

6836-204

4-18-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

APR 18 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Certified Mail

Bob Sloan
Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: EPA Reg. No. 6836-204 "Lonza Formulation DC-110N"
Addition of HBV Claim
Amendment Date: April 9, 2001

Dear Mr. Robinson

The amendment reference above, submitted in connection with registration under FIFRA section 3(c)(7)(A) to add a Hepatitis B Virus (HBV) claim to the label is acceptable. Your amendment was originally unacceptable due to outstanding 6(a)(2) issues. Lonza has submitted all the Agency's requirements needed to rectify the outstanding adverse effects. (See Agency letter referring to Failed 6(a)(2) dated April 2003).

The submitted data in MRID No.452657-01 demonstrated that Lonza Formulation DC-110N diluted 1:200 in 400ppm water and added on two glass carriers carrying Duck Hepatitis B Virus (DHBV) for a 10 minute contact time at 20° ± 2° proved to be virucidal against DHBV. The actual science review is attached for your records as well as a stamped label.

If you have any questions regarding this letter, please contact me at (703) 308-6427 or Velma Noble, Product Manager 31 on 703-308-6233.

Sincerely,

ShaRon V. Carlisle
6(a)(2) Coordinator
Antimicrobials Division/RMB II (7510C)

cc: Velma Noble, PM31
Connie B. Welch, AD

CONCURRENCES

SYMBOL	SURNAME	DATE					
RM	SCARLISLE	4/17/02					

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves when handling. May be fatal if swallowed. 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 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.

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

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

(Note to Reviewer: If the 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.

**LONZA FORMULATION
DC-110N**

Disinfectant - Cleaner - Sanitizer - Fungicide -
Mildewstat - Virucide* - Deodorizer
for Hospitals, Institutional and Industrial Use

Effective in hard water up to 400 ppm hardness (Calculated as CaCO₃) in the presence of 5% serum contamination

Fresh / Clean / Lemon / Pine / Mint / Floral / Citrus
(scent) (fragrance) (scented) (odor)

Formulated for effective poultry premise sanitation
Formulated for effective swine premise sanitation

Active Ingredient:	
Didecyl dimethyl ammonium chloride	3.85%
Inert Ingredients:	96.15%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

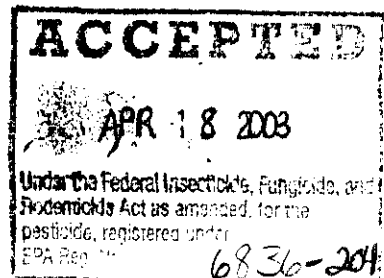
DANGER

PELIGRO

See (side) (left) (right) (back) panel for Precautionary Statements and First Aid.

EPA Reg. No. 6836-204
EPA Est. No. *(as noted on the container)*
Net Contents *(as noted on the container)*

Manufactured by:
LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410



Cross-contamination is of major housekeeping concern not only in hospitals, but also in schools, institutions and industry. **LONZA FORMULATION DC-110N** has been formulated to aid in the reduction of cross-contamination from treated surfaces in these areas.

LONZA FORMULATION DC-110N a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1 and HBV), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION DC-110N is an effective one-step sanitizer-cleaner for use on non-food, contact surfaces.

When used as directed, **LONZA FORMULATION DC-110N** will deodorize surfaces in restrooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

LONZA FORMULATION DC-110N is an effective fungicide against *Trichophyton mentagrophytes* (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

Use **LONZA FORMULATION DC-110N** in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels. For use in households. This product contains no phosphorous.

LONZA FORMULATION DC-110N is a no-rinse neutral pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA FORMULATION DC-110N can be used with a mop and bucket, trigger sprayers, sponge or by soaking.

LONZA FORMULATION DC-110N provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to re-coat.

LONZA FORMULATION DC-110N improves labor results by effectively controlling odors.

LONZA FORMULATION DC-110N cleans, shines, deodorizes and disinfects hard, nonporous household surfaces. Inhibits the growth mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.

