

# Getinge

## Items Biological Test Pack

### 1.0 Product and Company Identification

<b>Product Name</b>	Getinge Australia Items Biological Test Pack
<b>Product Code</b>	6005500407
<b>Recommended Use</b>	For diagnostic use only. Not for normal consumer use. The Items Biological Test Pack is designed for use in steam sterilizer operating at either 121°C or 134°C. Not for use with other types of sterilization. The Integrator Indicator card gives visible indication that sterilizing parameters (time, temperature and steam) were met at specific locations e.g. pack or pouch.
<b>Supplier</b>	Getinge Sterility Assurance 74 Inverness Drive East Englewood, CO 80112 USA
<b>Supplier Australia:</b>	Getinge Australia Pty Ltd 1/160 Lytton Road, Morningside, QLD 4170, Australia Phone: 1800 438 464
<b>Supplier New Zealand:</b>	Getinge Australia (NZ Branch) Ground Floor, Building A, Unit D Millenium Business Centre 600 Great South Road Ellerslie 1051 Auckland Phone: 0800 1438 4643
<b>Web</b>	<a href="http://www.getinge.com">http://www.getinge.com</a>
<b>Email</b>	info@getinge.com
<b>Emergency No.:</b>	1-800-424-9300 (CHEMTREC) 24-Hour All Emergencies 1-703-527-3887 (From Outside USA - Collect Calls Accepted)

### 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: Hazardous to Aquatic Life, Category 1

**Precautionary Statement(s):**

P264 – Wash hands thoroughly after handling.  
P270 – Do not eat, drink or smoke when using this product.  
P280 – Wear protective eye protection.

### 3.0 Composition / Information on Ingredients

Component	CAS Number	EC Number	Weight %
Trade Secret 1	Registered	Registered	< 1
Trade Secret 2	Registered	Registered	< 0.1
Non-Hazardous Component	Not Applicable	Not Applicable	99.44 – 99.67

Note: The BI Test Pack contains a glass ampule filled with a proprietary formulated culture medium. A pH indicator is added to the medium which changes color when viable spores are present. The Biological Indicator is supplied by Mesa Labs.

### 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 assistance at once 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 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 oxides of chromium, magnesium, carbon and nitrogen. May emit toxic fumes of chlorine containing compounds.

## 6.0 Accidental Release Measures

### Personal Precautions, Protective Equipment And Emergency Procedures For Non-Emergency Personnel:

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

### Personal Precautions, Protective Equipment And Emergency Procedures For 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 if wearing impermeable 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. Consult your safety representative for more details. 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 (30 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/m <sup>3</sup> )	ACGIH TLV (mg/m <sup>3</sup> )
Trade Secret 1	Registered	0.5	0.5
Trade Secret 2	Registered	15 (Total Dust) 5 (Respirable Fraction)	None Established
Non-Hazardous Component	Not Applicable	Not Applicable	Not Applicable

### 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 substance 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:

None anticipated when this product is used in its prescribed manner by qualified personnel. 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

<b>Appearance</b>	Pink/Green Test Strip (Solid)
<b>Odor</b>	None
<b>Odor Threshold</b>	None
<b>pH</b>	Not Applicable
<b>Melting Point</b>	Not Applicable
<b>Freezing Point</b>	Not Applicable
<b>Boiling Point</b>	Not Applicable
<b>Boiling Range</b>	Not Applicable
<b>Flash Point</b>	Not Applicable
<b>Evaporation Rate</b>	Not Applicable
<b>Flammability</b>	Not Flammable
<b>Upper Flammable Limit</b>	Not Applicable
<b>Vapor Pressure</b>	Not Applicable
<b>Vapor Density</b>	Not Applicable
<b>Relative Density</b>	Not Applicable
<b>Solubility</b>	Not Soluble
<b>Octanol/Partition Coefficient</b>	Not Applicable
<b>Auto Ignition Temperature</b>	Not Available
<b>Decomposition Temperature</b>	Not Available
<b>Viscosity</b>	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 oxides, chlorine, carbon and nitrogen.

