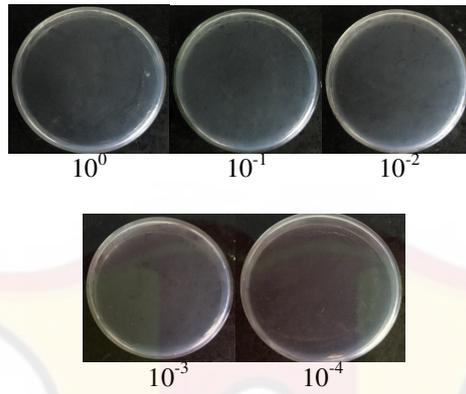
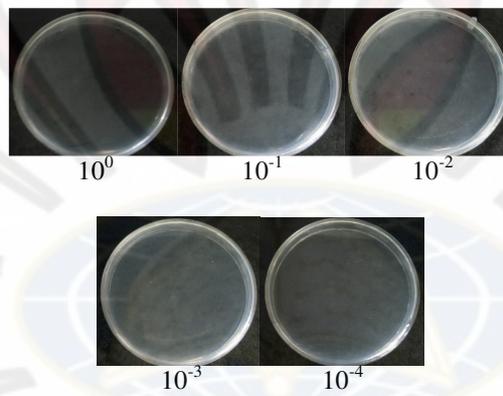


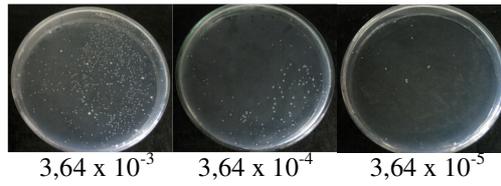
**LAMPIRAN A**  
**HASIL PENELITIAN**



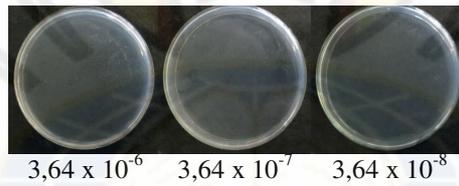
**Gambar L.A1.** Hasil pengujian kontrol negatif (pengenceran pertama)



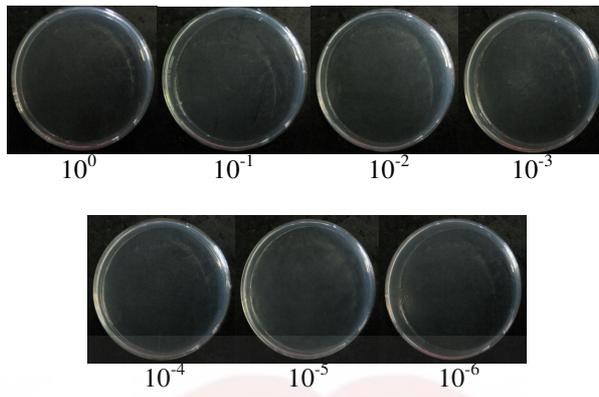
**Gambar L.A2.** Hasil pengujian kontrol negatif (pengenceran kedua)



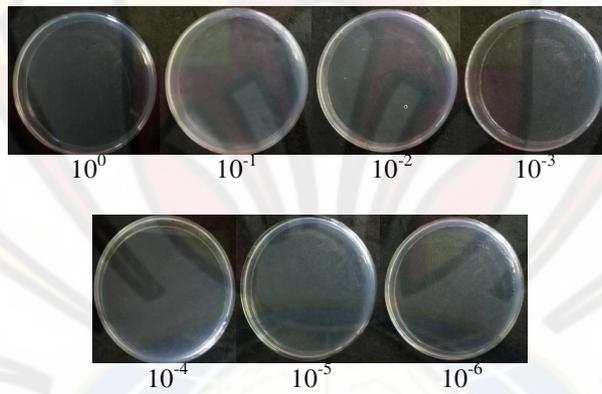
**Gambar L.A3.** Hasil pengujian kontrol positif (pengenceran pertama)