Use **LONZA FORMULATION DC-110N** for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use **LONZA FORMULATION DC-110N** in kitchens, bathrooms and other household areas.

LONZA FORMULATION DC-110N kills household germs; effective against *Pseudomonas aeruginosa* (*Pseudomonas*), *Staphylococcus aureus* (*Staph*) and *Streptococcus pyogenes* (*Strep*), *Influenza A/PR* and *Trichophyton mentagrophytes* (*Athlete's foot fungus*).

LONZA FORMULATION DC-110N is a neutral pH multi-surface cleaner, deodorizer and disinfectant. Use on windows, mirrors and other glass surfaces.

Use **LONZA FORMULATION DC-110N** on the multi-touch surfaces responsible for cross-contamination.

Use **LONZA FORMULATION DC-110N** on finished floors, high speed burnished floors, conductive flooring, washable walls, tables, chairs, bathroom bowls, sinks, basins, shower stalls, tubs, tiles, toilets, countertops, stove tops, appliances, refrigerators, cabinets, garbage cans, tables, outdoor furniture, chairs, desks, telephones, door knobs and handles, and glass surfaces including windows and mirrors.

LONZA FORMULATION DC-110N is recommended for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area	Tray Dumping Area	Chick Processing Area
Egg Holding Area	Chick Holding Room	Chick Loading Area
Setter Room	Hatchery Room	Poultry Buildings

LONZA FORMULATION DC-110N is recommended for Swine Premise Sanitation:

Farrowing Barns & Areas	Dressing Plants	Blocks
Waterers and Feeders	Loading Equipment	Creep Area
Hauling Equipment	Nursery	Chutes

LONZA FORMULATION DC-110N is a Hospital Disinfectant at 2 oz. per gallon (16 mL per liter, 1:64 dilution), modified in the presence of 250 ppm hard water, and at 3 oz. per gallon (24 mL per liter, 1:42 dilution), modified in the presence of 400 ppm hard water.

LONZA FORMULATION DC-110N is Bactericidal according to the AOAC Use-Dilution Test method, Virucidal* according to the virucidal qualification on hard, inanimate surfaces, Fungicidal according to the AOAC fungicidal test, modified in the presence of 5% organic serum against:

- | | |
|---------------------------------------|----------------------------|
| Pseudomonas aeruginosa | Proteus vulgaris |
| Salmonella choleraesuis | Salmonella schottmuelleri |
| Staphylococcus aureus | Salmonella typhi |
| Acinetobacter baumannii | Salmonella typhimurium |
| Brevibacterium ammoniagenes | Serratia marcescens |
| Chlamydia psittaci | Shigella dysenteriae |
| Enterobacter aerogenes | Shigella flexneri |
| Enterobacter cloacae | Shigella sonnei |
| Enterococcus (Streptococcus) faecalis | Staphylococcus epidermidis |
| Escherichia coli | Streptococcus pyogenes |
| Klebsiella pneumoniae | |

- Escherichia coli - Methicillin resistant
- Enterococcus faecalis - Vancomycin-resistant (VRE)
- Enterococcus (Streptococcus) faecalis-Methicillin-resistant
- Klebsiella pneumoniae - Methicillin resistant
- Staphylococcus aureus - Methicillin resistant (MRSA)
- Staphylococcus aureus - Vancomycin Intermediate Resistant (VISA)

- Aspergillus niger
- Candida albicans
- Trichophyton mentagrophytes

- *Hepatitis B Virus
- *Herpes Simplex Type 1
- *Herpes Simplex Type 2
- *HIV-1 (AIDS virus)
- *Influenza A/PR
- *Rubella
- *Vaccinia

LONZA FORMULATION DC-110N is a sanitizer for hard, nonporous, non-food, contact surfaces at 2 - 3 oz. per gallon (16 - 24 mL per liter) against:

- | | |
|------------------------|-----------------------|
| Enterobacter aerogenes | Staphylococcus aureus |
|------------------------|-----------------------|

DIRECTIONS FOR USE:

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

(Note to 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 medical devices prior to sterilization or high-level disinfection.

