

MSDS

MATERIAL SAFETY DATA SHEET

| Client | Lingen Precision Medical Products (Shanghai) Co., Ltd. No.59, Yewang Road, Yexie Industrial Park, 201609, Songjiang District, Shanghai, China |
|--------------------|---|
| Prepared by | : Shenzhen CCT Testing Technology Co., Ltd. |
| | 8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China |
| | |
| Report Date | : 2020-06-17 |
| Report No. | : CCT20061203LRS |
| | |
| ******FOR FU | RTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)************************************ |
| Shenzhen CCT Testi | ng Technology Co., Ltd |
| Drafted By: | Mark |
| Review By: | TESTING TECHNOLO |
| Review by. | Trence CCT |
| Approved By: | Cloryo Testing Service |



SECTION 1.CHEMICAL PRODUCT INFORMATION

Product details:

Product name : Disposable virus sampling tube

Mode : MTM, VTM, ATM, UTM

Mark : /

TEL : 021-57802277 Fax : 86-21-64857822

E-mail : marketing@labtub.com

Supplier/Manufacturer

Applicant : Lingen Precision Medical Products (Shanghai) Co., Ltd.

Address : No.59, Yewang Road, Yexie Industrial Park, 201609, Songjiang

District, Shanghai, China

Summary:

As specified by the client, This safety data sheet was prepared in accordance with Un GHS Rev.7, The EU CLP REGULATION(EC) No 1272/2013, and US OSH Hazard Communication Standards(29 CFR 1910.1200). Please refer to attached report for details.

SECTION 2.HAZARDS IDENTIFICATION

| Emergency Overview | Not likely to be an irritant in the solid form. Not likely to form a dust in the solid filament form. |
|--------------------------------------|--|
| Potential Acute Health Effects: | Inhalation: Not likely to form an inhalable dust in the solid filament form and for the intended use. Thermal decomposition may result in release of toxic airborne contaminants. Sensitization: Not likely to result in a sensitizing effect under the intended use. |
| Potential Chronic Health Effects: | Carcinogenic Effects: No known carcinogenic effects Mutagenic Effects: No known mutagenic effects Teratogenic Effects: No known teratogenic effects Developmental Toxicity: No known developmental toxicity |
| Reported as carcinogen | Not applicable |



SECTION 3. COMPOSITION /HAZARDOUS INGREDIENTS

| Chemical Name | CAS No. | Content (wt%) |
|--|----------------|---------------|
| MTM | | |
| Isothiocyanate Gua | - | 23.6 |
| Guanidine hydrochloride | 50-01-1 | 10 |
| NLS | | 0.5 |
| TCEP | 701 | 0.03 |
| Tris-HCL | | 10 |
| Chelating agent | | 1 |
| Organic alcohol | | 11.5 |
| Defoamer | | 0.2 |
| Water | 7732-18-5 | 43.17 |
| VTM | | |
| Bovine serum albumin BSA | 17879-45-7 | 0.5 |
| E-mem basic medium | | 0.96 |
| Sodium bicarbonate | 144-55-8 | 0.08 |
| Phenol red solution | - | 10 |
| Benzylpenicillin potassium | 132-98-9 | |
| Streptomycin sulfate | 3810-74-0 | 2 |
| Gentamicin sulfate | 1405-41-0 | |
| Amphotericin B | 1397-89-3 | 0.2 |
| Sulfamethoxazole | 723-46-6 | 2 |
| Water | 7732-18-5 | 84.26 |
| ATM | | |
| Sodium chloride | 7647-14-5 | 0.3 |
| Potassium chloride | 7447-40-7 | 0.02 |
| Calcium chloride | 10035-04-8 | 0.01 |
| Magnesium chloride (6 crystal water) | 7786-30-3 | 0.02 |
| Potassium dihydrogen phosphate | 7778-77-0 | 0.02 |
| Two sodium hydrogen phosphate (12 crystal water) | 7558-79-4 | 0.29 |
| Sodium mercaptoglycolate | 367-51-1 | 0.1 |
| Water | 7732-18-5 | 99.24 |
| UTM | | |
| Sodium chloride | 7647-14-5 | 0.7 |
| Potassium chloride | 7447-40-7 | 0.04 |



| SHE: VEH | in cel lesitivo lectrologi co, el | D. NO CC120001203LN |
|--|-----------------------------------|---------------------|
| Calcium chloride | 10035-04-8 | 0.014 |
| Magnesium chloride | 7786-30-3 | 0.01 |
| Potassium dihydrogen phosphate | 7778-77-0 | 0.11 |
| Two sodium hydrogen phosphate (12 crystal water) | 7558-79-4 | 0.06 |
| Glucose | 50-99-7 | 0.1 |
| L-cysteine | 52-90-4 | 0.05 |
| L-glutamic acid | 56-86-0 | 0.03 |
| Sucrose | 57-50-1 | 0.15 |
| Gelatin | 9000-70-8 | 0.1 |
| Water | 7732-18-5 | 94.736 |
| Phenol red solution | - 100 | 1 |
| Benzylpenicillin potassium | 132-98-9 | |
| Streptomycin sulfate | 3810-74-0 | 2 |
| Gentamicin sulfate | 1405-41-0 | |
| Amphotericin B | 1397-89-3 | 0.2 |
| Sulfamethoxazole | 723-46-6 | 0.2 |
| Bovine serum albumin BSA | 17879-45-7 | 0.5 |

SECTION 4. FIRST AID MEASURES

| Eye Contact: | Rinse immediately with plenty of water. Call a physician immediately. |
|---------------|---|
| Skin Contact: | Rinse immediately with plenty of water. If skin irritation persists, call a physician. Cool skin rapidly with cold water after contact with hot polymer |
| Inhalation: | Move to fresh air. Call a physician immediately if irritation persists. |
| Ingestion: | Drink water as a precaution. Never give anything by mouth to an unconscious person. Do not induce omitting without medical advice. Call a physician immediately. |

SECTION 5. FIGHTING MEASURES

| Suitable extinguishing Media | Water spray, dry chemical, foam. CO2 may be ineffective on large fires |
|---------------------------------|---|
| Unsuitable extinguishing Media | Not applicable |
| Fire fighting instructions: | Fire fighters should wear positive pressure self-contained breathing apparatus and should be equipped with protective clothing. Keep people away and isolate fire area. |
| Special measures | Not applicable |



SECTION 6. ACCIDENTAL RELEASE MEASURES

| Fire fighting | In case of spill sweep up material and place in containers for re-use or |
|---------------|--|
| instructions: | disposal. |

SECTION 7. HANDING AND STORAGE

| HANDING | Use normal good industrial hygiene and housekeeping practices. Take precautionary measures against static discharges. |
|---------|---|
| STORAGE | Store in a cool, dry, well-ventilated area. Keep away from heat, sparks and flames. Keep containers closed. Avoid moisture contamination. Transferring dry pellets or granules between containers or charging into solvents can cause a build-up of static electricity which can be sufficient to cause fires and/or explosions in the presence of flammable materials. Equipment should provide a means of dissipating any charges that may develop. |

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| Recommended monitoring procedures | If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. |
|-----------------------------------|---|
| Engineering Controls: | No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits |
| Personal Protection: | Respiratory: In case of inadequate ventilation wear respiratory protection. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. Hands: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Eyes: safety glasses with side-shields |
| Exposure Limits: | None known. |



SECTION 9. PHYSICAL AND CHEMICAL PROPERTIED

| Appearance: | Solid | |
|-----------------------------------|---------------------|--|
| Color: | Colorless/light red | |
| Odor: | Slightly smelly | |
| Density: | Not available. | |
| Boiling Point: | Not available. | |
| Melting Point: | Not available. | |
| Flashpoint: | Not available. | |
| Vapour pressure: | Not available. | |
| Solubility in water: | Not available. | |
| Viscosity: | Not available. | |
| PH Value: | Not available. | |
| Permission of solvent inhalation: | Not available. | |
| Ignition temperature: | Not available. | |

SECTION 10. STABILITY AND REACTIVITY

| Stability: | The product is stable. |
|--|--|
| Instability Temperature: | Not available |
| Incompatibility with various substances: | Reactive with oxidizing agents, metals, acids |
| Special Remarks on Reactivity: | Incompatible with air, unsaturated oils, 2-Nitrobenzaldehyde, strong oxidizers such as fluorine, chlorine trifluoride, and potassium peroxide. |
| Conditions to avoid: | Not available. |
| Special Remarks on Corrosivity: | Not available. |
| Polymerization: | Will not occur. |



SECTION 11.TOXICOLOGICAL INFORMATION

| Potential acute health effects | Inhalation: Non-irritating to the respiratory system. Ingestion: Not hazardous in normal industrial use. Skin: Non-irritating. Molten polymer will adhere to skin causing deep thermal burns. Eyes: May cause physical abrasion in contact with eyes. Molten polymer will cause serious burns to the eyes. |
|--|--|
| Toxicity to Animals: | LD50: Not available. LC50: Not available. |
| Chronic effects | No known significant effects or critical hazards. |
| Target organs | No known significant effects or critical hazards. |
| Special Remarks on Toxicity to Animals: | Not available. |
| Special Remarks on Chronic Effects on Humans: | May cause adverse reproductive effects. |