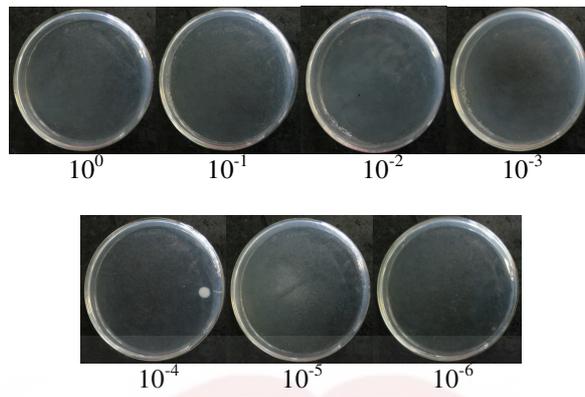
**Gambar L.A4.** Hasil pengujian kontrol positif (pengenceran kedua)



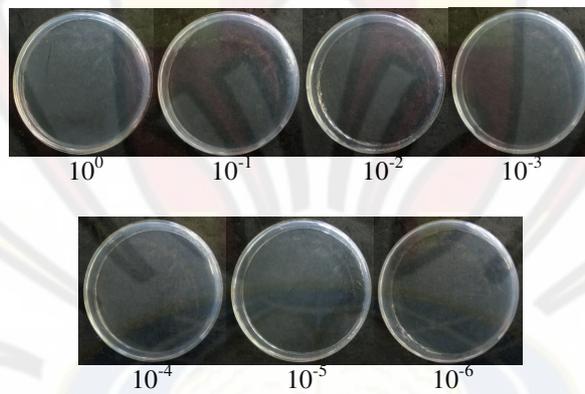
**Gambar L.A5.** Hasil pencucian dengan disinfektan (pengenceran pertama)



**Gambar L.A6.** Hasil pencucian dengan disinfektan (pengenceran kedua)



**Gambar L.A7.** Hasil pencucian dengan disinfektan dan deterjen enzimatik (pengenceran pertama)



**Gambar L.A8.** Hasil pencucian dengan disinfektan dan deterjen enzimatik (pengenceran kedua)

## LAMPIRAN B

### DISINFEKTAN

#### X\* High-Level Disinfectant Products

##### Basic Description & Why It's Important

###### X\* Activated Dialdehyde Solution

- ◆ A 2.4% alkaline glutaraldehyde solution with excellent tuberculocidal and high-level disinfection capabilities.
- ◆ Does not contain surfactants, so is compatible with lensed instruments such as flexible endoscopes.
- ◆ Reusable for 14 days (with proper verification of effective concentration); cost effective.

###### X PLUS\* 28 Day Solution

- ◆ A 3.4% alkaline glutaraldehyde solution with excellent tuberculocidal and high-level disinfection capabilities.
- ◆ Offers effective high-level disinfection: destroys 100% of *Mycobacterium tuberculosis* in 20 minutes at 25° C; can be used as sterilant for instruments for which other methods are not appropriate.
- ◆ Surfactant increases wetting properties for easier disinfection.
- ◆ 28 day reuse life (with proper verification of effective concentration) makes it the most cost effective high-level disinfectant available

## Common Features & Advantages

| Features   | Advantages  |
|--|---|
| Alkaline pH provides broad kill spectrum, accelerated kill time                  | ➤ Offers effective high-level disinfection; destroys all vegetative forms of bacteria as well as 100% of <i>Mycobacterium tuberculosis</i> in 45 minutes at 25 ° C (X* Activated Dialdehyde Solution) and 20 minutes at 25 ° C (X PLUS* 28 Day Solution); can be used as sterilant for instruments for which other methods are not appropriate. |
| Effective in the presence of 2% organic soil                                     | ➤ Offers enhanced margin of safety  |
| Excellent compatibility; alkaline pH   | ➤ Will not corrode instruments  |
| Test Strips offer easy method of measuring minimum effective concentration (MEC) | ➤ Ensures reliability of products during use life   |



**Efficacy of Disinfection**

- ◆ X\* Solutions were the first products to receive FDA 510 (k) clearance; clearance is based on a quantitative test of product's ability to kill 100% of *Mycobacterium tuberculosis* in a specified time. X\* Solutions are now the "reference" product for glutaraldehyde high-level disinfectants—the standard against which other products' efficacy claims are measured.
- ◆ Label Claims: for your reference, below are European label claims for X\* Activated Dialdehyde Solution (14 day) and for X\* Long Life 28 Day Solution. Review the label claims for specific X\* Solutions being sold in your local market (See table below).

