

For collection, transport, maintenance and long term freeze storage of Viruses, Chlamydia, Mycoplasma and Ureaplasma

## SMART TRANSPORT MEDIUM AND ACCUSWAB

Viruses, Chlamydia, Mycoplasma and Ureaplasma



## Smart Transport Medium (STM)



1.5 ml Vial Phenol Red



al 1.5 ml Vi



1.5 ml Vial



3 ml Vial



3 ml Vial Clear

#### AccuSwab™

Nasopharyngeal

Oropharyngeal

#### Distributed by:



#### staff@kecklermedical.com (209) 505-5959 www.kecklermedical.com

#### **ADVANTAGES**

- Stable at room temperature.
- Patient sample material and particles are rapidly released and dispersed.
- Our STM includes antibiotics to help inhibit bacteria and fungal flora in the sample for the most accurate result.
- ► The molded break points are both safe and reliable.
- Our STM is a stand-up and shatter proof tube enabling quality centrifugation of the sample.



#### STM15 - 1.5 ml - Phenol Red

	Package	50 units per package
	Vial	Screw cap with tube
	Active ingredient	Phenol Red (11%)
	Chemical name	Phenolsulfonphthalein
	Storage temperature	5 to 25 C
	Intended use	Culture: Viruses, Chlamydia, Micoplasma and Ureaplasma

### STM15 - 1.5 ml - Clear

	Package	50 units per package	
	Vial	Screw cap with tube	
	Storage temperature	5 to 25 C	
	Intended use	Culture: Viruses, Chlamydia, Micoplasma and Ureaplasma	

#### STM30 - 3 ml - Phenol Red

	Package	50 units per package
	Vial	Screw cap with tube
	Active ingredient	Phenol Red (11%)
	Chemical name	Phenolsulfonphthalein
	Storage temperature	5 to 25 C
	Intended use	Culture: Viruses, Chlamydia, Micoplasma and Ureaplasma

### STM30-3 ml - Clear

	Package	50 units per package
	Vial	Screw cap with tube
	Storage temperature	5 to 25 C
	Intended use	Culture: Viruses, Chlamydia, Micoplasma and Ureaplasma

N	Package	1000 units per box	
l II	Tip	Nylon Fiber	
	Rod	Nylon	
	Sterility	Gamma Sterile	

## AccuSwab™ Nasopharyngeal AccuSwab™ Oropharyngeal

Π	Package	1000 units per box	
Ų	Tip	Nylon Fiber	
	Rod	Nylon	
	Sterility	Gamma Sterile	

(AccuSwab and Smart Transport System (STM) are sold separately)

Distributed by:







Version 1.0 Dated April 2nd 2020 Printed April 3rd 2020

## SAFETY DATA SHEET

#### **Section 1: Identification**

**Product Name:** MedSchenker STM (Smart Transport Medium)

Company: Vectornate USA inc, 10 Industrial Ave, Ste 4, Mahwah, NJ, 07430

In an emergency call 911.

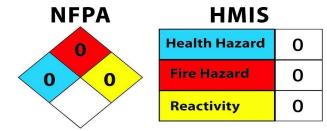
For information about this SDS, use this department contact phone#: +1 201 482 9835 or email to

info@vectornate.com

#### Section 2: Hazard(s) Identification

See <a href="https://www.sigmaaldrich.com/safety-center/globally-harmonized.html">https://www.sigmaaldrich.com/safety-center/globally-harmonized.html</a> for a list of hazard classifications, signal words, hazard statements, pictograms, precautionary statements, and a description of hazards.

Hazard Classification: This product is not classified under a globally harmonized system (GHS).



