

Getinge Assured

Titems Diagnostic Emulator

1.0 Product and Company Identification

Product Name Getinge Titems Diagnostic Emulator

Product Code 6005500400

Recommended Use For diagnostic use only. Not for normal consumer use. The Getinge

Titems Diagnostic Emulator is designed for use in steam sterilizers. Not intended for other sterilization methods. The Emulator gives visual confirmation of the attainment of sterilization conditions at

the location within the sterilizer chamber.

Supplier Getinge Sterility Assurance

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Supplier Australia: Getinge Australia Pty Ltd

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Supplier New Getinge Australia (NZ Branch)

Zealand: 600 Great South Road, Building B, Level 2

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Phone: 0800 1 438 464

Telephone No. For emergency event of spillage, inhalation or ingestion of products,

please contact the emergency hotline:

Australia: +61 280 144 558 New Zealand: +64 9 929 1484

Web http://www.getinge.com

Email info@getinge.com

2.0 Hazards Identification

This product is an "article" as defined by the OSHA Hazard Communication Standard (29 CFR 1910.1200), and the seventh revised edition of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and is not classified under EC Directives or Regulation. The professional and proper use of this product is not expected to result in exposures to any chemical substance at or above regulatory limits. For informational purposes, this SDS is being provided to convey valuable information to users of this product which are important for the safe handling and proper use of this product. The classifications reflect information for chemicals in this product, even though they are below regulatory limits. This SDS should be retained and be made available to users of this product.

GHS Classification:

Acute Toxicity (Oral), Category 4 Hazardous to Aquatic Life, Category 1

GHS Label Code(s):

H303, H400

Pictogram(s):



Signal Word(s): Warning

Hazard Statement(s):

H303 May be harmful if swallowed. H400 Very Toxic to Aquatic life

Precautionary Statement(s):

P264 - Wash hands thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

3.0 Composition / Information on

Ingredients

| Component | EC Number | CAS Number | Weight % | |
|--|------------------|-------------------|-----------------|--|
| Trade Secret 1 | Registered | Registered | < 1 | |
| Trade Secret 2 | Registered | Registered | < 0.1 | |
| Antimony Trioxide* | 1309-64-4 | 215-175-0 | < 0.1 | |
| Butyl Benzyl Phthalate** | 85-68-7 | 201-622-7 | < 0.1 | |
| Non-Hazardous Component | Not Applicable | Not Applicable | > 99.38 - 99.69 | |
| *Trace levels with carcinogenicity: IARC Category 2B | | | | |

^{*}Trace levels with carcinogenicity: IARC Category 2B

4.0 First Aid Measures

Treat symptomatically as described below.

Inhalation:

Breathing difficulty caused by inhalation of particulates requires removal to fresh air. If breathing has stopped, perform artificial respiration if qualified and trained and obtain medical assistance at once.

Ingestion:

Obtain medical advice regardless of the presence or absence of symptoms. Only induce vomiting if advised by a medical professional.

Skin:

Subcutaneous deposition through skin cuts and abrasions can be treated by standard first aid measures. Skin contamination through direct contact can be removed by washing with soap and water. If irritation persists, obtain medical assistance.

Eyes:

Material should be flushed from the eyes with copious amounts of clean water. If irritation persists, obtain medical assistance. DO NOT rub the eyes if particulate matter or foreign objects are present as corneal damage can occur.

5.0 Firefighting Measures

Suitable Extinguishing Media:

Use water, dry chemical, foam, or carbon dioxide to extinguish fire.

Fire Fighting Procedures:

Do not flush extinguishing water down sewers or other drainage systems. Exposed firefighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full-face mask and full protective clothing.

Unusual Fire and Explosion Hazards:

None Known.

Combustion Products:

Irritating or toxic substances may be emitted upon thermal decomposition including metallic oxides, and oxides of carbon and nitrogen.

^{**}Trace levels with Reproductive Toxicity: Category 1B

6.0 Accidental Release Measures

Personal Precautions, Protective Equipment And Emergency ProceduresFor Non-Emergency Personnel:

Wear protective gloves when cleaning spilled or re-leased material.

Personal Precautions, Protective Equipment And Emergency ProceduresFor Emergency Responders:

Wear protective gloves. Respiratory protection should be worn if material is involved in a fire. (See Section 8.0).