**Safety**

- ◆ While glutaraldehyde can irritate skin and respiratory tracts, precautions can prevent any problems. In addition, even at concentrations in excess of the accepted 0.2 ppm threshold limit value for glutaraldehyde, no evidence of acute toxicity has been found.
- ◆ Glutaraldehyde is not listed as a carcinogen by any authority (e.g., OSHA, the International Agency for Research on Cancer, etc.)
- ◆ Studies to date have not shown glutaraldehyde to be a teratogen—i.e., it does not produce fetal abnormalities.
- ◆ ASP offers, via partner companies, ventilation hoods and monitoring devices to measure and reduce glutaraldehyde vapor odor and irritation below OSHA permissible exposure limit of 0.2 ppm.

**Cost Effectiveness**

- ◆ 14 and 28 day reuse life.
- ◆ In automated endoscope reprocessors, X\* Solutions cost @ US\$1.00/cycle, vs. \$5 dollars for Steris, a major competitor.

## Hospital Areas Using Product

- ◆ Hospital Central Supply/Sterilization (for a variety of instruments)
- ◆ GI Labs and Operating Rooms (Disinfection of endoscopes)
- ◆ Respiratory Therapy (disinfection of tubing, resuscitators, nebulizers)
- ◆ Physician/Dental Offices (disinfection of office equipment such as speculums, dental equipment, etc.)

## X\* Solutions : European Label Claims

|   | <b>X* 14 Day</b>      | <b>X* Long Life<br/>28 Day</b> |
|---|-----------------------|--------------------------------|
| Intermediate-level disinfection                   | 10 Mins. at 20-25 ° C | 10 Min. at 20-25 ° C           |
| High-level disinfection—TB                        | 20 Mins. at 20 ° C    | 60 Mins. at 25 ° C             |
| After known or suspected atypical I Mycobacterium | 90-120 Mins.          |                                |
| Sterilization/Sporicidal                          | 10 hours at 25 ° C    | 10 hours at 25 ° C             |

## Anticipated Objections and Concerns

- ◆ Glutaraldehyde exposure has irritating effect on staff's skin, respiratory tract.
- ◆ Is high-level disinfection the safest instrument processing method, given the rise of nosocomial infection and the increasing prevalence of minimally invasive surgery?
- ◆ Is glutaraldehyde less effective against pathogens like HIV and CJD?
- ◆ The X\* Solutions labels have changed in response to FDA rules about disinfectants. Have the Efficacy claims changed?
- ◆ Won't the surfactants in X PLUS\* 28 Day Solution damage flexible scopes?

## Competition

### **INTERNATIONAL**

- ◆ Maruishi
- ◆ Schulke & Mayr
- ◆ Local Competitors: efficacy claims and formulations vary by country and region. Local competitors can claim special knowledge of the local market and local relationships, and sometimes offer lower prices. However, local products often have acidic pH (with potential corrosion damage for instruments) or other formulation differences that make them less attractive. Further, few such competitors offer test strips to determine product MEC and efficacy. Also, local competitors seldom offer product support and inservicing.

### **UNITED STATES**

- ◆ M : low price; offers 14, 28 and 30 day reusable solutions. Does not use more rigorous quantitative TB test to substantiate efficacy claims; does not offer test strips to determine MEC of solutions in use. No endorsements from scope companies.
- ◆ B : private label M, offered in 14 and 28 day solutions. No endorsements from scope companies.
- ◆ WE : low price. Acidic pH, i.e., corrosive. No educational support.
- ◆ R & C : claims 30 minute TB kill at 20 degrees C. Acidic pH, i.e., corrosive. Test strips difficult to use. No educational support.
- ◆ S automated closed system, using S 20 Sterilant concentrate cartridges, whose active ingredient is peracetic acid. S claims system is efficacious as a sterilizer, but claim lacks peer review support. Lacks FDA approved biological indicator. Concentrate is single use solution. Cost is high: US\$5.00/cycle, vs. X\* Solutions' \$1.00.