- \* NFPA: Health = 0, Flammability = 0, Reactivity = 0
- \* HMIS: Health = 0, Flammability = 0, Reactivity = 0

**Hazard Statements:** VN has a triple 0 rating for their solution in their UTM others give simple examples such as

a. Skin Contact: *Irritant*b. Eye Contact : *irritant* 

#### Pictograms:





Version 1.0 Dated April 2nd 2020 Printed April 3rd 2020

#### **Section 3: Composition/Information on Ingredients**

1. Chemical characterization: Mixture

2. Description: Mixture consisting of the following components.

Chemical Name	Synonym	CAS#	Conc.
Water (reverse osmosis)			0.99L
Sucrose			118g
L-glutamic			2.65g
Phenol Red			0.1g
Vancomycin			0.12g
Amphotericin B			0.088g

#### **Section 4: First-Aid Measures**

**After skin contact:** Immediately wash with water and soap, rinse thoroughly **After eye contact:** Flush open eye with plenty of water for 15 minutes.

**After inhalation:** Consult doctor **After swallowing**: Consult doctor

#### **Section 5: Fire-Fighting Measures**

Suitable extinguishing agents: CO2, dry chemical or water spray. Fight larger fires with water

spray or alcohol resistant foam

Special protective equipment for firefighters: No special measures required

#### **Section 6: Accidental Release Measures**



Version 1.0 Dated April 2nd 2020 Printed April 3rd 2020

Personal precautions: Ensure adequate ventilation

**Measures for environmental protection:** Do not allow water to enter sewers or groundwater. **Measures for cleaning/collecting:** Absorb with liquid-binding material (sand, diatomite, acid

binders, universal binders, sawdust).

#### **Section 7: Handling and Storage**

Handling: No special measures required

**Storage:** Store at 2- 25 Celcius.

#### **Section 8: Exposure Controls/Personal Protection**

Breathing equipment: N/A

**Protection of hands:** Disposable Rubber Gloves

Eye protection: Safety Glasses

#### **Section 9: Physical and Chemical Properties**

Form: Liquid

Odor: Characteristic pH: 7.3 +/- 0.2

Melting point/melting range: Not determined Boiling point/boiling range: Not determined

Flash point: N/A Evaporation rate: N/A

Auto ignition temperature: Not self igniting Danger of explosion: No explosion hazard present

Solubility in/Miscibility with water: Soluble

#### **Section 10: Stability and Reactivity**

**Reactivity:** No further relevant information available.

**Chemical stability**: Thermal decomposition / conditions to be avoided:

Conditions to avoid: No further relevant information available.

**Incompatible materials:** strong oxidizers.

Hazardous decomposition products: No dangerous decomposition products known

#### **Section 11: Toxicological Information**

#### Acute toxicity:

#### Potential routes of exposure/potential health effects

The product shows the following dangers according to internally approved calculation methods for preparations: The product is not subject to OSHA classification according to internally approved



Version 1.0 Dated April 2nd 2020 Printed April 3rd 2020

calculation methods for preparations. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Skin: No irritating effect.Eye: No irritating effect.

Sensitization: No sensitizing effects known.

#### Section 12: Ecological Information (non-mandatory)

**Ecotoxicity:** No further relevant information available. **Mobility:** No further relevant information available.

**Biodegradation:** No further relevant information available. **Bioaccumulation:** No further relevant information available.

#### **Section 13: Disposal Considerations (non-mandatory)**

- 1. This product is not considered a RCRA hazardous waste. Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements. Smaller quantities can be disposed of with solid waste
- 2. Uncleaned packagings:
  - Recommendation: Disposal must be made according to state and federal regulations.
  - b. Recommended cleansing agent: Water, if necessary with cleansing agents

#### **Section 14: Transport Information (non-mandatory)**

#### **DOT regulations:**

- Hazard class:
- Land transport ADR/RID (cross-border):
- ADR/RID class:
- Maritime transport IMDG:

#### Air transport ICAO-TI and IATA-DGR:

• ICAO/IATA Class:

#### **Section 15: Regulatory Information (non-mandatory)**

Safety, health and environmental regulations specific for the product in question