Environmental Precautions:

Prevent water used to extinguish fires from reaching drains, sewers, surface waters or groundwater.

Methods and Materials for Containment and Cleanup:

Released material in dry form may be swept up using a broom and dust pan or picked up by hand, using protective gloves. Prevent water used to extinguish fires from reaching drains, sewers, surface waters or groundwater by diking, berming, or using vacuuming methods to clean up extinguishing media.

7.0 Handling and Storage

Precautions for Safe Handling:

Wear protective gloves when handling product. DO NOT eat, drink or smoke when handling this product. Wash hands thoroughly after handling.

Storage:

Keep product sealed in its original container at room temperature 10 to 38° C (50 to 100° F) and at normal humidity (10 to 60 %). DO NOT store this product with volatile chemicals, oxidizers or reducing agents, strong acids, or bases, as these may interfere with the proper function.

8.0 Exposure Controls / Personal Protection

| Component | CAS Number | OSHA PEL (mg/m3) | ACGIHTLV (mg/m3) |
|----------------------------|----------------|--|------------------|
| Trade Secret 1 | Registered | 0.5 | 0.5 |
| Trade Secret 2 | Registered | 15 (Total Dust) 5 (Respirable Fraction) | None Established |
| Antimony Trioxide | 1309-64-4 | 0.5 | 0.5 |
| Butyl Benzyl Phthalate | 85-68-7 | 5 | 5 |
| Non-Hazardous Component | Not Applicable | None Established | None Established |

Appropriate Engineering Controls:

None needed when this product is used in its prescribed manner by qualified personnel. Eye/Face Protection:

None required. If desired, use safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin Protection:

Wear protective PPE if skin exposure is for extended periods. The type of protective equipment should be selected according to the concentration and amount of the dangerous sub-stance at the specific workplace.

Respiratory Protection:

Where risk assessment shows air-purifying respirators are appropriate use a particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal Hazards:

Product may be hot when removing from sterilization equipment.

Hygiene Measures:

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9.0 Physical and Chemical Properties

Appearance White/Green Test Strip (Solid)

Odor None Odor Threshold None

pН Not Applicable **Melting Point** Not Applicable **Freezing Point** Not Applicable **Boiling Point** Not Applicable **Boiling Range** Not Applicable **Flash Point** Not Applicable **Evaporation Rate** Not Applicable **Flammability** Not Flammable **Upper Flammable Limit** Not Applicable **Vapor Pressure** Not Applicable **Vapor Density** Not Applicable **Relative Density** Not Applicable Not Soluble Solubility **Octanol/Partition Coefficient** Not Applicable **Auto Ignition Temperature** Not Available **Decomposition Temperature** Not Available **Viscosity** Not Applicable

10.0 Stability and Reactivity

Reactivity: This product is not reactive.

Chemical Stability: This product is stable under normal handling conditions.

Possibility of Hazardous Reactions: This product will not polymerize. **Conditions to Avoid:** Avoid open flames as test paper is combustible.

Incompatible Materials: Acids, Bases, Oxidizers, Reducing Agents and Halogens.

Hazardous Decomposition Products: Irritating or toxic substances including metallic

Hazardous Decomposition Products: Irritating or toxic substances including meta oxides and oxides of carbon and nitrogen.

11.0 Toxicological Information

The toxicological properties of this product have not been fully investigated as a whole.

Acute Toxicity: No Data Available **Skin Corrosion/Irritation:** No Data Available Serious Eye Damage/Irritation: No Data Available **Respiratory or Skin Desensitization:** No Data Available **Germ Cell Mutagenicity:** No Data Available **Carcinogenicity:** No Data Available **Reproductive Toxicity:** No Data Available **STOT-Single Exposure:** No Data Available **STOT - Repeated Exposure:** No Data Available **Aspiration Hazard:** No Data Available Ingestion: No Data Available Inhalation: No Data Available No Data Available Skin / Eye Exposure: **Acute and Chronic Effects:** No Data Available **Potential Health Effects:** No Data Available No Data Available Signs and Symptoms of Exposure: No Data Available **Synergistic Effects:**

12.0 Ecological Information

The ecological properties of this product have not been fully investigated as a whole.