SECTION 12. ECOLOGICAL INFORMATION

| Ecotoxicity: | Not available |
|---|---|
| BOD5 and COD: | Not available. |
| Products of Biodegradation: | Not Determined |
| Toxicity of the Products of Biodegradation: | The product itself and its products of degradation are not toxic. |
| Special Remarks on the Products of Biodegradation: | Not available |

SECTION 13. DISPOSAL CONSIDERATIONS

| Waste Disposal: | Disposal should be in accordance with applicable regional, |
|-----------------|--|
| | national and local laws and regulations. |



SECTION 14.TRANSPORT INFORMATION

This product applied to by sea, by air and by land

| DOT Classification: | Not applicable. |
|--------------------------------------|-----------------------------------|
| IATA: | Not regulated as dangerous goods. |
| IMDG Class | Not applicable |
| UN-Unmber | Not applicable. |
| UN Proper shipping name | Not applicable. |
| Identification: | Not applicable. |
| Special Provisions for Transport: | Not applicable |

SECTION 15. REGULATORY INFORMATION

《Dangerous Goods Regulation》

《Recommendations on Transport of Dangerous Goods Model Regulations》

《International Maritime Dangerous Goods》

《Technical Instructions for the Safe Transport of Dangerous Goods》

《Classification and code of dangerous goods》

《Occupational Safety and Health Act》(OSHA)

《Toxic Substances Control Act》(CPSA)

《Federal Environmental Pollution Control Act》(FEPCA)

《The Oil Pollution Act》(OPA)

《Superfund Amendments and Reauthorization Act III(302/311/312/313)》(SARA)

《Resource Conservation and Recovery Act》(RCRA)

《Safety Drinking Water Act》(CWA)

《California Proposition 65》

《Code of Federal Regulations》(CFR) In accordance with all Federal, State and local laws.

SECTION 16. REGULATORY INFORMATION

The above information is based on the data of which we are aware and is believed to be correct as of the data hereof. Since this information may be applied under conditions beyond our control and with which may be unfamiliar and since data made available subsequent to the data hereof may suggest modifications of the information, we do not assume any responsibility for the results of its use. This information is furnished upon condition that the person receiving it shall make his own determination of the suitability of the material for his particular purpose.

***** THE END *****



Safety Data Sheet (SDS) Report

Applicant: WUXI NEST BIOTECHNOLOGY CO.,LTD Issue Date: 2020-04-14

NO.530 XIDA Road, Wuxi Meicun Industrial Park, Jiangsu province, China

Sample Description:

The sample information was submitted and identified on client's behalf to be:

Product Name : Disposable sampler(VTM)

Physical State : Liquid

Data Received : Apr 08, 2020
Data Reviewed : Apr 14, 2020

Service Requested:

Based on the information provided by the applicant, the Safety Data Sheet (SDS) was generated in accordance with requirements of OSHA HazCom Standard (2012), for details please refer to attached pages.

Authorized By:

On Behalf Of Regulatory Affairs in Intertek Testing Services Ltd., Shanghai

Anna Wang Regulatory Consultant This report shall not be reproduced except in full, without the written approval of the laboratory.

SDS number: WUXH00099737

Intertek Health, Environmental & Regulatory Services (HERS)

5th Floor,Building No.86,1198 QinZhou Road(North),Cao Hejing Development Zone,ShangHai,China.

Tel: +86 021 53397917 ZIP: 200233 E-mail:hers@intertek.com

Safety Data Sheet



Disposable sampler(VTM)

WUXI NEST BIOTECHNOLOGY CO.,LTD

SDS Number:WUXH00099737 Issue Date:14/04/2020

GHS.USA.EN

Version No:1.0 According to OSHA HazCom Standard (2012) requirements

SECTION 1 IDENTIFICATION

| Product Identifier |
|--------------------|
|--------------------|

| Product name | Disposable sampler(VTM) |
|-------------------------------|-------------------------|
| Other means of identification | Not Available |

Recommended use of the chemical and restrictions on use

| Rele | vant identified uses | Use according to manufacturer's directions. |
|------|----------------------|---|
| | | |

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

| WUXI NEST BIOTECHNOLOGY CO.,LTD |
|--|
| NO.530 XIDA Road, Wuxi Meicun Industrial Park, Jiangsu province, China |
| 0086-13814261600 |
| 0086-18352528192 |
| QAmanager00@nest-wuxi.com |
| |
| |
| |
| |
| |

Emergency phone number

| Association / Organisation | |
|-----------------------------------|--|
| Emergency telephone numbers | |
| Other emergency telephone numbers | |

SECTION 2 HAZARD(S) IDENTIFICATION

Classification of the substance or mixture

Not considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes. Classification Not Classified

Label elements

| Hazard pictogram(s) | Not Applicable |
|---------------------|----------------|
| SIGNAL WORD | NOT APPLICABLE |

Hazard statement(s)

Not Applicable

Hazard(s) not otherwise classified

Not Applicable

Supplementary statement(s)

Not Applicable

Precautionary statement(s) General

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

| CAS No | %[weight] | Name |
|------------|-----------|--------------------|
| 24634-61-5 | 0.025 | potassium sorbate |
| 10043-52-4 | 0.014 | calcium chloride |
| 1405-41-0 | 0.005 | gentamicin sulfate |
| 143-74-8 | 0.001 | phenol red |
| 1397-89-3 | 0.000025 | amphotericin B |

SECTION 4 FIRST-AID MEASURES

Description of first aid measures

| Eye Contact | If this product comes in contact with eyes: • Wash out immediately with water. • If irritation continues, seek medical attention. • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
|--------------|--|
| Skin Contact | If skin or hair contact occurs: F Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation. |
| Inhalation | If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary. |
| Ingestion | Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. |

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIRE-FIGHTING MEASURES

Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

| Fire Incompatibility None known. | |
|----------------------------------|-----------------------------------|
| Special protective equipment a | and precautions for fire-fighters |
| | |

| Fire Fighting | Use water delivered as a fine spray to control fire and cool adjacent area. Do not approach containers suspected to be hot. |
|-----------------------|--|
| Fire/Explosion Hazard | Non combustible. Not considered a significant fire risk, however containers may burn. |

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

| Minor Spills | ▶ Clean up all spills immediately. |
|--------------|------------------------------------|
| | |

| | Avoid breathing vapours and contact with skin and eyes. |
|--------------|---|
| Major Spills | Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. |

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

| Safe handling Limit all unnecessary personal contact. Wear protective clothing when risk of exposure occurs. | |
|--|----------------|
| Other information | Not Applicable |

Conditions for safe storage, including any incompatibilities

| Suitable container | Polyethylene or polypropylene container. Packing as recommended by manufacturer. | |
|-------------------------|---|--|
| Storage incompatibility | None known | |

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

EMERGENCY LIMITS

| Ingredient | Material name | TEEL-1 | TEEL-2 | TEEL-3 |
|-------------------------|------------------|----------|---------------|-----------|
| calcium chloride | Calcium chloride | 12 mg/m3 | 130 mg/m3 | 790 mg/m3 |
| Ingredient | Original IDLH | | Revised IDLH | |
| Disposable sampler(VTM) | Not Available | | Not Available | |

Exposure controls

| Appropriate engineering controls | Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. | |
|--|--|--|
| Personal protection | | |
| Eye and face protection P Safety glasses with side shields P Chemical goggles. P Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. | | |
| Skin protection | See Hand protection below | |
| Hands/feet protection Wear general protective gloves, eg. light weight rubber gloves. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advantant has therefore to be checked prior to the application. | | |
| Body protection | See Other protection below | |
| Other protection | No special equipment needed when handling small quantities. OTHERWISE: Overalls. | |

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| Appearance | Red Liquid | | |
|-----------------|---------------|---|---------------|
| Physical state | Liquid | Relative density (Water = 1) | Not Available |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |

| pH (as supplied) | Not Available | Decomposition temperature | Not Available |
|--|---------------|----------------------------------|---------------|
| Melting point / freezing point (°C) | Not Available | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | Not Available | Molecular weight (g/mol) | Not Available |
| Flash point (°C) | Not Available | Taste | Not Available |
| Evaporation rate | Not Available | Explosive properties | Not Available |
| Flammability | Not Flammable | Oxidising properties | Not Available |
| Upper Explosive Limit (%) | Not Available | Surface Tension (dyn/cm or mN/m) | Not Available |
| Lower Explosive Limit (%) | Not Available | Volatile Component (%vol) | Not Available |
| Vapour pressure (kPa) | Not Available | Gas group | Not Available |
| Solubility in water | Not Available | pH as a solution (1%) | Not Available |
| Vapour density (Air = 1) | Not Available | VOC g/L | Not Available |

