

Getinge Assured

Emulating Indicators, Biological Test Card

1.0 Product and Company Identification

Product Name	Emulating Indicator 5.3, Emulating Indicator 7, Emulating Indicator 18, Smart-Read Biological Test Pack Card, Self-Contained Biological Test Pack Card
Product Code	504050800, 504050900, 504051400, 504054500, 504054600
Recommended Use	For diagnostic use only. Not for normal consumer use. The Getinge Assured Emulating Indicator is designed for use in steam sterilizer operating at either 121°C or 134°C. The Emulating Indicator gives visible indication that sterilizing parameters (time, temperature and steam) were met at specific locations e.g. pack or pouch.
Supplier	Getinge Infection Control AB, PO Box 69, 305 05, Getinge, Sweden
Telephone No.	+46 10 335 00 0
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 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.

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. The aluminum strip or the holder may be hot to the touch if handled immediately after the wash cycle. 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	EC Number	CAS Number	Weight %
Trade Secret 1	Registered	Registered	< 1
Trade Secret 2	Trade Secret	Registered	< 0.1
Non-Hazardous Components	Not Applicable	Not Applicable	> 99.44 - 99.67

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 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:

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	0.5	0.5
Trade Secret 2	Registered	15 (Total Dust) 5 (Respirable Fraction)	None Established
Non-Hazardous Components	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:

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:

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 P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. 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 workday.

9.0 Physical and Chemical Properties

Appearance	Pink/Green 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 metallic oxides, chlorine, 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

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:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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 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/m ³	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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