

SAFETY DATA SHEET u-test Biological Indicators

Preamble:

This product is not subject to the Hazardous Products Act (HPA) Part II (Hazardous Products) as per paragraph 12(j); Schedule 1 (Non-Application of Part II).

This restriction states that Part II does not apply in respect of the sale or importation of anything listed in Schedule 1 which includes any pest control product as defined in subsection 2(1) of the Pest Control Products Act, any explosive as defined in section 2 of the Explosives Act, any cosmetic, <u>device</u>, drug or food, as defined in section 2 of the Food and Drugs Act, any consumer product as defined in section 2 of the Canada Consumer Product Safety Act and any wood or product made of wood.

prophy paste is Exempt - medical device

1: Identification

Product identifier u-test Biological Indicators

Other means of identification u-test Biological Indicators Plus (BI Plus)

Recommended use of the chemical and restrictions on use Biological indicator device for monitoring

sterilization efficacy of hospital and industrial sterilization

processes, including steam. No restrictions.

Supplier's details maxill inc., 80 Elm Street, St. Thomas, ON, N5R 6C8, Canada

Telephone: 1-800-268-8633, E-mail: info@maxill.com, Website: www.maxill.com

Emergency phone number (24h) CANUTEC: 1-888-CAN-UTEC (226-8832),

ChemTel: 1-800-255-3924, outside US and Canada, 1-813-248-0585

2: Hazard identification

Classification of the substance or mixture This product is a medical device with intended and reasonably

foreseeable use, intended for institutional use.

Physical hazards None.

Health hazards If ampoule is ruptured, may cause skin irritation.

Environmental hazards None.

WHMIS 2015 defined hazards Not classified. Label elements Not applicable. See Preamble.

WHMIS 2015: Health hazards not otherwise classified Not applicable. See Preamble. WHMIS 2015: Physical hazards not otherwise classified Not applicable. See Preamble.

3: Composition/information on ingredients

All ingredients in the mixture fall below the (GHS) cut-off concentration limits for reporting. Mixture is non-hazardous and non-pathogenic.

4: First-aid measures

Inhalation Not a likely route of exposure.

Skin Contact Under normal circumstances contact with the device should not result in skin irritation. If liquid

media comes in contact with skin, wash with soap and water. If the media ampoule is crushed outside of the plastic body, glass splinters may enter the hands or fingers. Remove splinters with

tweezers and apply antiseptic to cut areas.



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Eye Contact If liquid media enters the eye, flush with water. If the media ampoule is crushed outside of the

plastic body, glass splinters may enter the eye. Do not rub eye. Flush with water. If glass cannot

be dislodged with water, medical assistance may be required.

Ingestion Not a likely route of exposure.

Indication of immediate medical attention and special treatment needed

If you feel unwell, seek medical advice and show the label where possible.

General information If exposed or concerned, get medical advice/attention. Ensure that first aid responders

are aware of the materials involved and take precautions to protect themselves (PPE).

5: Fire-fighting measures

Suitable Extinguishing Media Use dry chemical, foam, water or CO₂ for surrounding fire.

Specific Hazards Arising from the Mixture

Fire Hazard Not applicable.

Explosion Hazard Not applicable.

Reactivity Will not occur under normal conditions.

Special protective actions for fire-fighters Keep containers cool with water spray

6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Non-emergency personnel For accidental spills of the this product, personnel should wear impervious

gloves (e.g. Nitrile or latex rubber, vinyl, neoprene) when handling the material. See Section 8 of the SDS.

Emergency responders For accidental spills of the this product, personnel should wear impervious

gloves (e.g. Nitrile or latex rubber, vinyl, neoprene) when handling the material. See Section 8 of the SDS.

Environmental precautions Not applicable.

Other information This product is compatible with all glove materials (PPE). There are no inappropriate

containment measures of clean up processes. Disinfect are where media is spilled.