## Inservicing Requirements

- ◆ Activation and proper use
- ◆ Test Strips and MEC
- ◆ 510(k) history; definition; label changes and efficacy claims
- ◆ Value Added programs:
  - Information Stations
  - Trays and Buckets
  - “Just the Facts” Newsletter
  - Ventilation Device
  - Assay Technologies Glutaraldehyde Monitor

## Primary Sales Aids

- ◆ X\* Family of Products (Product Brochure)
- ◆ X PLUS\* 28 Day Solution (Product Brochure)
- ◆ The Perfect Solution for Testing Our Solution (Test Strips Product Brochure)
- ◆ Locally offered Product Brochures

## LAMPIRAN C

### DETERJEN ENZIMATIK

#### Y\* Enzymatic Detergent

##### Basic Description & Why It's Important

Y\* (sold as Y\* in the U.S. market) Enzymatic Detergent

- ♦ A mild enzyme-based presoak-plus-cleaner designed to thoroughly clean instruments before they are disinfected or sterilized.
- ♦ Proteolytic enzyme action enhances the cleaning process by penetrating and lifting off tough, dried-on, hard-to-reach organic matter from endoscopic instruments and general equipment.
- ♦ Enzymatic detergents are recommended for scopes and other instruments by AORN, APIC, SGNA. Endoscopic procedures continue to grow in importance and frequency—84% growth (US) from 1987-93.

## Common Features & Advantages

| <b>Features</b>  | <b>Advantages</b>   |
|--|---|
| Proteolytic enzymes penetrate and break down protein, organic matter | <ul style="list-style-type: none"> <li>• Effective. Reduces the need for mechanical cleaning and health care worker exposure to contaminated equipment.</li> </ul>                  |
| Presoak-plus-cleaner   | <ul style="list-style-type: none"> <li>• One step process reduces the need for mechanical cleaning and unnecessary exposure to contaminated equipment</li> </ul>                    |
| Mild detergent, easy rinsing   | <ul style="list-style-type: none"> <li>• Mild pH means safety for delicate instruments, will not clog scopes or leave residue on instruments</li> </ul>                             |
| Results begin in one minute  | <ul style="list-style-type: none"> <li>• Fast action reduces instrument downtime, enhances efficiency</li> </ul>  |
| Low foaming  | <ul style="list-style-type: none"> <li>• Works in automated equipment such as endoscope reprocessors, ultrasonic cleaners and washer-sterilizers, washer-decontaminators</li> </ul> |
| Effective at room temperature  | <ul style="list-style-type: none"> <li>• Eliminates the need for hot water</li> </ul>   |
| Pump dispenses premeasured amounts                                   | <ul style="list-style-type: none"> <li>• Ease of use, helps ensure effective cleaning</li> </ul>  |
| Pleasant mint fragrance  | <ul style="list-style-type: none"> <li>• Pleasant smell masks odors from instruments</li> </ul>   |

**Efficacy of Cleaning**

- ♦ Y\* Detergent serves the needs of cleaning technicians and nurses for fast, effective precleaning, via its enzymatic formula and quick action
- ♦ Effective in removing dried soils without mechanical action, so can be used in areas such as lumens that are difficult or impossible to clean by other means

**Safety**

- ♦ Technicians, nurses and others are increasingly concerned about exposure to blood-borne pathogens (e.g., HIV) from contaminated instruments. Y\* Detergent reduces the need for manual cleaning, which reduces healthcare workers' unnecessary exposure to pathogens during cleaning phase.
- ♦ Mild pH and compatibility with a wide range of materials means that Y\* Detergent is safe for use with delicate instruments.

**Cost Effectiveness**

- ♦ Y\* Detergent serves the needs of Purchasing and other departments for cost effectiveness in several ways.
  - Y\* Detergent is relatively low in price, offering high value.
  - Y\* Detergent is compatible with automated washer-sterilizers/decontaminators, ultrasonic cleaning machines and automatic endoscope reprocessors. This enables a facility or department to buy in bulk and avoid purchasing multiple products.
  - Y\* Detergent's fast action saves instrument processing time, reduces inventory cost.