SECTION 10 STABILITY AND REACTIVITY

| Reactivity | See section 7 | |
|------------------------------------|---|--|
| Chemical stability | uct is considered stable and hazardous polymerisation will not occur. | |
| Possibility of hazardous reactions | See section 7 | |
| Conditions to avoid | See section 7 | |
| Incompatible materials | See section 7 | |
| Hazardous decomposition products | See section 5 | |

SECTION 11 TOXICOLOGICAL INFORMATION

| SECTION 11 TOXICOLOGIC | AL INFORMATION |
|--|---|
| nformation on toxicological ef | fects |
| Acute Toxicity | calcium chloride Oral (mouse) LD50: 1940 mg/kg ^[2] Oral (Rabbit) LD50: 1384 mg/kg ^[2] Oral (rat) LD50: 1000 mg/kg ^[2] phenol red Oral (rat) LD50: >600 mg/kg ^[2] potassium sorbate dermal (rat) LD50: >2000 mg/kg ^[1] Oral (rat) LD50: 3200-10500 mg/kg ^[2] gentamicin sulfate Oral (rat) LD50: >5000 mg/kg ^[2] amphotericin B Oral (rat) LD50: >5000 mg/kg ^[2] |
| Skin Irritation/Corrosion | Based on available data, the classification criteria are not met. |
| Serious Eye Damage/Irritation | Based on available data, the classification criteria are not met. |
| Respiratory or Skin sensitisation | Based on available data, the classification criteria are not met. |
| Mutagenicity | Based on available data, the classification criteria are not met. |
| Carcinogenicity | Based on available data, the classification criteria are not met. |
| Reproductivity Based on available data, the classification criteria are not met. | |
| STOT - Single Exposure | Based on available data, the classification criteria are not met. |
| STOT - Repeated Exposure | Based on available data, the classification criteria are not met. |
| Aspiration Hazard | Based on available data, the classification criteria are not met. |
| Legend: | 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise |

specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

| Disposable sampler(VTM) | Based on available data, the classification criteria are not met. |
|-------------------------|---|
| | |

Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|----------------|-------------------------|------------------|
| phenol red | HIGH | HIGH |
| amphotericin B | LOW | LOW |

Bioaccumulative potential

| Ingredient | Bioaccumulation |
|----------------|------------------------|
| phenol red | LOW (LogKOW = 3.02) |
| amphotericin B | LOW (LogKOW = -3.5441) |

Mobility in soil

| Ingredient | Mobility |
|----------------|---------------------|
| phenol red | LOW (KOC = 1170000) |
| amphotericin B | LOW (KOC = 7692000) |

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.

Product / Packaging disposal

- ▶ DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
 Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.

SECTION 14 TRANSPORT INFORMATION

| Marine Pollutant | NO |
|------------------|----|
| | |

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

CALCIUM CHLORIDE IS FOUND ON THE FOLLOWING REGULATORY LISTS

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

US TSCA Chemical Substance Inventory - Interim List of Active Substances

PHENOL RED IS FOUND ON THE FOLLOWING REGULATORY LISTS

US List of Active Substances Exempt from the TSCA Inventory Notifications (Active-Inactive) Rule

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

POTASSIUM SORBATE IS FOUND ON THE FOLLOWING REGULATORY LISTS

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

US TSCA Chemical Substance Inventory - Interim List of Active Substances

GENTAMICIN SULFATE IS FOUND ON THE FOLLOWING REGULATORY LISTS

Chemical Footprint Project - Chemicals of High Concern List US - California Proposition 65 - Reproductive Toxicity

US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List

AMPHOTERICIN B IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

| 020110110111111111111111111111111111111 | |
|--|----|
| Flammable (Gases, Aerosols, Liquids, or Solids) | No |
| Gas under pressure | No |
| Explosive | No |
| Self-heating | No |
| Pyrophoric (Liquid or Solid) | No |
| Pyrophoric Gas | No |
| Corrosive to metal | No |
| Oxidizer (Liquid, Solid or Gas) | No |
| Organic Peroxide | No |
| Self-reactive | No |
| In contact with water emits flammable gas | No |
| Combustible Dust | No |
| Carcinogenicity | No |
| Acute toxicity (any route of exposure) | No |
| Reproductive toxicity | No |
| Skin Corrosion or Irritation | No |
| Respiratory or Skin Sensitization | No |
| Serious eye damage or eye irritation | No |
| Specific target organ toxicity (single or repeated exposure) | No |
| Aspiration Hazard | No |
| Germ cell mutagenicity | No |
| Simple Asphyxiant | No |
| Hazards Not Otherwise Classified | No |

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES (40 CFR 302.4)

None Reported

State Regulations

US. CALIFORNIA PROPOSITION 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm

US - CALIFORNIA PROPOSITION 65 - REPRODUCTIVE TOXICITY: LISTED SUBSTANCE

Aminoglycosides Listed

SECTION 16 OTHER INFORMATION

Other information

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

Definitions and abbreviations

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index



Nomination No.: MPTJ2000003-01AE-US

Safety Data Sheet (SDS)

Product Name: Virus Sampling Kit

Report Version: Prepared according to American OSHA HazCom Standard (2012)

Application Company Name: Yocon Biology Technology Company

Application Company Address: 3/F, Bldg.B, No.7, Fengxian Rd, Yong FENG Base, Haidian District

Contract Information: 010-58711655

24 Hour Emergency Call: 010-58711552

Report Edit time: 2020-5-9



2020-5-11



The report would be invalid without authorized signature. The report shall not be reproduced except in full, without written approval of

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/en/Terms-and-conditions.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention. only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

TJMIN

069180 www.sgsgroup.com.cn e sgs.china@sgs.com

Safety Data Sheet

Virus Sampling Kit

Version: V1.0.0.1

Report No.: MPTJ2000053-01AE-US

Creation Date: 2020/05/09 Revision Date: 2020/05/09

*Prepared according to American OSHA HazCom Standard (2012)

Identification of the chemical and supplier

Product identifier

| Product Name | Virus Sampling Kit |
|-------------------|---|
| Product Model | Virus Sampling Kit MT0301-1 MT0301-2 |
| CAS No. | Not applicable |
| EC No. | Not applicable |
| Molecular Formula | Not applicable |

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

The virus sampling kit is based on Hank's solution. The solution contains inorganic salts, amino acids, and protein-stable ingredients. The virus sampling kit has a stable osmotic pressure, which provides astable transport and storage environment for nasopharyngeal swab samples. Samples are sent to the laboratory for follow-up testing to determine whether the collected samples are infected with the virus.

Uses advised against

For in vitro diagnosis only.

Details of the supplier of the Safety Data Sheet

| l | Name of the company |
|---|---------------------|
| ١ | Address of the |
| ı | company |
| ı | Post code |

Yocon Biology Technology Company

3/F, Bldg.B, No.7, Fengxian Rd, Yong FENG Base, Haidian District

100094

Telephone number

010-58711655

Fax number

010-58711655

E-mail address

Lihaifeng@yocon.com.cn

Emergency phone number

| Emergency | phone |
|-----------|-------|
| n | umber |

010-58711552

Hazards identification

Hazard classification according to GHS

| Hazard | classi | fica | ation |
|--------|--------|------|------------|
| acco | rding | to | GHS |

Not applicable

Label elements

| PPIICUDIC |
|-----------|
| pplicable |
| |

Hazard statements

Hazard statements | Not applicable

Precautionary statements

Prevention

Prevention | Not applicable

Response

Response | Not applicable

Storage

Storage | Not applicable

Disposal

Disposal | Not applicable

Other hazards

Not applicable

| Hazard description

Physical and chemical hazards

Liquid, toxic smoke/fumes in a fire.

Health hazards

Inhaled

Inhalation of the product may produce adverse health effects or irritation of the respiratory tract following discomfort.

Ingestion

Accidental ingestion of the product may be harmful to the health of the individual.

Skin Contact

Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

This product may cause temporary discomfort following direct contact with the

Eye eye.

Environmental hazards

Please refer to 12th chapter of SDS.