7: Handling and storage

Precautions for safe handling Avoid contact of leaked media with the eyes and the skin.

Conditions for safe storage, including any incompatibilities Keep container closed. Keep cool.

8: Exposure controls/personal protection

Control parameters Not available.

Appropriate engineering controls This product is a medical device with intended and reasonably

foreseeable use, intended for institutional use with no engineering

controls required.

<u>Individual protection measures, such as personal protective equipment (PPE)</u>

Eye/face protection Not normally required when used as directed.

Skin protection Not normally required when used as directed.

Respiratory protection Not normally required.

Thermal hazards Not applicable.



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9: Physical and chemical properties and safety characteristics

Physical state	Glass media ampoule contained in sealed plastic
	body
Colour	Not available (N/Av)
Odour	N/Av
Melting point / freezing point	N/Av
Boiling point	N/Av
Flammability	Not applicable (N/Ap)
Lower and upper explosion limit / flammability limit	N/Av
Flash point	N/Av
Auto-ignition temperature	N/Av
Decomposition temperature	N/Av
На	N/Av
Kinematic viscosity	N/Av
Solubility	N/Av
Partition coefficient: n-octanol/water (log value)	N/Av
Vapour pressure	N/Av
Density or specific gravity	N/Av
Relative vapour density	N/Av
Particle characteristics	N/Ap

10: Stability and reactivity

Reactivity Not available.

Chemical stability Stable under normal storage, handling and transportation.

Possibility of hazardous reactions Not available.

Conditions to avoid Avoid extremely high or freezing temperatures to maintain product integrity.

Incompatible materials No data is available.

products ought not be produced.

11: Toxicological information

Toxicological health effects: hazards

Acute toxicity Not available (N/Av)

Skin corrosion/irritation N/Av
Serious eye damage/irritation N/Av
Respiratory or skin sensitization N/Av
Germ cell mutagenicity N/Av
Carcinogenicity N/Av
Reproductive toxicity N/Av
STOT -single exposure N/Av



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STOT-repeated exposure N/Av
Aspiration hazard N/Av
Information on the likely routes of exposure

Ingestion There are no known significant effects or critical hazards.

Skin contact There are no known significant effects or critical hazards.

Eye contact There are no known significant effects or critical hazards.

There are no known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics Not available.

Delayed and immediate effects and also chronic effects from short and long term exposure

Not available.

Numerical measures of toxicity (such as acute toxicity estimates) Not available.

Interactive effects Not available.

Where specific chemical data are not available Not available.

Mixtures and mixture versus ingredient information Not available.

Other information Nothing.

12: Ecological information

This product contains no known ecological hazards. The microorganisms it contains are non-pathogenic and found in nature. The chemicals it contains are non-toxic biological nutrients and a non-toxic pH sensitive dye.

Ecotoxicity Not available.

Persistence and degradability

Bioaccumulative potential

Mobility in soil

Not available.

Not available.

Other adverse effects There are no known significant effects or critical hazards.

13: Disposal considerations

Disposal methods Autoclave at >= 121°C for 30 minutes prior to disposal or incinerate.

14: Transport information

Not a Dangerous Good.

UN NumberNot applicable.Packing group, if applicableNot applicable.UN Proper Shipping NameNot applicable.Environmental hazardsNot available.Transport hazard class(es)Not applicable.Special precautions for userNot available.

Safety, health and environmental regulations specific for the product in question Not available.

15: Regulatory information

Safety, health and environmental regulations specific to the product

CANADA

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explosive as defined in section 2 of the Explosives Act, any cosmetic, <u>device</u>, drug or food, as defined in section 2 of the Food and Drugs Act, any consumer product as defined in section 2 of the Canada Consumer Product Safety Act and any wood or product made of wood.

Exempt - medical device

UNITED STATES

Medical device (21 CFR 872.6030, Product Code JOJ)

16: Other information

Disclaimer Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

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