## 11.0 Toxicological Information

The toxicological properties of this product have not been fully investigated as a whole.	
<b>Acute Toxicity:</b>	No Data Available
<b>Skin Corrosion/Irritation:</b>	No Data Available
<b>Serious Eye Damage/Irritation:</b>	No Data Available
<b>Respiratory or Skin Desensitization:</b>	No Data Available
<b>Germ Cell Mutagenicity:</b>	No Data Available
<b>Carcinogenicity:</b>	No Data Available
<b>Reproductive Toxicity:</b>	No Data Available
<b>STOT - Single Exposure:</b>	No Data Available
<b>STOT - Repeated Exposure:</b>	No Data Available
<b>Aspiration Hazard:</b>	No Data Available
<b>Ingestion:</b>	No Data Available
<b>Inhalation:</b>	No Data Available
<b>Skin / Eye Exposure:</b>	No Data Available
<b>Acute and Chronic Effects:</b>	No Data Available
<b>Potential Health Effects:</b>	No Data Available
<b>Signs and Symptoms of Exposure:</b>	No Data Available
<b>Synergistic Effects:</b>	No Data Available

<b>12.0 Ecological Information</b>	<p>The ecological properties of this product have not been fully investigated as a whole.</p> <table> <tr> <td><b>Toxicity to Fish and Invertebrates</b></td><td>No Data Available</td></tr> <tr> <td><b>Persistence and Degradability</b></td><td>No Data Available</td></tr> <tr> <td><b>Bioaccumulative Potential</b></td><td>No Data Available</td></tr> <tr> <td><b>Mobility in Soil</b></td><td>No Data Available</td></tr> <tr> <td><b>PBT and vPvB Assessment</b></td><td>No Data Available</td></tr> <tr> <td><b>Other Adverse Effects</b></td><td>No Data Available</td></tr> </table>	<b>Toxicity to Fish and Invertebrates</b>	No Data Available	<b>Persistence and Degradability</b>	No Data Available	<b>Bioaccumulative Potential</b>	No Data Available	<b>Mobility in Soil</b>	No Data Available	<b>PBT and vPvB Assessment</b>	No Data Available	<b>Other Adverse Effects</b>	No Data Available
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<b>13.0 Disposal Considerations</b>	<p><b>Product:</b> Disposal should be in accordance with local, state, and federal laws and regulations. Product contains trace amounts of chromium (III).</p> <p><b>Contaminated Packaging:</b> Dispose of as unused product.</p>												
<b>14.0 Transport Information</b>	<p>This product is not a hazardous material when shipped according to DOT, IATA or IMDG shipping regulations.</p>												
<b>15.0 Regulatory Information</b>	<p><b>Emergency Planning and Community Right-to-Know Act (EPCRA):</b> This product is exempt from regulation under the "article exemption".</p> <p><b>Toxic Substances Control Act (TSCA):</b> All constituents are listed on the TSCA Inventory.</p> <p><b>Clean Air Act (CAA):</b> This product is exempt from regulation under the "article exemption".</p> <p><b>Clean Water Act (CWA):</b> This product is exempt from regulation under the "article exemption".</p> <p><b>Comprehensive Environmental Response Compensation And Liability Act:</b> This product is exempt from regulation under the "article exemption".</p> <p><b>State Right To Know Lists:</b> No substances in this product are present above any U.S. State's respective thresholds.</p> <p><b>CALIFORNIA PROPOSITION 65 COMPONENTS:</b> This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.</p> <p><b>SECTION 313 SUPPLIER NOTIFICATION</b> This product is exempt from regulation under the "article exemption".</p> <p><b>European Inventory of Existing Commercial Chemical Substances:</b> All substances contained in this product are listed on the EINECS.</p>												
<b>16.0 Other Information</b>	<p>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.</p>												

## 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/m <sup>3</sup>	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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END of SDS

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Authored By: SteriTec Products

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