

Getinge Assured

Helix Tests

1.0 Product and Company Identification

Product Name	Getinge Assured Helix Test 3.5, Getinge Assured Helix Test 4, Getinge Assured Helix Test 5.3, Getinge Assured Helix Test 7, Getinge Assured Helix Test 3.5 (Refill Kit), Getinge Assured Helix Test 4 (Refill Kit), Getinge Assured Helix Test 5.3 (Refill Kit), Getinge Assured Helix Test 7 (Refill Kit)
Product Code	504052700, 504052800, 504052900, 504053000, 6005500037, 6005500038, 6005500038, 6005500039, 6005500040
Recommended Use	For diagnostic use only. Not for normal consumer use. Getinge Assured Helix Test verifies air removal, steam penetration, exposure levels and deep vacuum achievement necessary for the sterilization of hollow lumen instruments. The Helix Test is suitable for daily sterilizer monitoring (Helix Test 3.5 complies according to EN 867-5). The test is designed to be used in each sterilization cycle as an independent control device.
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
NOTICE	Notice: This product meets the definition of an "article" and is exempted from SDS requirements as defined by Section 1.3.2.1.1 of the GHS fourth revised edition (2011), 29 CFG part 1910.1200 of the U.S. OSHA Hazard Communication Standard, and Section 3 of the Canadian Hazardous Products Act. The information provided in this SDS is for informational purposes only and does not necessarily reflect warning and precautionary statements indicated on the product's packaging or container label. Additionally, the ingredients contained in this product are below the respective cut-off levels for SDS development under the above referenced regulations.

2.0 Hazards Identification

GHS Classification:

Acute Toxicity (Oral), Category 4
Acute Toxicity (Dermal), Category 2

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.

This product presents no health or physical hazards under normal conditions of use. Inhalation of decomposition products from burning may cause eye and respiratory irritation. If irritation develops following inhalation of decomposition products, remove the victim from area to fresh air. If symptoms persist, get prompt medical attention.

This product is essentially nonirritating to skin. Prolonged exposure to skin is not likely to result in material being absorbed through skin in harmful amounts. Ingestion of significant amounts of this product is highly unlikely. Ingestion of physical article may cause choking if swallowed. Single dose toxicity is believed to be very low.

3.0 Composition / Information on Ingredients

Component	CAS Number	EC Number	Weight %
Trade Secret 1	Registered	Registered	< 0.1
Trade Secret 2	Trade Secret	Registered	< 0.1
Non-Hazardous Components	Not Applicable	Not Applicable	99.934

4.0 First Aid Measures

Due to the low levels of hazardous components contained in this product, no acute, delayed or chronic adverse health effects are expected to occur via any exposure route under normal conditions of use by qualified persons. 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:

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 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 sulfur, bismuth, carbon and nitrogen.

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.

7.0 Handling and Storage

Precautions for Safe Handling:

Under conditions of normal handling and use expected for this product, no handling precautions other than those explained below are believed to be necessary. Handling precautions will be dependent on the method in which the product is used. 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 (10 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)
Trade Secret 1	Registered	None Established	None Established
Trade Secret 2	Registered	None Established	None Established
Non-Hazardous Components	Registered	None Established	None Established

Appropriate Engineering Controls:

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

Eye/Face Protection:

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:

None needed when this product is used in its prescribed manner by qualified personnel. Wear impervious clothing if exposures to skin are excessive. 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

Appearance	White/Purple Test Strip (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 sulfur, 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:

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.

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

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)
U.S. United States
vPvB Very Persistent, Very Bioaccumulative Chemical (See REACH).
WHIMS Canadian Workplace Hazardous Materials Information System

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END of SDS

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