## Hospital Areas Using Product

- ◆ Hospital Central Supply/Sterilization (precleaning a variety of instruments)
- ◆ GI Labs and Operating Rooms (cleaning of endoscopes)
- ◆ Respiratory Therapy (pre-cleaning of tubing, resuscitators, nebulizers)
- ◆ Physician/Dental Offices (precleaning of office equipment such as speculums, dental equipment, etc.)
- ◆ Nursing homes (for a variety of instruments, surfaces)

## Anticipated Objections and Concerns

- ◆ Why use Y\* Detergent when E is market leader?
- ◆ Y\* Detergent does not claim to be bacteriostatic in solution form. Does this mean it is less effective/safe than other detergents?
- ◆ Concerns about enzymes:
  - Protease vs. amylase: which is more effective?
  - Are two protease enzymes better than one?
  - All enzymatic detergents contain surfactants. Are they safe with scopes?

## Inservicing Requirements

- ◆ Proper use, proper precleaning of instruments
- ◆ When and how to dispose of Y\* Detergent
- ◆ Manual dispensing systems

## Competition

### UNITED STATES

- ◆ R Corporation
  - E : market leader. Dual enzyme (protease and amylase). Bacteriostatic claim with in use solution. Enzyme activity low (<10% that of Y\* Detergent). Neutral pH (7±1)
  - P : single enzyme (protease). Very high cost in relation to Y\* Detergent. Enzyme activity low (<10% that of Y\* Detergent). Attacks aluminum. Alkaline pH (10-11).
- ◆ C-V (K): single enzyme (protease). Activity level matches that of Y\* Detergent. Similar price. Neutral pH (7±1)
- ◆ B (E-C): Dual enzyme (protease and amylase). Enzyme activity low (<10% that of Y\* Detergent). Neutral pH (7±1)
- ◆ M : dual enzyme (two proteases). Activity level matches that of Y\* Detergent. Higher price. Formulation is unstable—layers separate. Neutral pH (7±1).
- ◆ W E : single enzyme (protease). Enzyme activity low (<10% that of Y\* Detergent). Neutral pH (7±1).

### Primary Sales Aids

- ◆ X\* Family of Products (Y\* Product Brochure)
- ◆ Y\* Enzymatic Detergent (Data Sheet)
- ◆ Y\* Enzymatic Detergent (Product Brochure)

**ENZOL\* Enzymatic Detergent/  
CIDEZYME\* Enzymatic Detergent**

\*Trademark

| SECTION 2 – HAZARDOUS INGREDIENTS / IDENTITY INFORMATION |           |       |                        |                        |                |  |
|--|-----------|-------|------------------------|------------------------|----------------|--|
| COMPONENTS:  | CAS#      | %     | OSHA PEL               | ACGIH TLV              | OSHA 1910.1200 |  |
| Subtilisin   | 9014-01-1 | 1-10  | 1.08 ug/m <sup>3</sup> | 1.08 ug/m <sup>3</sup> | N/A            |  |
| Dodecylphenoethoxylate                                   | 9014-92-0 | 1-10  | N/A                    | N/A                    | N/A            |  |
| Sodium xylene sulfonate                                  | 1300-72-7 | 1-10  | N/A                    | N/A                    | N/A            |  |
| Propylene glycol   | 57-55-6   | 20-30 | N/A                    | N/A                    | N/A            |  |
| Water  | 7732-18-5 | 40-77 | N/A                    | N/A                    | N/A            |  |