(or)

This product is not for use on medical device surfaces.

Preparation of use-solution:

For water hardness up to 250 ppm, add 2 oz. per gallon (16 mL per liter) of water (1:64).

For water hardness up to 400 ppm, add 3 oz. per gallon (24 mL per liter) of water (1:42).

For heavy duty use, add 8 oz. per gallon (64 mL per liter) of water (1:16).

(Note to reviewer: The following Preparation of Use Solution is to be used with the closed spray bottle system and small cartridge containing concentrate [cartridge label and Preparation of use appears on pages 6 & 7 of this master label.] 0.37 fl. oz. per 24 oz. is equivalent to 2 oz per gallon)

For water hardness up to 250 ppm, add 0.37 fl. oz. (11 mL) of Lonza Formulation DC-110N in 24 fl. oz. of water.

DISINFECTION / VIRUCIDAL / FUNGICIDAL DIRECTIONS:

Apply use-solution to hard, nonporous surfaces thoroughly wetting surfaces with a cloth, mop, sponge or sprayer.

Treated surfaces must remain wet for 10 minutes (2 minutes for disinfection against all viruses claimed except HBV). Wipe dry with a clean cloth or sponge or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray.

Prepare a fresh solution daily or more often if use solution becomes diluted or soiled.

Rinse all surfaces that come in contact with food, such as countertops, appliances, tables and stovetops, with potable water before reuse. Do not use on utensils, glassware and dishes.

MOLD AND MILDEW CONTROL DIRECTIONS:

To control the growth of mold and mildew and their odors on hard, nonporous surfaces, apply use-solution to thoroughly wet all treated surfaces completely. Let air dry. Repeat application weekly or more often if growth or odor reappears.

***KILLS HIV AND HBV ON PRECLEANED 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 or body fluids and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal protection: Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

Cleaning* procedure: Blood and other body fluids containing HIV or HBV must be thoroughly cleaned from surfaces and objects before application of Lonza Formulation DC-110N.

Contact time:

For HIV-1: Use 2 oz. of Lonza Formulation DC-110N per gallon of water (16 mL per liter). Leave surfaces wet for 2 minutes.

For HBV: Use 3 oz. of Lonza Formulation DC-110N per gallon of water (24 mL per liter). Leave surfaces wet for 10 minutes.

For disinfection against all other bacteria and fungi claimed: Use a 10-minute contact time

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:

From concentrate:

Add 2 - 3 oz. (60 - 90 mL) to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim. Allow to stand for 10 minutes and flush.

From use-solution:

Empty toilet bowl or urinal and apply 2 - 3 oz. per gallon (16 - 24 mL per liter) use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Allow to stand for 10 minutes and flush.

For Heavy-duty use:

Empty toilet bowl or urinal and apply 8 oz. per gallon (64 mL per liter) use-solution to exposed surfaces, including under the rim with a cloth, mop, sponge or sprayer. Allow to stand for 10 minutes and flush.

GLASS CLEANING / DEODORIZING DIRECTIONS:

Add 1 - 4 oz. per gallon of water (8 - 32 mL per liter) to clean and deodorize windows, mirrors and glass surfaces.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with sponge or cloth. Do not breathe spray.

DIRECTIONS FOR FOOD PROCESSING PLANTS:

For use on non-food, contact surfaces such as floors, walls, tables, garbage cans and disposal areas. Follow disinfection directions.

DIRECTIONS FOR FOOD STORAGE AREAS:

For use on non-food, contact surfaces such as shelves, floors, walls and tables: Before using this product, food products and packaging materials must be removed from the room or carefully protected. Then follow disinfection directions.

DIRECTIONS FOR RESTAURANTS, CAFETERIAS, BARS:

Rinse all surfaces which come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use this product to disinfect utensils, glassware and dishes.