3 Composition/information on ingredients

| Component | Cas No. | EC No. | Concentration (weight percent, %) |
|---|------------|-----------|-----------------------------------|
| Protein and amino acid | 1 | | Commercial secrets |
| Sodium chloride | 7647-14-5 | 231-598-3 | 0.8 |
| D()-Glucose | 50-99-7 | 200-075-1 | 0.1 |
| Potassium chloride | 7447-40-7 | 231-211-8 | 0.04 |
| Sodium bicarbonate | 144-55-8 | 205-633-8 | 0.035 |
| Magnesium sulfate heptahydrate | 10034-99-8 | 600-073-4 | 0.02 |
| Gentamicin | 1403-66-3 | 215-765-8 | Commercial secrets |
| Calcium chloride | 10043-52-4 | 233-140-8 | 0.014 |
| Disodium hydrogen phosphate heptahydrate | 7782-85-6 | 616-512-8 | 0.012 |
| Potassium dihydrogen phosphate | 7778-77-0 | 231-913-4 | 0.006 |

| Phenol red sodium salt | 34487-61-1 | 252-057-8 | 0.002 | |
|------------------------|------------|-----------|--------|--|
| Purified water | 7732-18-5 | 231-791-2 | 97.897 | |

Version: V1.0.0.1 Revision Date: 2020/05/09

First aid measures

Description of first aid measures

| Description of mot ara | |
|----------------------------|---|
| General advice | Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance. |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if feel uncomfortable. |
| Skin contact | No harm in general situation. First aid is not needed. |
| Ingestion | Never give anything by mouth to an unconscious person. Call a physician immediately. |
| | Move victim into fresh air. If breathing is difficult, give oxygen. Do not use mouth to mouth resuscitation if victim ingested or inhaled the substance. If not breathing, give artificial respiration and consult a physician immediately. |
| Protecting of first-aiders | Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination. |

Most important symptoms and effects, both acute and delayed

1 Please see section 11.

Indication of any immediate medical attention and special treatment needed

- 1 | Treat symptomatically.
- 2 Symptoms may be delayed.

Firefighting measures

Extinguishing media

| Suitable | extinguishing |
|----------|---------------|
| | media |
| | Unsuitable |
| exting | uishing media |

Use extinguishing media suitable for surrounding area.

There is no restriction on the type of extinguisher which may be used.

Specific hazards arising from the substance or mixture

- 1 Development of hazardous combustion gases or vapor possible in the event of fire.
- 2 Not considered a significant fire risk, however containers may burn.

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.
- 2 Fight fire from a safe distance, with adequate cover.
- 3 Prevent fire extinguishing water from contaminating surface water or the ground water system.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

- 1 Ensure adequate ventilation. Remove all sources of ignition.
- 2 Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
- 3 Use personal protective equipment. Avoid breathing vapours, mist or gas.

| Environmental precautions

- 1 Prevent further leakage or spillage if safe to do so.
- 2 Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up

- 1 Absorb spilled material in dry sand or inert absorbent. In case of large amount of spillage, contain a spill by bunding.
- Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.
- 3 Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

7 Handling and storage

Precautions for handling

- 1 Handling is performed in a well ventilated place.
- 2 Avoid contact with eyes.
- 3 Keep away from heat/sparks/open flames/ hot surfaces.

Precautions for storage

- 1 Keep containers tightly closed.
- 2 Keep containers in a dry, cool and well-ventilated place.
- 3 Keep away from heat/sparks/open flames/hot surfaces.
- 4 Store away from incompatible materials and foodstuff containers.

Exposure controls/personal protection

| Control parameters

Occupational Exposure limit values

| Component | | Limit value - Eight hours | | Limit value - Short term | |
|---------------------------------|------------------|---------------------------|-------|--------------------------|---------------|
| | Country/Region | ppm | mg/m³ | ppm | mg/m³ |
| Sodium chloride 7647-14-5 | Latvia | - | 5 | | - |
| Potassium chloride 7447-40-7 | Latvia | 7 | 5 | 147 | -5 |
| Sodium bicarbonate 144-55-8 | Latvia | <u></u> <u>2</u> | 5 | | /- |
| Calcium chloride 10043-52-4 | Latvia | - | 2 | (4) | - |
| | Canada - Ontario | 4 | 5 | 0-0 | 3/ |

Biological limit values

Biological limit values | No relevant regulations

Monitoring methods

- 1 EN 14042 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.
- 2 GBZ/T 160.1~GBZ/T 160.81-2004 Determination of toxic substances in workplace air (Series standard).

| Engineering controls

- 1 Ensure adequate ventilation, especially in confined areas.
- 2 Ensure that eyewash stations and safety showers are close to the workstation location.

Version: V1.0.0.1 Revision Date: 2020/05/09

- 3 Set up emergency exit and necessary risk-elimination area.
- 4 Handle in accordance with good industrial hygiene and safety practice.

| Personal protection equipment

| General requirement | No special requirements, please see the description below. |
|----------------------------|--|
| Eye protection | In general situation, eye protection is not needed. In the production process, when contacting with vapour, tightly fitting safety goggles (approved by EN 166(EU) or NIOSH (US). |
| Hand protection | In general situation, hand protection is not needed. |
| Respiratory protection | In general situation, respiratory protection is not needed. If exposure limits are exceeded or if irritation or other symptoms are experienced, use a full-face respirator with multi-purpose combination (US) or type AXBEK (EN 14387) respirator cartridges. |
| Skin and body protection | In general situation, skin and body protection are not needed. |

Physical and chemical properties

Physical and chemical properties

| Appearance | Colorless clear liquid |
|--|--|
| The Red Control of the Control of th | - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 |
| Odor | No odor |
| Odor threshold | No information available |
| рН | 7.0~7.6 (20°C~25°C, Sample solution) |
| Melting point/freezing point(℃) | No information available |
| Initial boiling point and boiling range(°C) | >35 |
| Flash point(Closed cup,°C) | No information available |
| Evaporation rate | No information available |
| Flammability | Not flammable |
| Upper/lower explosive limits[%(v/v)] | Upper limit: No information available; Lower limit: No information available |
| Vapor pressure | No information available |
| Vapor density(Air = 1) | No information available |
| Relative density(Water=1) | No information available |
| Solubility(mg/L) | Miscible with water |
| n-octanol/water partition coefficient | No information available |
| Auto-ignition temperature(°C) | No information available |
| Decomposition temperature(°C) | No information available |
| Viscosity(mm ² /s) | No information available |

10 Stability and reactivity

Stability and reactivity

| Reactivity | Contact with incompatible substances can cause decomposition or other chemical reactions. |
|-----------------|---|
| nical stability | Stable under proper operation and storage conditions |

Possibility of hazardous reactions

In contact with organic peroxides cause a fire immediately. In contact with active metals (alkali metals, Na, Ca etc.) causes a reaction and release hydrogen.

Conditions to avoid Incompatible materials, heat, flame and spark.

Incompatible materials Hazardous Organic peroxides. Alkali, sodium, calcium, and other active metal, halogen, metal oxide, nonmetal oxide, acyl halide and metal phosphide.

Hazardous Under normal conditions of storage and use, hazardous decomposition decomposition products should not be produced.

11 Toxicological information

Acute toxicity

| Component | Cas No. | LD ₅₀ (oral) | LD ₅₀ (dermal) | LC ₅₀ (inhalation,4h) |
|---|------------|-----------------------------|---------------------------|----------------------------------|
| Gentamicin | 1403-66-3 | 6600mg/kg(Rat) | No information available | No information available |
| Potassium dihydrogen phosphate | 7778-77-0 | No information available | >4640mg/kg(Rabbit) | No information available |
| Sodium chloride | 7647-14-5 | 3000mg/kg(Rat) | >10000mg/kg(Rabbit) | No information available |
| D()-Glucose | 50-99-7 | 25800mg/kg(Rat) | No information available | No information available |
| Calcium chloride | 10043-52-4 | 1000mg/kg(Rat) | No information available | No information available |
| Potassium chloride | 7447-40-7 | 2600mg/kg(Rat) | No information available | No information available |
| Disodium hydrogen phosphate heptahydrate | 7782-85-6 | 12930mg/kg(Rat) | No information available | No information available |
| Sodium bicarbonate | 144-55-8 | 4220mg/kg(Rat) | No information available | No information available |

Carcinogenicity

| ID | Cas No. | Component | IARC | NTP |
|----|------------|--|------------|------------|
| 1 | 1 | Protein and amino acid | Not Listed | Not Listed |
| 2 | 7647-14-5 | Sodium chloride | Not Listed | Not Listed |
| 3 | 50-99-7 | D()-Glucose | Not Listed | Not Listed |
| 4 | 7447-40-7 | Potassium chloride | Not Listed | Not Listed |
| 5 | 144-55-8 | Sodium bicarbonate | Not Listed | Not Listed |
| 6 | 10034-99-8 | Magnesium sulfate heptahydrate | Not Listed | Not Listed |
| 7 | 1403-66-3 | Gentamicin | Not Listed | Not Listed |
| 8 | 10043-52-4 | Calcium chloride | Not Listed | Not Listed |
| 9 | 7782-85-6 | Disodium hydrogen phosphate heptahydrate | Not Listed | Not Listed |
| 10 | 7778-77-0 | Potassium dihydrogen phosphate | Not Listed | Not Listed |
| 11 | 34487-61-1 | Phenol red sodium salt | Not Listed | Not Listed |
| 12 | 7732-18-5 | Purified water | Not Listed | Not Listed |