| SECTION 1 – IDENTIFICATION   |   |
|--|---|
| <b>MANUFACTURER'S NAME AND ADDRESS:</b><br>ADVANCED STERILIZATION PRODUCTS<br>33 TECHNOLOGY DRIVE<br>IRVINE, CA 92618-2346<br><br><b>IDENTIFY:</b> Enzymatic Detergent<br><br><b>Product Code:</b> 2252, 2254, 2256, 2257<br>(CIDEZYME product codes 2251, 2258, 2260)<br><br><b>Trade Name:</b> ENZOL* Enzymatic Detergent/<br>CIDEZYME Enzymatic Detergent<br><br><b>SYNONYMS:</b> None<br><br><b>CHEMICAL FAMILY:</b> Enzymatic Detergents<br><br><b>RTECS#:</b> N/A<br><br><b>MOLECULAR FORMULA:</b> N/A<br><br><b>MOLECULAR WEIGHT:</b> N/A | <b>EMERGENCY TELEPHONE NUMBERS:</b><br>Chemtrec (800) 262-8200<br><br><b>TELEPHONE NUMBER FOR PRODUCT INFORMATION:</b><br>(800) 755-5900<br><br><b>Routes of Entry:</b><br>✓ Skin/eye<br>✓ Ingestion<br><br><b>Personal protection recommended:</b><br>• Rubber gloves<br>• Protective eye wear<br><br><b>HMS HAZARD RATINGS:</b><br>Health (Blue): 1<br>Reactivity (Yellow): 0<br>Flammability (Red): 0<br>Special Hazards: None |
| <b>SECTION 3 – PHYSICAL/CHEMICAL CHARACTERISTICS</b>   |   |
| <b>APPEARANCE AND ODOR:</b> Clear, violet liquid. Mint odor.   |   |
| <b>BOILING POINT:</b> > 212°F (>100°C)   | <b>SPECIFIC GRAVITY (75°F)</b><br>(H <sub>2</sub> O=1): 1.03g/cc  |
| <b>VAPOR PRESSURE:</b> N/D   | <b>MELTING POINT:</b> Not applicable  |
| <b>VAPOR DENSITY:</b> N/D  | <b>EVAPORATION RATE:</b><br>(H <sub>2</sub> O =1): N/D  |
| <b>SOLUBILITY IN WATER:</b> 100% (complete)  | <b>pH:</b> 6.0 – 8.0  |
| <b>FREEZING POINT:</b> 10°F (-12°C)  | <b>ODOR THRESHOLD:</b> N/A  |
| <b>SECTION 4 – FIRE AND EXPLOSION HAZARD DATA</b>  |   |
| <b>FLASH POINT (TEST METHOD USED):</b> None (TCC)  |   |
| <b>FLAMMABLE LIMITS IN AIR – LEL:</b> N/D <b>UEL:</b> N/D  |   |
| <b>EXTINGUISHING MEDIA:</b><br>As for surrounding fire. Use carbon dioxide or dry chemical for small fires. Use foam (alcohol, polymer, or ordinary) or water fog for  |   |

Page 1 of 3



**ENZOL\* Enzymatic Detergent/  
CIDEZYME\* Enzymatic Detergent**

\*Trademark

large fires.

**SPECIAL FIRE FIGHTING PROCEDURES:**

Self-contained breathing apparatus and protective clothing should be available to firemen.  
**UNUSUAL FIRE AND EXPLOSION HAZARDS:** None known.

**TOXIC GASES PRODUCED:** Carbon monoxide, carbon dioxide, sulfur oxides.

**SECTION 5 – REACTIVITY DATA**

**STABILITY:** Stable

**CONDITIONS TO AVOID:** Avoid temperatures above 104°F (40°C) and evaporation of water.

**INCOMPATIBILITY (MATERIALS TO AVOID):** Strong oxidizers.

**HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS:** None

**HAZARDOUS POLYMERIZATION:** Will not occur.

**SECTION 6 – HEALTH HAZARD DATA**

**ROUTE(S) OF ENTRY – INHALATION:** No    **SKIN:** Yes    **INGESTION:** Yes    **EYE:** Yes

**SIGNS AND SYMPTOMS OF SINGLE OR REPEATED OVEREXPOSURE:**

**EYES:** Contact with eyes causes irritation.

**SKIN:** Prolonged or repeated contact with skin may cause irritation or skin sensitization.

**INHALATION:** No adverse reaction expected.

**INGESTION:** May be harmful if swallowed.

**EMERGENCY AND FIRST AID PROCEDURE:**

**EYES:** Immediately flush eyes with water and continue washing for at least 15 minutes. Get medical attention.

**SKIN:** Flush with water and get medical attention if irritation occurs.

**INHALATION:** No adverse reaction expected.

**INGESTION:** Do not induce vomiting. Call physician or your local poison control center for most recent information.

**HEALTH HAZARDS (ACUTE AND CHRONIC):**

Acute, as listed under SIGNS AND SYMPTOMS OF SINGLE OR REPEATED EXPOSURE.