#### **US Federal Regulations**



Version 1.0 Dated April 2nd 2020 Printed April 3rd 2020

SARA Section 355 (extremely hazardous substances): None of the ingredients is listed SARA Section 313 (specific toxic chemical listings): None of the ingredients is listed Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs): None of the ingredients is listed TSCA (Toxic Substances Control Act): None of the ingredients is listed

#### **Section 16: Other Information**

Vectornate USA Inc provides the information in this document in good faith and believes the information to be accurate. The chemical, physical, and toxicological properties of this product have not been thoroughly investigated. It is the responsibility of the buyer to research and understand safe methods of handling, storing, and disposal of this product. Vectornate USA Inc makes no warranty with respect to such information and assumes no liability for any loss or injury, which may result from the use of this information. It is the buyers responsibility to comply with local, state, and federal regulations concerning use and disposal of this product.

SDS date of preparation/update: April 2nd, 2020



#### FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

#### **Establishment Registration & Device Listing**

**New Search** Back To Search Results

**Proprietary Name:** MedSchenker

CULTURE MEDIA, NON-SELECTIVE AND NON-**Classification Name:** 

**DIFFERENTIAL** 

**Product Code:** JSG<sup>6</sup> **Device Class:** 

**Regulation Number:** 866.2300<sup>7</sup> Microbiology **Medical Specialty:** 

**Registered Establishment** 

KOREA STANDARD CO., LTD8 Name:

**Registered Establishment** 

Number:

3012454752

**Owner/Operator:** KOREA STANDARD CO.,LTD9

**Owner/Operator Number:** 10050495

**Establishment Operations:** Manufacturer; Repackager/Relabeler

#### Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain

2. http://www.addthis.com/bookmark.php

3. https://www.fda.gov/

4. https://www.fda.gov/Medical-Devices

5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatoryassistance/medical-device-databases

6. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3375

7. /scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=866.2300

8. /scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=188584

9. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start search=1&OwnerOperatorNumber=10050495

Page Last Updated: 05/11/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisye | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسى | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies

#### FDA

U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Contact FDA















For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive



U.S. Department of Health & Human Services

#### Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. https://www.fda.gov/
- 4. https://www.fda.gov/Medical-Devices
- 5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
- 6. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3375
- 7. /scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=866.2300
- 8. /scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=188584
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start\_search=1&OwnerOperatorNumber=10050495



#### FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

#### **Establishment Registration & Device Listing**

**New Search** Back To Search Results

**Proprietary Name:** MedSchenker

APPLICATOR, ABSORBENT TIPPED, **Classification Name:** 

**STERILE** 

**Product Code:** KXG<sup>6</sup> **Device Class:** 

**Regulation Number:** 880.6025<sup>7</sup> General Hospital **Medical Specialty:** 

Registered Establishment Name: KOREA STANDARD CO., LTD<sup>8</sup>

**Registered Establishment** 

3012454752 Number:

**Owner/Operator:** KOREA STANDARD CO.,LTD9

**Owner/Operator Number:** 10050495

**Establishment Operations:** Manufacturer; Repackager/Relabeler

#### Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain

- 2. http://www.addthis.com/bookmark.php
- 3. https://www.fda.gov/
- 4. https://www.fda.gov/Medical-Devices
- 5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatoryassistance/medical-device-databases
- 6. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2668
- 7. /scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=880.6025
- 8. /scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=188584
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start search=1&OwnerOperatorNumber=10050495

Page Last Updated: 05/11/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | ਘਟਸ਼ਾਂ | Kreyòl Ayisye | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسى | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies

#### FDA

U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332)

Contact FDA















For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive



U.S. Department of Health & Human Services

#### Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. https://www.fda.gov/
- 4. https://www.fda.gov/Medical-Devices
- 5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
- 6. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2668
- 7. /scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=880.6025
- 8. /scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=188584
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start\_search=1&OwnerOperatorNumber=10050495