances, refrigerators, plastic and other nonporous cutting boards and chopping blocks; coolers, ice chests; non residential refrigerator bins for meat, fruit, vegetable and egg; food processing equipment (k-pac equipment, injectors, slicers, knives, steel mesh gloves, deboners, saws, grinders, cutters, racks, dairy equipment, interlocking belts, outside surfaces of kitchen equipment, beer fermentation and holding tanks, brewery pasteurizers, wine fermentation tanks, beverage dispensing equipment, beverage transfer lines, bottling or premix dispensing equipment);

Drinking water coolers, ice making machines, transfer line tubing, water lines, watering systems, farm animal nipple drinkers;

Cabinets, highchairs, garbage cans, garbage storage areas, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, tubs and glazed tiles, whirlpool bathtubs, bathtubs, sinks, urinals, exterior toilet bowl surfaces, other bathroom fixtures;

Kennel runs, cages, waterers and feeders, automatic feeders, hauling equipment, dressing plants, loading equipment, farrowing barns and related areas (nursery blocks, creep areas), chutes, feed racks, mangers, troughs, fountains and waterers, forks, shovels, scrapers, barns, pens, stalls, facilities and fixtures occupied or traversed by animals, hatchery areas (egg receiving and holding, setter room, tray dumping, chick holding, processing and loading), trays, buggies, racks, egg flats, poultry buildings, ceilings, sidewalls and floors, drinkers and other poultry house related equipment;

Coils and drain pans of air conditioning and refrigeration equipment and heat pumps, conductive flooring;

Nonporous salon/barber tools and instruments (combs, brushes, scissors, blades, pedicure and manicure instruments, pedicure and manicure tubs);

Hard nonporous surfaces, listed on this label, that are made of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, hard fiberglass, plastic (such as polystyrene, polypropylene), glazed porcelain tiling, enameled surfaces, finished/sealed and painted woodwork, finished floors, Formica®, vinyl and plastic upholstery.

DISINFECTION IN HOSPITALS, MEDICAL OFFICES, DENTAL OFFICES, DENTAL OPERATORIES, NURSING HOMES AND OTHER HUMAN HEALTH CARE FACILITIES:

NOTE:

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 medical devices prior to sterilization or high-level disinfection.

APPLICATION INSTRUCTIONS:

- 1) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir. Be sure all powder is dissolved.
- 2) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Allow surfaces to remain wet for at least 10 minutes
- 4) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1 25 g of Sterilex Ultra Powder to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Rinse all surfaces thoroughly with a potable water rinse.

INSTRUMENT PRE-SOAK:

For use as an instrument pre-soak, prepare a solution by adding 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir. Immerse instruments completely and allow to soak for 10 minutes. Rinse all surfaces thoroughly with a potable water rinse. Instruments must undergo high-level disinfection or sterilization following pre-soak treatment.

DISINFECTION IN ULTRASONIC BATHS:

NOTE:

Use **Sterilex Ultra Powder** to disinfect hard nonporous non-critical objects compatible with Ultrasonic Cleaning Units.

APPLICATION INSTRUCTIONS:

- 1) Pre-clean heavily soiled objects following the PRECLEANING INSTRUCTIONS below.
- 2) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir.
- 3) Pour fresh use-solution directly into bath chamber.
- 4) Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions.
- 5) Remove objects and wash with sterile water (sterile water for injection) and allow to air dry.
- 6) Prepare fresh solution for each use.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1 25 g of Sterilex Ultra Powder to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross fifth to be precleaned.
- 2) Clean surfaces with precleaning solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, pumping it through the system, or drawing it through the system.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

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DISINFECTION OF FOOD PROCESSING EQUIPMENT AND HARD SURFACES IN FOOD PROCESSING FACILITIES, BREWERIES, WINERIES AND OTHER BEVERAGE MANUFACTURING FACILITIES, RESTAURANTS, BARS, CAFETERIAS, INSTITUTIONAL KITCHENS, CONVENIENCE STORES FOOD PREPARATION AREAS, FOOD STORAGE AREAS AND FOOD SERVICE AREAS:

NOTE:

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected. Follow all applicable local health and sanitation codes for sanitizing food processing equipment post-disinfection.

