

PM31

5367-7

1/4

12 APR 1985.

Larson Laboratories, Inc.
1320 Irwin Drive
Erie, PA 16505

Attn: Arthur Z. Berenstein

Subject: STERIL-IZE
EPA Reg. No. 5367-7
Submission dated April 1, 1985

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable subject to the comments listed below.

Clarify whether you intend to have an alternate formulation for your product or you intend to change your basic formulation.

Submit a revised Confidential Statement of Formula and clarify which ingredients are in Glutaraldehyde solution and which are in the activator.

Based on your revised Confidential Statement of Formula you should declare 2.7% Glutaraldehyde.

Submit certification of limits the upper and lower limits for the active and inert ingredients.

Submit storage and stability data for this formulation. Refer to enclosed protocol for storage and stability data.

2/61

For additional label and data requirements concerning your efficacy claims, see the enclosure titled Technical Support Section Efficacy Review II.

A stamped copy of the label is enclosed for your records.

Sincerely,

John H. Lee
Product Manager 31
Disinfectants Branch
Registration Division (TS-767C)

Enclosures

3/4
5367-7

ACCEPTED
with COMMENTS
by EPA Label Board

APR 12 1965

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
5367-7

one color - green

Aqueous Disinfecting and Sterilizing Solution

Steril-Ize

Bactericidal
Pseudomonacidal
Virucidal*
Fungicidal
Sporicidal
Tuberculocidal**

activated dialdehyde

- Rapid-Acting
- Rust-Inhibiting
- Non-Staining

ACTIVE INGREDIENT:

Glutaraldehyde 2.0%

INERT INGREDIENTS: 98.0%

100.0%

DIRECTIONS FOR USE

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

DIRECTIONS FOR ACTIVATING

To Prepare the activated stock solution for disinfection, add the contents of the attached vial to one gallon of the solution. The life of the activated unused stock solution is 14 days.

For use in Hospitals, Nursing Homes and Health Care facilities. For disinfection or sterilization of medical instruments, the items must be thoroughly cleaned, rinsed and rubbed with the full strength activated solution. Flush and fill clean instrument. Avoid entrapment of air bubbles.

DISINFECTION: Immerse item completely for 10 minutes.

STERILIZATION: Immerse item completely for 10 minutes. Using aseptic technique, remove item from the solution and place in sterile water. **THE ACTIVATED SOLUTION MAY BE USED FOR FOURTEEN (14) DAYS.**

*When used as directed for Disinfection, Steril-Ize™ kills pathogens such as Pseudomonas aeruginosa and Coxsackie B-1, B-3, Echo type 6, Adenovirus type 4, A2, Hong Kong, Vaccinia on surfaces of inanimate objects.

**When used as directed for Sterilization, Steril-Ize™ kills spores of Clostridium sporogenes, Bacillus subtilis and Mycobacterium tuberculosis.

DANGER

KEEP OUT OF REACH OF CHILDREN
SEE LEFT PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

Activation
Date

Expiration
Date



Manufactured by:
E.P.A. Reg. No. 5357-7
E.P.A. Est. No. 5357-Pa-1

Larson Laboratories, Inc.
Erie, Pennsylvania 16506

414
5367-7

Directions for use and activation must be followed:

Record Activation and Expiration dates on label.

Formulated for the Disinfection or Sterilization of:
Sharp Instruments - Thermometers Oral and Rectal - Metal and Rubber Objects -
Lensed Instruments - Plastic Objects.

The directions recommended for sterilization should be used for the treatment of respiratory therapy equipment, anesthesia equipment or for any other item where a tuberculocidal product is desired. **DO NOT IMMERSE LESS THAN 45 MINUTES FOR TUBERCULOSIS DISINFECTION.**

STORAGE AND DISPOSAL

STORE IN A COOL PLACE

PROHIBITIONS:

Do not contaminate water, food or feed by storage or disposal. Dumping is prohibited.
Do not reuse empty container.

PESTICIDE DISPOSAL:

Pesticide, spray mixture, or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL:

Triple rinse (or equivalent). Then offer for recycling or reconditioning or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities.

GENERAL:

Consult Federal, State or Local Disposal authorities for appropriate alternative procedures.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes burns. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. May be absorbed through skin. Wear goggles or face shield and rubber gloves when handling.

HARMFUL IF SWALLOWED: Avoid contact with food. Use in ventilated area.

STATEMENT OF PRACTICAL TREATMENT

EYES - In case of eye contact, immediately flush with water and seek prompt medical attention.

SKIN - In case of skin contact, immediately flush thoroughly with water.