Chronic, none known from currently available information.

**MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:** None known from currently available information.

**LISTED CARCINOGENS:**

**NTP:** No    **IARC MONOGRAPHS:** No    **OSHA:** No    **California Proposition 65:** No

**TOXICITY:** ORAL LD50 (Rat).....N/D

OCCULAR (Rabbit).....N/D



MATERIAL SAFETY DATA SHEET

MSDS: 008  
EFFECTIVE:  
REVISION: C  
CO: 02600-6

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DERMAL LD50 (Rabbit).....N/D  
INHALATION LC50 (Rat).....N/D

**SECTION 7 – PRECAUTIONS FOR SAFE HANDLING AND USE**

**STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:**

For spills wipe with sponge or mop down area with water. Flush with large quantities of water.

**WASTE DISPOSAL METHOD:**

Discard solution with large quantities of water. Thoroughly rinse container before disposing in a waste receptacle for recycling in accordance with all federal, state, and local regulations.

EPA HAZARDOUS WASTE NUMBER: N/A

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING: Store at controlled room temperature (59-86 °F/15-30 °C).

**SECTION 8 – TRANSPORTATION DATA & ADDITIONAL INFORMATION**

|                              | <b>D.O.T</b> (ground) | <b>I.A.T.A</b> (air) | <b>I.M.O.</b> (ocean) |
|------------------------------|-----------------------|----------------------|-----------------------|
| <b>PROPER SHIPPING NAME:</b> | NOT REGULATED         | NOT RESTRICTED       | NOT REGULATED         |
| <b>HAZARD CLASS:</b>         | Enzymatic Detergent   | Enzymatic Detergent  | Enzymatic Detergent   |
| <b>LABELS:</b>               | None                  | None                 | None                  |
| <b>PACKAGING:</b>            | None Needed           | None Needed          | None Needed           |
| <b>ID#:</b>                  | None                  | None                 | None                  |
| <b>SPECIAL INSTRUCTIONS:</b> | None                  | None                 | None                  |
| <b>REPORTABLE QUANTITY:</b>  | None                  | None                 | None                  |

