

Getinge Assured

Multicritical Process Variable Indicator (Formaldehyde), Helix Test (Formaldehyde)

1.0 Product and Company Identification

Product Name	Getinge Assured Multicritical Process Variable Indicator (Formaldehyde), Helix Test (Formaldehyde)
Product Code	504051900, 504053100
Recommended Use	For diagnostic use only. Not for normal consumer use. Getinge Assured Multicritical Process Variable Indicator (Formaldehyde) and Helix Test (Formaldehyde) is designed to be used in low temperature steam/formaldehyde (LTSF) sterilizers. When used as directed the indicator gives a visual confirmation that the items being sterilized have been subjected to the following parameters of time, temperature and FO concentration. The Multicritical Process Variable Indicator (Formaldehyde) and Helix Test (Formaldehyde) are intended to be used in conjunction with a standard infection control monitoring protocol.
Supplier	Getinge Infection Control AB PO Box 69, SE 305 05 Getinge
Supplier Australia:	Getinge Australia Pty Ltd Suite 701, Level 7, 11 Help Street, Chatswood, NSW 2067, Australia Phone: 1800 438 464
Supplier New Zealand:	Getinge Australia (NZ Branch) 600 Great South Road, Building B, Level 2 Ellerslie, Auckland 1051, New Zealand 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 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

GHS Classification	None
GHS Label Code(s)	None
Pictogram(s)	None
Signal Word(s)	None
Hazard Statement(s)	None
Precautionary Statement(s)	None

3.0 Composition / Information on Ingredients

Component	EC Number	CAS Number	Weight %
Non-Hazardous Components	Not Applicable	Not Applicable	100

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

If skin irritation occurs, gently wash with plenty of soap and water. Get medical attention if irritation persists.

Eyes

Rinse cautiously with water for at least 15 minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

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 carbon and nitrogen.

6.0 Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

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.

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 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.

7.0 Handling and Storage

Precautions for Safe Handling

Avoid skin and eye contact. DO NOT eat, drink, or smoke when handling this product. Wash hands thoroughly after handling. Laboratory or protective clothing should be worn while handling this product, including disposable or cotton gloves to prevent skin contact.

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 mix this product with any other chemical substances.

8.0 Exposure Controls / Personal Protection

Component	CAS Number	OSHA PEL (mg/m3)	ACGIH TLV (mg/m3)
Non-Hazardous Components	Not Applicable	None Established	Not Applicable

Appropriate Engineering Controls

Do not get in eyes, on skin, or on clothing.

Eye/Face Protection

Use eye protection tested and approved under appropriate government standards such as NIOSH (US) or European Union EN 166 (EU)

Skin Protection

Laboratory or protective clothing should be worn while handling this product, including disposable or cotton gloves to prevent skin contact.

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.

Hygiene Measures

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

9.0 Physical and Chemical Properties

Appearance	White Test Strip with Purple Indicator Spot (Solid)
Odor	None
Odor Threshold	None
pH	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
Solubility	Not Soluble
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 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
Skin / Eye Exposure:	No Data Available
Acute and Chronic Effects:	No Data Available
Potential Health Effects:	No Data Available
Signs and Symptoms of Exposure:	No Data Available
Synergistic Effects:	No Data Available

12.0 Ecological Information

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

Toxicity to Fish and Invertebrates	No Data Available
Persistence and Degradability	No Data Available
Bioaccumulative Potential	No Data Available
Mobility in Soil	No Data Available
PBT and vPvB Assessment	No Data Available
Other Adverse Effects	No Data Available

13.0 Disposal Considerations

Product

Disposal should be in accordance with local, state, and federal laws and regulations.

Contaminated Packaging

Dispose of as unused product.

14.0 Transport Information

This product is not a regulated 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 material does not contain any listed hazardous air pollutants in quantities of concern. This material does not contain any Class 1 Ozone depleters. This material does not contain any Class 2 Ozone depleters.

Clean Water Act (CWA):

This material does not contain any listed priority pollutants in quantities of concern.

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:

Not a consumer product subject to Proposition 65.

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.

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.

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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