Others

| | Virus Sampling Kit |
|----------------------------------|--|
| Skin corrosion/irritation | Based on available data, the classific |
| Serious eye damage/irritation | Based on available data, the classific |
| Skin sensitization | Based on available data, the classific |
| | |

damage/irritation
Skin sensitization
Respiratory sensitization
Reproductive toxicity
STOT-single exposure
STOT-repeated exposure
Aspiration hazard
Germ cell mutagenicity
Reproductive

Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met Based on available data, the classification criteria are not met

12 Ecological information

toxicity(additional)

Acute aquatic toxicity

| Component | Cas No. | Fish | Crustaceans | Algae |
|-----------------------------------|------------|--|---|-----------------------------|
| Sodium chloride | 7647-14-5 | LC ₅₀ : 7400mg/L (96h)(Fish) | EC ₅₀ : 2120mg/L (48h)(Crustaceans) | No information available |
| Magnesium sulfate heptahydrate | 10034-99-8 | LC ₅₀ : 2820mg/L (96h)(Fish) | EC ₅₀ : 344mg/L (48h)(Crustaceans) | No information available |
| Calcium chloride | 10043-52-4 | LC ₅₀ : 9500mg/L (96h)(Fish) | EC ₅₀ : 1400mg/L (48h)(Crustaceans) | No information available |
| Potassium chloride | 7447-40-7 | LC ₅₀ : 880mg/L (96h)(Fish) | EC ₅₀ : 141mg/L (48h)(Crustaceans) | No information available |
| Sodium bicarbonate | 144-55-8 | LC ₅₀ : 8600mg/L (96h)(Fish) | No information available | No information available |

Chronic aquatic toxicity

Chronic aquatic toxicity No information available

Persistence and degradability

| Component | Cas No. | Persistence (water/soil) | Persistence (air) |
|-----------------------------------|------------|--------------------------|-------------------|
| Sodium chloride | 7647-14-5 | Low | Low |
| D()-Glucose | 50-99-7 | Low | Low |
| Potassium chloride | 7447-40-7 | High | High |
| Sodium bicarbonate | 144-55-8 | Low | Low |
| Magnesium sulfate heptahydrate | 10034-99-8 | High | High |
| Purified water | 7732-18-5 | Low | Low |

| Bioaccumulative potential

| Component | Cas No. | Bioaccumulative potential | comments | |
|-----------|---------|---------------------------|----------|--|
| | | | | |

| Sodium chloride | 7647-14-5 | Low | Log Kow=0.5392 |
|-----------------------------------|------------|-----|-----------------|
| D()-Glucose | 50-99-7 | Low | Log Kow=-3.3 |
| Potassium chloride | 7447-40-7 | Low | Log Kow=-0.4608 |
| Sodium bicarbonate | 144-55-8 | Low | Log Kow=-0.4605 |
| Magnesium sulfate heptahydrate | 10034-99-8 | Low | Log Kow=-2.2002 |
| Purified water | 7732-18-5 | Low | Log Kow=-1.38 |

| Mobility in soil

| Component | Cas No. | Mobility in soil | Soil Organic Carbon-Water Partitioning Coefficient (Koc) |
|-----------------------------------|---------------------------------|------------------|---|
| Sodium chloride | 7647-14-5 | Low | 14.3 |
| D()-Glucose | 50-99-7 | Low | 10 |
| Potassium chloride | 7447-40-7 | Low | 14.3 |
| Sodium bicarbonate | odium bicarbonate 144-55-8 High | | 1 |
| Magnesium sulfate heptahydrate | | | 6.124 |
| Purified water | 7732-18-5 | Low | 14.3 |

Results of PBT and vPvB assessment

| Component | Cas No. | Results of PBT and vPvB assessment (according to (EC) No 1907/2006) |
|--|------------|--|
| Sodium chloride | 7647-14-5 | not PBT/vPvB |
| D()-Glucose | 50-99-7 | not PBT/vPvB |
| Potassium chloride | 7447-40-7 | not PBT/vPvB |
| Sodium bicarbonate | 144-55-8 | not PBT/vPvB |
| Magnesium sulfate heptahydrate | 10034-99-8 | not PBT/vPvB |
| Gentamicin | 1403-66-3 | not PBT/vPvB |
| Calcium chloride | 10043-52-4 | not PBT/vPvB |
| Disodium hydrogen phosphate heptahydrate | 7782-85-6 | not PBT/vPvB |
| Potassium dihydrogen phosphate | 7778-77-0 | not PBT/vPvB |
| Phenol red sodium salt | 34487-61-1 | not PBT/vPvB |
| Purified water | 7732-18-5 | not PBT/vPvB |

13 Disposal considerations

Disposal considerations

Waste chemicals
Contaminated

packaging

Before disposal should refer to the relevant national and local laws and regulation. Recommend the use of incineration disposal.

Containers may still present chemical hazard when empty. Keep away from hot and ignition source of fire. Return to supplier for recycling if possible.

Disposal recommendations Refer to section waste chemicals and contaminated packaging.

14 Transport information

Label and Mark

Transporting Label

Not applicable

IMDG-CODE

IMDG-CODE NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

ICAO/IATA-DGR

ICAO/IATA-DGR | NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

UN-ADR

UN-ADR NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Notes

5-25°C transportation

15 Regulatory information

International chemical inventory

| Component | EINECS | TSCA | DSL | IECSC | NZIoC | PICCS | KECI | AICS | ENCS |
|---|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Protein and amino acid | × | × | × | × | × | × | × | × | × |
| Sodium chloride | √ | √ | √ | V | √ | V | √ | √ | √ |
| D()-Glucose | √ | V | √ | √ | √ | √ | √ | √ | V |
| Potassium chloride | √ | √ | V | V | V | V | √ | √ | √ |
| Sodium bicarbonate | √ | √ | √ |
| Magnesium sulfate heptahydrate | × | × | √ | √ | √ | √ | × | √ | × |
| Gentamicin | √ | × | × | V | √ | √ | × | √ | × |
| Calcium chloride | √ | √ | √ | √ | √ | V | V | √ | V |
| Disodium hydrogen phosphate heptahydrate | × | × | × | √ | V | √ | × | √ | × |
| Potassium dihydrogen phosphate | ✓ | V | √ | √ | √ | V | √ | √ | √ |
| Phenol red sodium salt | √ | × | × |
| Purified water | V | √ | V | √ | V | √ | √ | V | 1 |

[EINECS] European Inventory of Existing Commercial Chemical Substances

[TSCA] United States Toxic Substances Control Act Inventory

[DSL] Canadian Domestic Substances List

[IECSC] China Inventory of Existing Chemical Substances

New Zealand Inventory of Chemicals [NZIoC]

[PICCS] Philippines Inventory of Chemicals and Chemical Substances

Existing and Evaluated Chemical Substances [KECI]

[AICS] Australia Inventory of Chemical Substances

[ENCS] **Existing And New Chemical Substances** Note

" $\sqrt{}$ " Indicates that the substance included in the regulations

"x" That no data or included in the regulations

16 Others

Information on revision

 Creation Date
 2020/05/09

 Revision Date
 2020/05/09

 Reason for revision

Reference

[1]IPCS: The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home.

[2]IARC, website: http://www.iarc.fr/.

[3]OECD: The Global Portal to Information on Chemical Substances, website:

http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en.

[4]CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple.

[5]NLM: ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp.

[6]EPA: Integrated Risk Information System, website: http://cfpub.epa.gov/iris/.

[7]U.S. Department of Transportation: ERG, website: http://www.phmsa.dot.gov/hazmat/library/erg.

[8]Germany GESTIS-database on hazard substance, website: http://gestis-en.itrust.de/.

Abbreviations and acronyms

CAS - Chemical Abstracts Service

PC-STEL- Short term exposure limit

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC₅₀ - Lethal Concentration 50%

NOEC -No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

BCF - Bioconcentration factor (BCF)

IMDG-International Maritime Dangerous Goods

UN-The United Nations

NFPA-National Fire Protection Association

CMR - Carcinogens, mutagens or substances toxic to reproduction

Version: V1.0.0.1 Revision Date: 2020/05/09

PC-TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

PNEC - Predicted No Effect Concentration

LD₅₀ - Lethal Dose 50%

EC₅₀ - Effective Concentration 50%

POW - Partition coefficient Octanol: Water

vPvB - very Persistent, very Bioaccumulative

ICAO/IATA-International Civil Aviation Organization/International Air

Transportation Association

ACGIH-American Conference of Governmental Industrial Hygienists

OECD-Organization for Economic Co-operation and Development

Disclaimer

This Safety Data Sheet (SDS) was prepared according to OSHA HazCom Standard (2012). The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.



Page 1/5

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.04.2020 Revision: 22.04.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- · Trade name: GBO Buffer pH7.4 (PBS Solution)
- · Article number: HL0721
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Life cycle stages IS Use at industrial Sites
- · Sector of Use SU20 Health services
- · Application of the substance / the mixture Tubes for transporting samples
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Greiner Bio-One GmbH

Bad Haller Str. 32

4550 Kremsmuenster, Austria

T: +43 7583 6791-0

www.gbo.com/preanalytics

- · Further information obtainable from: msdsoffice@gbo.com
- · 1.4 Emergency telephone number: Poison Information Center: +44 845 4647, +44 8454 24 24 24

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.
- · Dangerous components: Void
- · Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.