APPLICATION INSTRUCTIONS FOR SURFACES:

- 1) Remove gross food particles and soil from all articles using a pre-flush, or pre-scrape and, if necessary, presoak.
- 2) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir.
- 3) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 4) Allow surfaces to remain wet for at least 10 minutes
- 5) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1-25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

APPLICATION INSTRUCTIONS FOR TRANSFER LINES:

- 1) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir.
- 2) Introduce use solution into transfer lines and tanks.
- 3) Soak or circulate use solution for at least 10 minutes.
- 4) Drain transfer lines.
- 5) Rinse all surfaces thoroughly with a potable water rinse.

DISINFECTION OF VETERINARY FACILITIES, ANIMAL CARE FACILITIES, ANIMAL LABORATORIES, ZOOS, PET SHOPS, KENNELS AND ANIMAL QUARTERS, FARM AND DAIRY FARM PREMISES, POULTRY AND SWINE PREMISES, FARM AND DAIRY FARM PREMISE EQUIPMENT, POULTRY AND SWINE PREMISE EQUIPMENT AND HATCHERIES.

- 1) Remove all animals and feed from premises, vehicles, and enclosures.
- 2) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water or follow PRECLEANING INSTRUCTIONS below.
- 5) Saturate all surfaces with a solution prepared by adding 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stirring.
- 6) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. The use-solution can be used to disinfect hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces in

AMENDED LABEL PAGE 6 - REVISES MASTER LABED Lated 08/12/ 3



hatcheries. 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.

- 7) Allow surfaces to remain wet for at least 10 minutes
- 8) Rinse all surfaces thoroughly with a potable water rinse.
- 9) Ventilate buildings, cars, boats, and-other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
- 10) Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

APPLICATION INSTRUCTIONS FOR TRANSFER LINES:

- 1) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir.
- 2) Introduce use solution into transfer lines and tanks for watering systems and nipple drinkers.
- 3) Soak or circulate use solution for at least 10 minutes.
- 4) Drain transfer lines and tanks.
- 5) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1-25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

DISINFECTION IN REFRIGERATED TRUCKS AND OTHER VEHICLES, INSTITUTIONS, INDUSTRIAL FACILITIES, SCHOOLS, ATHLETIC FACILITIES, REST ROOMS, HOTELS, MOTELS, OFFICE BUILDINGS AND OTHER PUBLIC AREAS, AND HOUSEHOLDS:

APPLICATION INSTRUCTIONS:

- 1) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir.
- 2) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Clean all areas of vehicles, including mats, crates, cabs and wheels.
- 3) Allow surfaces to remain wet for at least 10 minutes.
- 4) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1-25 g of Sterilex Ultra Powder to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross fifth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

DISINFECTION OF SALON (BARBER) INSTRUMENTS AND TOOLS:

APPLICATION INSTRUCTIONS:

- 1) Add 50 g of Sterilex Ultra Powder to 1 liter tap water in an appropriate plastic container and stir.
- 2) Completely immerse combs, brushes, rollers, manicure and other hard, nonporous salon instruments and tools for 10 minutes.
- 3) Allow surfaces to remain wet for at least 10 minutes.



- 4) Rinse all thoroughly with potable water and dry before use.
- 5) Fresh solution should be prepared daily or more often if solution becomes diluted 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.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning heavily soiled instruments and tools may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1-25 g of Sterilex Ultra Powder to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging or immersing.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

PRE-CLEANING OF WHIRLPOOL BATHTUBS:

Circulate a solution of 6.5 oz of Sterilex Ultra Disinfectant Clooper Solution found 0.5 canof Sterilex Ultra Activator Solution per 1 gel top mater through tub and associated piping and filters at a temperature 90°F.

PRECAUTIONARY STATEMENTS

Hazard To Humans And Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Wear protective eyewear (goggles and/or face shield), protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

WHEN POWDER IS DILUTED: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid breathing vapor. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. 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. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin, or if these are not available, drink large quantities of water. Avoid alcohol.

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 further treatment advice.



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

STORAGE AND DISPOSAL

STORAGE: Keep out of children's reach. Store at room temperature out of direct sunlight, DO NOT

store about 30°C (or 86°F).

DISPOSAL: Do not reuse empty pouch, discard in trash.

Made in USA