

# Getinge Assured

## Multicritical Process Variable Indicator (Ethylene Oxide)

### 1.0 Product and Company Identification

<b>Product Name</b>	Getinge Assured Multicritical Process Variable Indicator (Ethylene Oxide)
<b>Product Code</b>	504051600
<b>Recommended Use</b>	For diagnostic use only. Not for normal consumer use. The Multicritical Process Variable Indicator (Ethylene Oxide) was designed to provide an integrated response to EO gas sterilization. The Multicritical Process Variable Indicator EO gives visible confirmation of the attainment of sterilization conditions at their locations within the sterilizer chamber. Not to be used in other types of sterilization diagnostics.
<b>Supplier</b>	Getinge Infection Control AB, PO Box 69, 305 05, Getinge, Sweden
<b>Supplier Australia:</b>	Getinge Australia Pty Ltd Suite 701, Level 7, 11 Help Street, Chatswood, NSW 2067, Australia Phone: 1800 438 464
<b>Supplier New Zealand:</b>	Getinge Australia (NZ Branch) 600 Great South Road, Building B, Level 2 Ellerslie, Auckland 1051, New Zealand Phone: 0800 1 438 464
<b>Telephone No.</b>	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
<b>Web</b>	<a href="http://www.getinge.com">http://www.getinge.com</a>
<b>Email</b>	<a href="mailto:info@getinge.com">info@getinge.com</a>

### 2.0 Hazards Identification

#### This Product is an Article and Presents No Known Hazards

This product meets the definition of an "Article" as defined by Section 1.3.2.1.1 of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Seventh Revised Edition (2017), 29 CFR Subpart Z Section 1910.1200 of the U.S. Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (2012), and Part II Section 12(i) of the Canadian Hazardous Products Act as amended (5/23/18).

Additionally, this product does not meet any classification and/ or labeling criteria as defined by the Classification, Labeling and Packaging (CLP) of Substances and Mixtures as defined by regulation (EC) No 1272/2008 of the European Parliament and of the Council as amended on 03/01/2018.

The information provided in this Safety Data Sheet (SDS) is for informational purposes only and does not necessarily reflect any warning and/or precautionary statements as may be indicated on the product's packaging or container label

This product contains trace amounts of chemicals that are considered hazardous. For informational purposes, the following information for the hazardous chemicals is provided.

**GHS Classification:**

Acute Toxicity (Oral), Category 5  
 Acute Toxicity (Dermal), Category 5

**GHS Label Code(s):**

H303 + H313

**Pictogram(s):**

None

**Signal Word(s):**

Warning

**Hazard Statement(s):**

H303 + H313 May be harmful if swallowed or in contact with skin.

**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	EC Number	CAS Number	Weight %
Talc*	Registered	14807-96-6	< 0.1
Trade Secret 2	Registered	Registered	< 0.1
Trade Secret 3	Registered	Registered	< 0.1
<b>Non-Hazardous Components</b>	Not Applicable	Not Applicable	99.5

\*Contains a suspected known or suspected carcinogen: IARC Group 2B. Traces of silicon dioxide may also be present: Carcinogen (respiratory) category 1

### 4.0 First Aid Measures

For sensitive or susceptible individuals, 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:**

If risk assessment recommends, use protective gloves when handling. 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 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 metals, carbon and nitrogen.

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## 6.0 Accidental Release Measures

### **Personal Precautions, Protective Equipment and Emergency Procedures for Non-Emergency Personnel:**

Spills or releases of this product are not expected to result in significant emergency response procedures. Wear protective cotton gloves or their equivalent when cleaning spilled or released material.

### **Personal Precautions, Protective Equipment and Emergency Procedures for Emergency Responders:**

If large amounts of spilled or released materials are involved, wear appropriate and approved protective clothing appropriate to the incident to prevent skin contact. 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 protective cotton gloves or their equivalent. 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.

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## 7.0 Handling and Storage

### **Precautions for Safe Handling:**

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 mix this product with any other chemical substances.

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## 8.0 Exposure Controls / Personal Protection

Component	CAS Number	OSHA PEL (mg/m3)	ACGIH TLV (mg/m3)
Talc	14807-96-6	20 mppcf per 8hr	2
Trade Secret 2	Registered	None Established	None Established
Trade Secret 3	Registered	2	2
<b>Non-Hazardous Components</b>	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:

If risk assessment requires: Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

### Skin Protection:

Select appropriate protective gloves. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### Respiratory Protection:

None needed when this product is used in its prescribed manner by qualified personnel. For nuisance exposures use type P1 (EU EN 143) particle respirator. For higher level protection use type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as CEN (EU).

### Thermal Hazards:

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

### 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>	Peach 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 and Halogens.

**Hazardous Decomposition Products:** Irritating or toxic substances including, under fire conditions: metal oxides,, carbon and nitrogen.

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## 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

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## 12.0 Ecological Information

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

<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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## 13.0 Disposal Considerations

**Product:**

Offer surplus and non-recyclable material to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

**Contaminated Packaging:**

Dispose of as unused product.

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## 14.0 Transport Information

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

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## 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:**

This product has trace elements of silica and arsenic which may be on individual states right to know lists.

### **CALIFORNIA PROPOSITION 65 COMPONENTS:**

WARNING! This Product contains a chemical (crystalline silica) known to the state of California to cause cancer.

WARNING! This Product contains chemicals (arsenic) known to the state of California to be a reproductive toxin.

NOTE: Silica, Arsenic and other substances listed by the State of California are present solely because they are naturally occurring trace elements in the Talc as mined.

### **SECTION 313 SUPPLIER NOTIFICATION**

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

### **European Inventory of Existing Commercial Chemical Substances:**

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

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## 16.0 Other Information

This Safety Data Sheet complies with Section 13 of the Canadian Hazardous Products Act (HPA), the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals and the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) requirements.

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### Abbreviations

%	Percent
C	Degrees Celsius
CAS	Chemical Abstracts Number
EC	European Commission Number
EC50	Half maximal effective concentration
EINECS	European Inventory Of Existing Commercial Chemical Substances
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
PBT	Persistent Bioaccumulative Toxin
PEL	Permissible Exposure Limit Averaged Over 8 Hours (See OSHA)
ppb	Parts Per Billion
ppm	Parts Per Million
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)
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: Michael Boozer / ChemReport, Incorporated and Jane Barcelo/ SteriTec Manufacturing Inc.

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Getinge Infection Control AB, P O Box 69, SE-305 05 Getinge, Sweden

**[www.getinge.com](http://www.getinge.com)**