INGESTION - If swallowed, drink milk, egg whites, gelatin solution or, if these are not available, large quantities of water. Avoid alcohol. Call a physician.

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

Harm can be caused to carbon steel instruments immersed for over 24 hours. Steri-Ize™ Solution contains a rust inhibitor but will not inhibit rust caused by poor or damaged plating or improper care of instruments.

Net Contents: One Gallon (3.785 Liters)

ORDER NO. LLI-250

NSN 6840-00-926-9117



Aqueous Disinfectant

Steri-Ize

Bactericidal
Pseudomonacidal
Virucidal
Fungicidal
Sporicidal
Tuberculocidal

activate

- Rapid-Acting
- Rust-Inhibiting
- Non-Staining

DANGER



Manufactured by:
E.P.A. Reg. No. 5367-7
E.P.A. Est. No. 5367-Pa-1

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Submit certification of limits the upper and lower limits for the active and inert ingredients.

Submit storage and stability data for this formulation. Refer to enclosed protocol for storage and stability data.

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A stamped copy of the label is enclosed for your records.

Sincerely,

John H. Lee
Product Manager 31
Disinfectants Branch
Registration Division (TS-767C)

Enclosures

BEST AVAILABLE COPY

ACCEPTED
with 4025-1075
to EPA under 40 CFR

APR 10 1965

5367-7

ave color - green

Aqueous Disinfecting and Sterilizing Solution

Steril- Ize

Bactericidal
Pseudomonacidal
Virucidal*
Fungicidal
Sporicidal
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activated dialdehyde

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ACTIVE INGREDIENT

INERT INGREDIENTS

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product

DIRECTIONS FOR ACTIVATING

To Prepare the activated stock solution for disinfection, add the contents of the attached vial to one gallon of the liquid. The activated unused stock solution is 14 days. Use in Hospital, Nursing Homes and Health Centers for disinfection or sterilization of medical instruments. Items must be thoroughly cleaned, rinsed and dried before using activated solution. Flush and fill with water. Avoid entrapment of air bubbles.

DISINFECTION: Immerse item completely for 10 minutes.

STERILIZATION: Immerse item completely for 30 minutes. Using aseptic technique, remove item from the solution. **THE ACTIVATED SOLUTION MAY BE USED FOR FOURTEEN (14) DAYS.**

When used as directed for Disinfection, Sterilizes pathogens such as Pseudomonas aeruginosa, Coxsackie B-1, B-3, Echo type 6, Adenovirus A2, Hong Kong, Vaccinia on surfaces of inanimate objects.

When used as directed for Sterilization, Sterilizes spores of Clostridium sporogenes, Bacillus subtilis, Mycobacterium tuberculosis.

DANGER

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PRECAUTIONARY STATEMENTS

Activation
Date

Expiration
Date



Manufactured by:
EPA Reg. No. 5367-7
EPA Est. No. 5367-Pa-1

Larson Laboratories, Inc.
Erie, Pennsylvania 16501

BEST AVAILABLE COPY

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Formulated for the Disinfection or Sterilization of:
Sharp Instruments - Thermometers Oral and Rectal - Metal and Rubber Objects
Lensed Instruments - Plastic Objects.

The directions recommended for sterilization should be used for the treatment of respiratory therapy equipment, anesthesia equipment or for any other item where a tuberculocidal product is desired. DO NOT IMMERSE LESS THAN 10 MINUTES FOR TUBERCULOSIS DISINFECTION.

STORAGE AND DISPOSAL STORE IN A COOL PLACE PROHIBITIONS:

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

Do not reuse empty container.

PESTICIDE DISPOSAL:

Pesticide, spray mixture, or rinse water that cannot be used, according to label instructions must be disposed of according to Federal or applicable state procedures under Subtitle C of the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL:

Triple rinse (or equivalent). Then offer for recycling or reconditioning or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities.

GENERAL:

Consult Federal, state or local authorities for restricted use procedures.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes burns. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. May be absorbed through skin. Wear goggles or face shield and rubber gloves when handling.

HARMFUL IF SWALLOWED: Avoid contact with food. Use in ventilated area.

STATEMENT OF PRACTICAL TREATMENT

EYES: In case of eye contact, immediately flush with water and seek prompt medical attention.

SKIN: In case of skin contact, immediately flush thoroughly with water.

INGESTION: If swallowed, drink milk, egg whites, gelatin solution or, if these are not available, large quantities of water. Avoid alcohol. Call a physician.

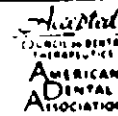
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