(Contd. on page 2)

Printing date 22.04.2020 Revision: 22.04.2020

Trade name: GBO Buffer pH7.4 (PBS Solution)

(Contd. of page 1)

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Dilute with plenty of water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Storage class: 12
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

(Contd. on page 3)

Printing date 22.04.2020 Revision: 22.04.2020

Trade name: GBO Buffer pH7.4 (PBS Solution)

(Contd. of page 2)

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Dynamic:

Kinematic:

· Solvent content:

Water: VOC (EC)

Nitrile rubber, NBR Butyl rubber, BR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

| General Information | |
|---|---|
| Appearance: | Fluid |
| Form: Colour: | r iuia Colourless |
| Cotour: Odour: | Odourless |
| Odour threshold: | Not determined. |
| | |
| pH-value: | Not determined. |
| Change in condition | |
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range | : 100 °C |
| Flash point: | Not applicable. |
| Flammability (solid, gas): | Not applicable. |
| Decomposition temperature: | Not determined. |
| Auto-ignition temperature: | Product is not selfigniting. |
| Explosive properties: | Product does not present an explosion hazard. |
| Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| Vapour pressure: | Not determined. |
| Density at 20 °C: | ~1 g/cm³ |
| Relative density | Not determined. |
| Vapour density | Not determined. |
| Evaporation rate | Not determined. |
| Solubility in / Miscibility with | |
| water: | Fully miscible. |
| Partition coefficient: n-octanol/water: | Not determined. |

Not determined.

Not determined.

<97.0 %

0.00 %

(Contd. on page 4)

Printing date 22.04.2020 Revision: 22.04.2020

Trade name: GBO Buffer pH7.4 (PBS Solution)

(Contd. of page 3)

Solids content: <2.5 %

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

(Contd. on page 5)

Printing date 22.04.2020 Revision: 22.04.2020

Trade name: GBO Buffer pH7.4 (PBS Solution)

(Contd. of page 4)

· Recommended cleansing agents: Water, if necessary together with cleansing agents.

| SECTION 14: Transport informat | tion | |
|---|------------------------------------|--|
| · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void | |
| · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void | |
| · 14.3 Transport hazard class(es) | | |
| · ADR, ADN, IMDG, IATA · Class | Void | |
| · 14.4 Packing group · ADR, IMDG, IATA | Void | |
| · 14.5 Environmental hazards: | Not applicable. | |
| · 14.6 Special precautions for user | Not applicable. | |
| · 14.7 Transport in bulk according to Anno Marpol and the IBC Code | ex II of Not applicable. | |
| · UN ''Model Regulation'': | Void | |

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

* * Data compared to the previous version altered.

GB

Version: 02 Date: 29/10/2020

SAFETY DATA SHEET according to Hazard Communication Standard (HCS) 29 CFR 1910.1200

SECTION 1.0 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Product name: PrimeStore Molecular Transport Medium® (MTM)

1.2 Relevant identified uses of the substance or mixture and uses advised

against

Identified uses: Transport medium for swabs

1.3 Details of the supplier of the safety data sheet

Name: Longhorn Vaccines and Diagnostics LLC

Address: 1747 Citadel Plaza, Ste 206, San Antonio, TX 78209

Telephone: USA (210) 826-0910 Email: info@lhnvd.com

1.4 Emergency telephone number

001-301-233-1551 (24 hours).

SECTION 2.0 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS classification according to 29 CFR 1910.1200 (OSHA HCS)

| Hazard classes and hazard categories | Hazard statements |
|--|-------------------|
| Acute toxicity, category 4, inhalation | H332 |
| Skin corrosion, category 1C | H314 |
| Serious eye damage, category 1 | H318 |
| Chronic aquatic toxicity, category 3 | H412 |

For the full text of the H-Statements mentioned in this section, see section 16.

2.2 GHS Label elements

Hazard pictograms



Signal word: Danger

| Hazard statements | |
|-------------------|--|
| H332 | Harmful if inhaled. |
| H314 | Causes severe skin burns and eye damage. |
| H412 | Harmful to aquatic life with long lasting effects. |

Version: 02 Date: 29/10/2020

| Precautionary stateme | ents |
|-----------------------|--|
| P304 + P340 | IF INHALED: Remove to fresh air and keep at rest in a position |
| | comfortable for breathing. |
| P303 +P361 + P353 | IF ON SKIN (or hair): Remove/ Take off immediately all |
| | contaminated clothing. Rinse skin with water/shower. |
| P305 +P351 +P338 | IF IN EYES: Rinse cautiously with water for several minutes. |
| | Remove contact lenses, if present and easy to do. Continue |
| | rinsing. |
| P301 + P330 + P331 | IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. |
| P260 | Do not breathe fumes/mist/vapours/spray. |
| P280 | Wear protective gloves/protective clothing/eye protection/face |
| | protection. |
| P264 | Wash hands thoroughly after handling. |
| P273 | Avoid release to the environment. |

2.3 Hazards not otherwise classified (HNOC)

Contact with acids liberates very toxic gas.

< 0.7% of the mixture consists of ingredients of unknown dermal toxicity.

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3.0 COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

| Chemical Name | Percentage Range | CAS No. | Classification |
|---------------------------------------|---------------------|----------|--|
| Guanidine Thiocyanate | 20 - 30 | 593-84-0 | Acute Tox. 4; H302+H312+H332 Skin Corr. 1C; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 |
| Ethanol | 19 - 25 | 64-17-5 | Flam. Liq.2; H225 Eye Irrit.2; H319 Specific concentration limits: ≥ 50% Eye. Irrit. 2 |
| N-Lauroylsarcosine Na ⁺ | < 0.7 | 137-16-6 | Acute Tox.2; H330 Skin Irrit.2; H315 Eye Dam.1; H318 Specific concentration limits: ≤ 34.5% Acute Tox. 4 > 34.5% Acute Tox. 2 > 30% Skin Irrit. 2; Eye damage 1 ≥ 1 - ≤ 30% Eye Irrit. 2 |

PrimeStore Molecular Transport Medium® (MTM)

Version: 02 Date: 29/10/2020

SECTION 4.0 FIRST AID MEASURES

4.1 Description of first aid measures General advice

If exposed or in case of symptoms caused by eye or skin contact, inhalation or swallowing, consult a physician. Show this safety data sheet to the physician in attendance. Never give anything by mouth to an unconscious person. Do not leave affected person unattended.

In case of inhalation: Remove patient immediately from

source of exposure. Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical

device.

In case of eye contact: Rinse immediately with plenty of water

(also under the eyelids) for at least 15 minutes, holding the eye open. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain immediate

medical attention.

In case of skin contact: Wash off immediately with plenty of soap

and water. Take off contaminated clothing and shoes immediately and wash before reuse. Obtain immediate

medical attention.

In case of ingestion: Immediately call a POISON

CENTRE/doctor. Do not induce

vomiting. Immediately rinse mouth with water and drink plenty of water (200-

300ml).

4.2 Most important symptoms and effects, both acute and delayed

Product is a corrosive material. Causes severe burns by all exposure routes. May cause perforation of the stomach or oesophagus. Ingestion causes severe swelling, severe damage to delicate tissue and possible perforation.

4.3 Indication of any immediate medical attention and special treatment needed Obtain immediate medical attention following inhalation, ingestion or skin, or eye contact. Treatment should be symptomatic and supportive.

Version: 02 Date: 29/10/2020

SECTION 5.0 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, alcohol resistant foam, carbon

dioxide or dry powder.

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Produces hazardous combustion products of hydrogen sulphide, sulphur dioxide, ammonia, hydrocyanic acid, carbon oxides, nitric oxides.

5.3 Advice for firefighters

Self-contained breathing apparatus with full-face mask and full protective clothing. Containers may explode in heat of fire. Use water to cool fire-exposed containers and to disperse vapour. Prevent run-off from fire-fighting entering drains, sewers or watercourses.

5.4 Further information

None.

SECTION 6.0 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation. Wear appropriate protective clothing - see Section 8. Do not breathe fumes/mist/vapours/spray. Avoid contact with skin and eyes.

6.2 Environmental precautions

Product or extinguishing media with product must not be allowed to enter soil, drains, sewers or watercourses. Do not flush into surface water or sanitary sewer system. Advise Authorities if spillage has entered water course or sewer or has contaminated soil or vegetation.

6.3 Methods and material for containment and cleaning up

Absorb using earth, sand or other inert material then transfer into suitable, closed containers for disposal. Ventilate contaminated area thoroughly. Flush with water. Dispose of as hazardous waste.

6.4 Reference to other sections

See also Sections 8 and 13.