**SECTION 9 – CONTROL MEASURES**

**VENTILATION:**

**ROUTINE:** Use with standard room ventilation, air conditioning, or natural drafts.

**EMERGENCY:** Enhanced ventilation.

**RESPIRATORY PROTECTION:**

**ROUTINE:** None required.

**EMERGENCY:** N/A

**EYE PROTECTION:**

**ROUTINE:** Safety goggles

**EMERGENCY:** Safety goggles recommended.

**SKIN PROTECTION:**

**ROUTINE:** Rubber gloves recommended.

**EMERGENCY:** Rubber gloves.

**WORK/HYGIENIC PRACTICES:** Avoid contamination of food.

**SECTION 10 – SPECIAL REQUIREMENTS**

NONE

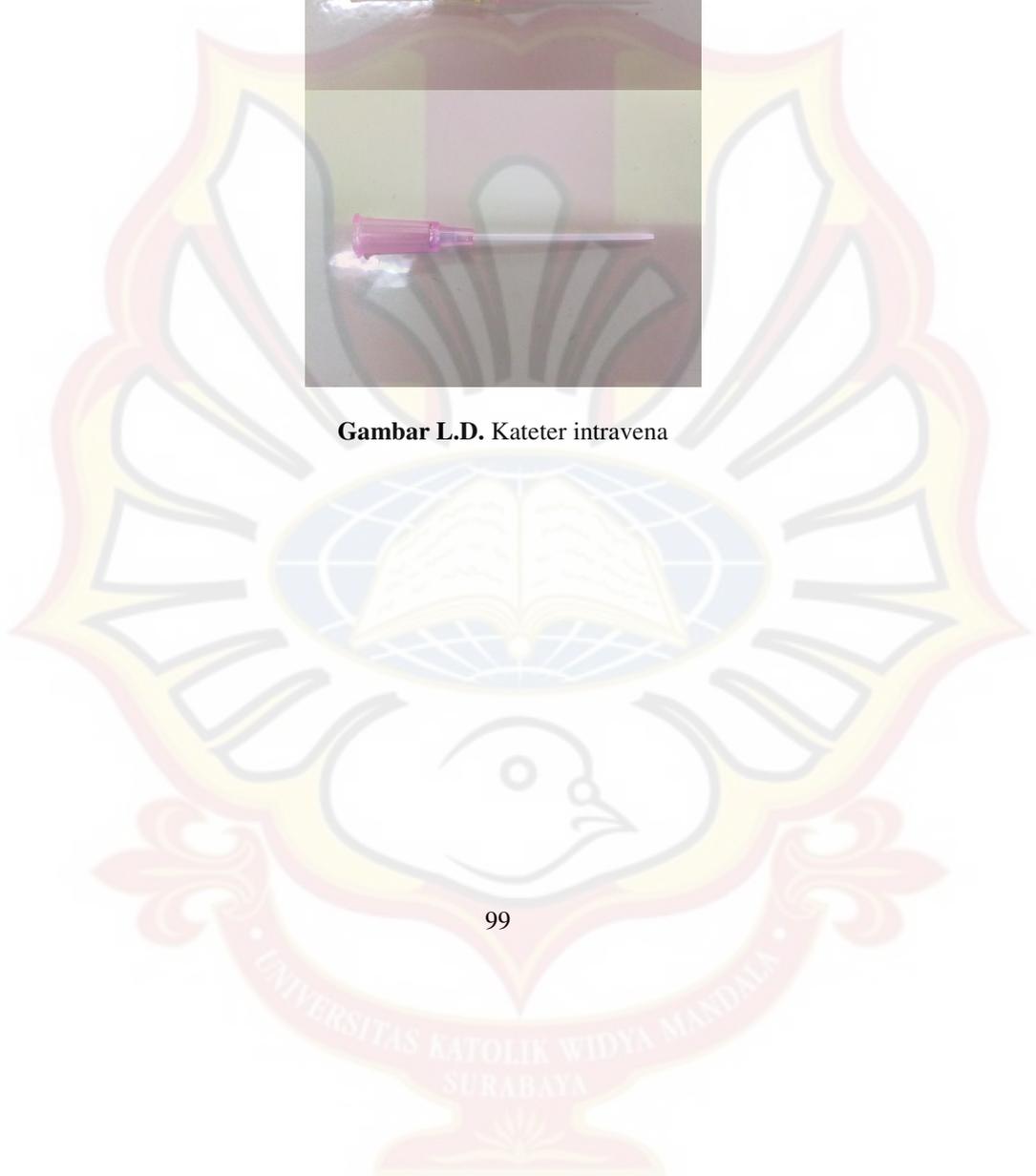
Key: N/A = Not Applicable    N/D = Not determined    C = Ceiling    PEL = Permissible Exposure Limit  
TLV = Threshold Limit Value    RTECS = Registry of Toxic Effects of Chemical Substances    TCC = Tag Closed Cup

We believe that the information contained herein is current as of the date this Material Safety Data Sheet. Since the use of this information and the conditions of the use of the product are not under the control of Advanced Sterilization Products, Inc., it is the user's obligation to determine conditions of safe use of the product. The data contained above are not to be taken as a warranty or

**LAMPIRAN D**  
**KATETER INTRAVENA**



**Gambar L.D.** Kateter intravena

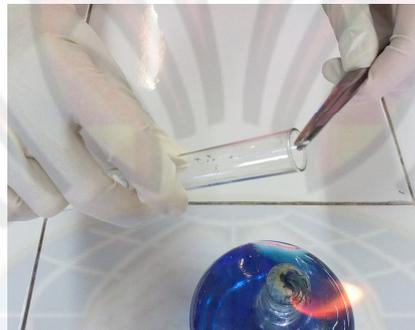


**LAMPIRAN E**  
**CARA MEMOTONG KATETER INTRAVENA**



(1)

(2)



(3)

**Gambar L.E1. Cara memotong kateter intravena**



**Gambar L.E2.** Kateter intravena yang telah dimasukkan dalam media