Toxicity to Fish and InvertebratesNo Data AvailablePersistence and DegradabilityNo Data AvailableBioaccumulative PotentialNo Data AvailableMobility in SoilNo Data AvailablePBT and vPvB AssessmentNo Data AvailableOther Adverse EffectsNo Data Available

13.0 Disposal Considerations

Product:

Disposal should be in accordance with local, state, and federal laws and regulations. Product contains trace amounts of chromium (III).

Contaminated Packaging:

Dispose of as unused product.

14.0 Transport Information

This product is not a hazardous material when shipped according to DOT, IATA or IMDG shipping regulations.

15.0 Regulatory Information

Emergency Planning and Community Right-to-Know Act (EPCRA):

This product is exempt from regulation under the "article exemption".

Toxic Substances Control Act (TSCA):

All constituents are listed on the TSCA Inventory.

Clean Air Act (CAA):

This product is exempt from regulation under the "article exemption".

Clean Water Act (CWA):

This product is exempt from regulation under the "article exemption".

Comprehensive Environmental Response Compensation And Liability Act:

This product is exempt from regulation under the "article exemption".

State Right To Know Lists:

No substances in this product are present above any U.S. State's respective thresholds.

CALIFORNIA PROPOSITION 65 COMPONENTS:

WARNING! This product contains a chemical known to the State of California to cause cancer.

Antimony Trioxide

WARNING! This product contains a chemical known to the State of California to cause developmental harm.

Butyl Benzyl Phthalate

SECTION 313 SUPPLIER NOTIFICATION

This product is exempt from regulation under the "article exemption".

European Inventory of Existing Commerical Chemical Substances:

All substances contained in this product are listed on the EINECS.

16.0 Other Information

This Material Safety Data Sheet complies with the U.S. Hazard Communication Requirements contained in 29 CFR Part 1910.1200 as promulgated by the U.S. Occupational Health and Safety Administration (OSHA), the American National Standards Institute (ANSI) recommended practice for preparing MSDS sheets as contained in ANSI Z400.1- 2004, Section 13 of the Canadian Hazardous Products Act (HPA) and the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals.

Abbreviations

% Percent

ACGIH U.S. American Conference of Governmental Industrial Hygienists

C Degrees Celcius CAA U.S. Clean Air Act

CAS Chemical Abstracts Number

CERCLA U.S. Comprehensive Environmental Response Compensation and Liability Act

CWA U.S. Clean Water Act

DOT U.S. Department of Transportation EC European Commission Number EC50 Half maximal effective concentration

EINECS European Inventory of Existing Commercial Chemical Substances EPCRA U.S. Emergency Planning and Community Right-To-Know Act

EU European Union F Degrees Fahrenheit

GHS Globally Harmonized System (GHS) of Classification and Labeling of Chemicals

H Hours

HPA Hazardous Products Act

IARC International Agency for the Research on Cancer

IATA International Air Transport Association
IMDG International Maritime Dangerous Goods

LC50 Lethal Dose to kill 50% of test species via inhalation

LD50 Lethal Dose to kill 50% of test species via oral or dermal administration

LDLO Lethal Dose - Low Concentration mg/kg Milligram per kilogram of body weight

mg/l Milligrams per liter

mg/m3 Milligrams per cubic meter MSDS Material Safety Data Sheet

NAAQS National Ambient Air Quality Standard established under CAA

NPDES U.S. National Pollutant Discharge Elimination System

NTP U.S. National Toxicology Program

OSHA U.S. Occupational Safety and Health Administration (See OSHA)

PBT Persistent Bioaccumulative Toxin

PEL Permissible Exposure Limit Averaged Over 8 Hours (See OSHA)

Ppb Parts Per Billion Ppm Parts Per Million

Prop 65 California Proposition 65

REACH Registration, Evaluation, Authorization and Restriction of Chemicals (See EU)

RQ Reportable Quantity RTK Right-To-Know SDS Safety Data Sheet

SVHC Substances of Very High Concern (See REACH)

TLV Threshold Limit Value Averaged over 8 Hours (See ACGIH)

TSCA U.S. Toxic Substances Control Act

U.S. United States

vPvB Very Persistent, Very Bioaccumulative Chemical (See REACH) WHIMS Canadian Workplace Hazardous Materials Information System

IMPORTANT USE NOTICE

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