Version: 02 Date: 29/10/2020

SECTION 7.0 HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Provide appropriate exhaust ventilation at machinery.

Do not inhale vapours, mists or aerosols. Avoid contact with eyes, skin and clothing. Keep away from heat.

Wear protective gloves/protective clothing/eye protection/face protection. Wash parts of the body in contact with substance thoroughly after handling. Do not eat, drink or smoke when using this product. See section 8.2 for occupational hygiene and exposure prevention measures.

7.2 Consideration for safe storage, including any incompatibilities

Store unused product at 2 to 25 Deg C. Store in the dark. Storage area should be dry, well ventilated, out of direct sunlight and separated from oxidants and acids. Store in tightly closed, original containers. Store away from sources of heat. Do not smoke eat or drink in areas of use and storage.

7.3 Specific end use(s)

Refer to Section 1.

SECTION 8.0 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters:

| Chemical Name | CAS No. | Value | Control parameters | Comments |
|---|----------|-------|--------------------------------------|--|
| Guanidine Thiocyanate | 593-84-0 | | parameters | No Occupational Exposure Limit assigned |
| Ethanol | 64-17-5 | TWA | 1,000 ppm 1,900 mg/m ³ | USĂ - OSHA |
| | | STEL | 1,000 ppm | USA – ACGIH Threshold Limit Value (TLV) |
| | | TWA | 1,000 ppm 1,900 mg/m ³ | USA - NIOSH |
| | | PEL | 1,000 ppm 1,900 mg/m ³ | California permissible exposure limits for chemical contaminants |
| N- Lauroylsarcosine Na ⁺ | 137-16-6 | | | No Occupational Exposure Limit assigned |

8.2 Exposure controls

The measures appropriate for a particular workplace depend on how the material is used and on the potential for exposure. If engineering controls and work practices are not effective in preventing or controlling exposure, then suitable personal equipment, which is known to perform satisfactorily, should be used. Check workplace health risk assessment.

Appropriate engineering controls

Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. In case of insufficient ventilation, wear suitable respiratory equipment.

Personal protective equipment

There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, permeability, contact temperature etc. See also Section 5.

Eye/face protection

Tightly fitting safety goggles/safety glasses with side protection.

Skin protection

Handling bulk mixture: Nitrile rubber gloves; break through time: > 480 min;

Glove thickness 0.4 mm. The exact choice of glove type depends on the type of work being undertaken. Gloves should be chosen in consultation with a glove manufacturer and after a full assessment of the working conditions. Gloves should be replaced regularly.

Body protection

Standard work wear for normal handling and use.

Respiratory protection

Required if vapours, mists or aerosols are generated.

Environmental exposure controls

Do not let product enter drains. Measures based on adequate handling practices and facilities, containment and filtered extraction intended to minimise exposure to the material should also minimise release of it to the environment. See also Section 6.2.

General hygiene

Wash hands after contact. Do not eat, drink or smoke in immediate work area. Remove contaminated clothing and protective equipment before entering eating areas.

SECTION 9.0 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| Appearance | Colourless liquid |
|---|------------------------------|
| Odour | Alcohol-like |
| Odour threshold | No information available |
| pH | 6.8 - 7.0 at 25 Deg C |
| Melting point/freezing point | No information available |
| Initial boiling point and boiling point range | >35 Deg C |
| Flash point | 37 Deg C (closed cup) |
| Evaporation rate | No information available |
| Flammability (solid, gas) | No information available |
| Upper/lower flammability or explosive limits | Upper explosion limit: 13.5% |
| | Lower explosion limit: 2.5% |
| | (Ethanol) |
| Vapour pressure | No information available |
| Vapour density | No information available |
| Relative density | No information available |
| Solubility in water | Miscible |
| Solubility in other | No information available |
| Partition coefficient: n- octanol/water | Not applicable |
| Autoignition temperature | Does not self-ignite |
| Decomposition temperature | No information available |
| Viscosity | No information available |
| Explosive properties | Not classified as explosive |
| Oxidising properties | Not oxidising |

9.2 Other information

This product does not sustain combustion, up to and including 75 Deg C, when tested in accordance with the L.2 Sustained Combustibility Test.

SECTION 10.0 STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions. Do not mix with bleach or other halogenated chemicals as this produces cyanide gas.

10.2 Chemical stability

Stable under normal temperature conditions. Light sensitive (Guanidine thiocyanate).

10.3 Possibility of hazardous reactions

Contact with acids or acid vapours may liberate cyanide vapours.

10.4 Conditions to avoid

Avoid temperatures above 40 °C. Avoid exposure to light.

10.5 Incompatible materials

Peroxides, oxidizing agents, acids and alkalis. Aluminium at higher temperatures.

10.6 Hazardous decomposition products

Hydrogen sulphide, sulphur dioxide, ammonia, hydrocyanic acid, carbon oxides,

nitric oxides.

SECTION 11.0 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Guanidine thiocyanate

Acute toxicity

LD50, Oral Rat - 593 mg/kg (OECD Test Guideline 401).

ATE, Dermal - 1100

ATE, Inhalation - 1.5

Skin corrosion/irritation

Skin, Rabbit, 4 Hr – Corrosive (OECD Test Guideline 404).

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Unlikely to cause sensitisation in contact with skin.

No data available on respiratory sensitisation.

Specific target organ toxicity (STOT) - single exposure

No information.

Specific target organ toxicity (STOT) - repeated exposure

No information.

Aspiration hazard

Not applicable.

Germ cell mutagenicity

No indications of germ cell mutagenicity.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal

to 0.1% is identified as probable, possible or confirmed human

carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal

to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal

to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No indications of reproductive toxicity.

Other toxicological information

High doses may cause an adverse effect on the thyroid gland.

PrimeStore Molecular Transport Medium® (MTM)

Version: 02 Date: 29/10/2020

Ethanol

Acute toxicity

LD50, Oral Rat - 10,470 mg/kg (OECD Test Guideline 401).

LD50, Dermal Rat - > 2,000 mg/kg Body Weight

LC50, Inhalation Rat, 4 Hr - 124.7 mg/l (OECD Test Guideline 403).

Skin corrosion/irritation

Skin, Rabbit, 24 Hr – No skin irritation (OECD Test Guideline 404).

Serious eye damage/irritation

Eyes, Rabbit – Causes serious eye damage (OECD Test Guideline 405).

Respiratory or skin sensitisation

Unlikely to cause respiratory or skin sensitisation.

Guinea Pig, Maximisation Test - Negative (OECD Test Guideline 406).

Specific target organ toxicity (STOT) - single exposure

No data available.

Specific target organ toxicity (STOT) - repeated exposure

No data available.

Aspiration hazard

No data available.

Germ cell mutagenicity

Ames Test (Salmonella typhimurium) – Negative.

In vitro mammalian cell gene mutation test, mouse lymphoma cells – Negative (OECD Test Guideline 478).

Mouse, Male - Positive results obtained in some in vivo tests.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal

to 0.1% is identified as probable, possible or confirmed human

carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal

to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal

to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available.

Other toxicological information

Repeated dose toxicity, Oral, Male Rat - No observed adverse effect level 1,730 mg/kg. Lowest observed adverse effect level 3,200 mg/kg.

Affects include, irritant effects, respiratory paralysis, dizziness, narcosis, inebriation, euphoria, nausea, vomiting.

PrimeStore Molecular Transport Medium® (MTM)

Version: 02 Date: 29/10/2020

N-Lauroylsarcosine Na⁺

Acute toxicity

LD50, Oral Rat - >5,000 mg/kg (OECD Test Guideline 401).

LD50, Dermal Rat - No data available.

LC50, Inhalation Rat, 4 Hr - >0.05 - 0.5 mg/l (OECD Test Guideline 403).

Skin corrosion/irritation

In vitro (skin) - Non-corrosive (OECD Test Guideline 431). Causes skin irritation.

Serious eye damage

Causes serious eye damage.

Respiratory or skin sensitisation

No data available on respiratory sensitisation.
Unlikely to cause sensitisation in contact with skin.
Guinea pig, Maximisation test – Negative (OECD Test Guideline 406).

STOT - single exposure

No data available.

STOT - repeated exposure

No data available.

Germ cell mutagenicity

Ames test, Salmonella typhimurium - Negative.

Mutagenicity (mammalian cell test) – Chromosome aberration.

Human lymphocytes – Negative.

In vitro mammalian cell gene mutation test, mouse lymphoma test – Negative.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal

to 0.1% is identified as probable, possible or confirmed human

carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal

to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal

to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available.