DIRECTIONS FOR SANITIZING NON-FOOD, CONTACT SURFACES:

Add 2 - 3 oz. per gallon of water (16 - 24 mL per liter), to sanitize hard, nonporous, environmental surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

**POULTRY AND SWINE PREMISE SANITATION
SITE PREPARATION:**

The first step in any on-going sanitation program should be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, disinfection can be accomplished in one easy step.

CLEANING:

For all general cleaning, use 2 - 3 oz. of **LONZA FORMULATION DC-110N** per gallon of water. Apply use-solution with a cloth, mop or pressure sprayer so as to thoroughly wet surfaces. Wipe dry with a clean cloth or sponge or allow to air dry.

DISINFECTION:

Remove all animals and feeds from premises, trucks, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 2 - 3 oz. of **LONZA FORMULATION DC-110N** per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. 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. Wipe dry with a clean cloth or sponge or allow to air dry. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

HATCHERIES: Use 2 - 3 oz. of **LONZA FORMULATION DC-110N** per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

VEHICLES: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and **LONZA FORMULATION DC-110N**. Use 2 - 3 oz. per gallon to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

SHOE BATH SANITIZER DIRECTIONS: Shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a 2 - 3 oz. per gallon of water solution for 60 seconds prior to entering the area. Change the solution in the bath daily or more often if the solution appears diluted or soiled.

DRESSING PLANT DISINFECTANT DIRECTIONS:

Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the recommended use solution of 2 oz. per gallon. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water. Wipe dry with a clean cloth or sponge or allow to air dry.

SANITIZING HATCHERY ROOMS USING FOGGING DEVICES

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix four parts **LONZA FORMULATION DC-110N** to five parts water (2 gallons of **LONZA FORMULATION DC-110N** to 2.5 gallons water). Insert the nozzle of the fogger through a suitable opening into the room. With the setting in maximum output, fog for one minute for each 4000 cubic feet of space in the room. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried.

SANITIZING INCUBATORS AND HATCHERS USING FOGGING DEVICES

Mix 24 oz. **LONZA FORMULATION DC-110N** to 122 oz. water. Fog 3 - 8 oz. of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatcher treatments at least 24 hours prior to pulling the hatch. Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed). It is acceptable to fog setters and hatchers with a 2 - 3 oz. per gallon solution of **LONZA FORMULATION DC-110N** on an hourly or every other hour basis. If this is done, fog for 30 - 90 seconds once per hour or once every two hours. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

NOTE: The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTING OR ROOM AND MACHINE SURFACES.

(If container size is one gallon or less, use the following Storage and Disposal statements:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Wrap and discard in trash or recycle.

(If container size is greater than one gallon, use the following Storage and Disposal statements:)

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 or mixture of 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

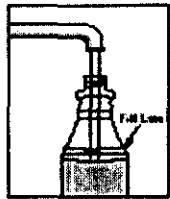
Do not reuse empty container.

(Plastic containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Metal containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

(Note to reviewer: The following Preparation of Use Solution is to be used with the closed spray bottle system, which consists of a small cartridge containing the concentrate. This information will appear on the outside of the box containing the cartridges)

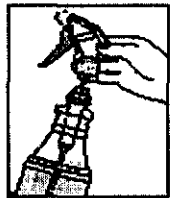
Preparation of Use Solution



1. Fill Lonza Formulation DC-110N work bottle to indicator line with tap water. (24 fl. oz.)



2. Insert Lonza Formulation DC-110N cartridge into the neck of the bottle.



3. Place the sprayer on the bottle by sliding the dip tube through the center of the cartridge.



4. Twist spray head securely onto the work bottle.

(Note to reviewer: Below is the cartridge label for the concentrate used in the closed spray bottle system. There are a number of cartridges inside a box. The outside of the box contains label language found on pages 1 through 6.)

LONZA FORMULATION DC-110N

Didecyl dimethyl ammonium chloride3.85%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

For additional information, see outer carton.

DISPOSAL: Wrap cartridge and discard in trash.

EPA Reg. No. 6836-204
Net Contents: 0.37 fl. oz (11 mL)