Date: 29/10/2020 Version: 02

ECOLOGICAL INFORMATION SECTION 12.0

Toxicity 12.1

| Guanidine thiocyanate | | |
|---|---|--|
| Harmful to aquatic organisms with lor | ng lasting effects. | |
| Toxicity to fish | LC50, Poecilia reticulata (guppy), 96 Hr - 89.1 mg/l (OECD Test Guideline 203) | |
| Toxicity to daphnia and other aquatic invertebrates | EC50, Daphnia magna (Water flea), 48 Hr - 42.4 mg/l (OECD Test Guideline 202) | |
| Ethanol | | |
| Toxicity to fish | LC50, Pimephales (fathead minnow), 96 Hr, flow-through – 15,300 mg/l | |
| Toxicity to daphnia and other aquatic invertebrates | EC50, Ceriodaphnia dubia (water flea), 48 Hr – 5,012 mg/l | |
| Toxicity to algae | ErC50, Chlorella vulgaris (fresh water algae), 72 Hr – 275 mg/l (OECD Test Guideline 201) | |
| Toxicity to bacteria | IC50, activated sludge, 3 Hr, static - >1,000 mg/l (OECD Test Guideline 209) | |
| N-LauroyIsarcosine Na+ | | |
| Toxicity to fish | LC50, Pimephales (Danio rerio), 96 Hr, semi-static - 107 mg/l (OECD Test Guideline 203) | |
| Toxicity to daphnia and other aquatic invertebrates | EC50, Daphnia magna (water flea), 48 Hr, static – 29.7 mg/l (OECD Test Guideline 202) | |
| Toxicity to algae | NOEC, Desmodesmus subspicatus (green algae), 72 Hr, static – 9.2 mg/l (OECD Test Guideline 201) | |
| Toxicity to bacteria | EC50, activated sludge, 3 Hr, static - >1,000 mg/l (OECD Test Guideline 209) | |

Persistence and degradability Biodegradability 12.2

Guanidine thiocyanate

No data available.

Ethanol

Readily biodegradable.

Biodegradability, aerobic (15 Days) – 95% (OECD Test Guideline 301E) Biochemical Oxygen Demand (BOD) 930 – 1,670 mg/g Theoretical Oxygen Demand (ThOD) – 2,100 mg/g

N-LauroyIsarcosine Na⁺

Readily biodegradable.

Biodegradability, aerobic (28 Days) – 82% (OECD Test Guideline 301E)

12.3 Bioaccumulative potential

Guanidine thiocyanate

No data available.

Ethanol

Accumulation in organisms is unlikely.

N-Lauroylsarcosine Na⁺

No data available.

12.4 Mobility in soil

Guanidine thiocyanate

No data available.

Ethanol

No data available.

N-Lauroylsarcosine Na⁺

No data available.

12.5 Results of PBT and vPvB assessment

None of the ingredients are PBT or vPvB.

12.6 Other adverse effects

Harmful to aquatic organisms with long lasting effects.

SECTION 13.0 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

This product must be disposed of as hazardous waste. Dispose of waste in accordance with local, state, and federal regulations. Incineration is the recommended method of disposal. Product must not be treated as household waste. Do not mix the product with bleach or other halogenated chemicals. Do not mix with other waste. Do not allow product to enter sewage system.

Contaminated packaging

Dispose of as unused product. Empty containers may contain hazardous residues. Contaminated containers or packaging must not be treated as household waste. Do not use bleach or other halogenated chemicals to clean or decontaminate containers or packaging. Do not mix with other waste.

SECTION 14.0 TRANSPORT INFORMATION

This product is dangerous for transport. If it is transported or offered for carriage it must be packaged, marked, labelled and documented in accordance with the applicable modal transport rules (49 CFR for Domestic Shipping within the USA, IMDG Code for international sea and ICAO/IATA Technical Instructions for international air).

UN number: 1760

UN proper shipping name: CORROSIVE LIQUID, N.O.S.

(GUANIDINE THIOCYANTE)

Transport hazard class: 8
Subsidiary hazard: None
Packing group: III

Environmental hazards: Not Environmentally Hazardous / Not

classified as a Marine Pollutant.

Reportable Quantity (RQ):

Poison Inhalation Hazard: No

SECTION 15.0 REGULATORY INFORMATION

15.1 This safety data sheet has been compiled according to Hazard Communication Standard (HCS) 29 CFR 1910.1200.

SARA 302 Components

This product does not contain any substances which are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

This product does not contain any substances which are subject to the reporting requirements of SARA Title III, Section 313.

Massachusetts Right To Know Components

Gaunidinium thiocyanate - Not listed Ethanol - Not listed N-Lauroylsarcosine Na⁺ - Not listed

Pennsylvania Right To Know Components

Gaunidinium thiocyanate - Not listed Ethanol - Listed N-Lauroylsarcosine Na⁺ - Not listed

New Jersey Right To Know Components

Gaunidinium thiocyanate - Not listed Ethanol - Listed N-Lauroylsarcosine Na⁺ - Not listed

California Proposition 65 Components

Gaunidinium thiocyanate - Not listed Ethanol - Not listed N-Lauroylsarcosine Na⁺ - Not listed

SECTION 16.0 OTHER INFORMATION

Abbreviations and acronyms used in this SDS

| ACGIH | American Conference of Governmental Industrial Hygienist's | |
|----------|---|--|
| EPA | Environmental Protection Agency | |
| IARC | International Agency for Research on Cancer | |
| IATA-DGR | International Air Transport Association- Dangerous Goods Regulations | |
| ICAO-TI | International Civil Aviation Organization- Technical Instructions | |
| IMDG | International Maritime Code for Dangerous Goods | |
| NIOSH | National Institute for Occupational Safety and Health | |
| NTP | National Toxicology Program | |
| OECD | Organisation for Economic Co-operation and Development | |
| OSHA | Occupational Safety & Health Administration | |
| PBT | Persistent, Bioaccumulative and Toxic | |
| PEL | Permissible Exposure Limit | |
| SARA | Superfund Amendments and Reauthorization Act | |
| STEL | Short Term Exposure Level | |
| TLV | Threshold Limit Value | |
| ACGIH | American Conference of Governmental Industrial Hygienist's | |
| EPA | Environmental Protection Agency | |
| IARC | International Agency for Research on Cancer | |

Sources of data used for this SDS:

Suppliers safety data sheets.

European Chemicals Agency: http://echa.europa.eu/

US Regulatory Lists.

Hazard Statements referred to in this SDS

| H302+H312+H332: | Harmful if swallowed, in contact with skin or if inhaled. |
|-----------------|---|
| H314: | Causes severe skin burns and eye |
| | damage. |
| H315: | Causes skin irritation. |
| H318: | Causes serious eye damage. |
| H319: | Causes serious eye irritation. |
| H330: | Fatal if inhaled. |
| H412: | Harmful to aquatic life with long lasting effects. |



FlexTrans™

Viral & Chlamydial Transport Medium

25 Vials REF B1029-90C REF B1029-90D 50 Vials

INTENDED USE

The Bartels FlexTrans™ Transport Medium is intended to stabilize viruses and chlaymdiae, and suppress microbial contamination during transport of clinical specimens from the point of collection to the testing site. For in vitro Diagnostic Use. Store at room temperature, 2-8°C or -70°C.

PRINCIPLE

Cell culture isolation is an important tool in the diagnosis of viral and chlamydial infections. A specimen is collected from the site of suspected infection and immediately placed into specialized transport medium formulated to maintain viability of any viral or chlamydial organisms present in the specimen and suppress overgrowth of other microbial agents. Additionally, FlexTrans™ is noninhibitory to cell culture, making it usable not only for transport but for cell culture inoculation. FlexTrans™ may also be used in rapid detection systems such as enzyme-linked immunosorbent assay (ELISA) and direct fluorescent testing. The specimen is transported on wet ice to the testing facility, where it is maintained at 2-8°C until it can be processed.

PRODUCT DESCRIPTION

FlexTrans™ - 2 ml of transport medium in a 15 ml conical centrifuge tube, allowing specimen collection, transport and processing in the same container. Medium contains Minimal Essential Medium supplemented with L-glutamine and Hanks Salts, bovine serum albumin, sucrose, amphotericin B, gentamicin and streptomycin buffered with HEPES Buffer to a pH range of 7.0-7.4. Phenol red is added as a pH indicator. The transport tube also contains glass beads to aid in the disruption of patient cells in the specimen, with subsequent release of viruses or chlamydiae into the medium. FlexTrans™ is available in a variety of packaging formats. Please contact a Customer Service Representative in the U.S. at 1-800-325-3424, or outside the U.S. at (353) 1 276 9800 for additional information.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- FlexTrans™ should not be used beyond its expiration date.
- 3. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Decontamination is most effectively accomplished with a 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).

STABILITY AND STORAGE

Prior to use, store at room temperature, 2-8°C or -70°C. The expiration dating on the vial applies to each storage temperature. The antifungal agent present in the FlexTrans™ kit may be light sensitive. It is recommended that the tubes are stored in the box or in the dark.

SPECIMEN COLLECTION

Proper specimen collection and handling are among the most important factors in successful detection of viruses and chlamydiae. Use sterile cotton or DACRON® swabs with plastic or wire shafts which are non-inhibitory to viruses and chlamydiae. Do ${f not}$ use calcium alginate swabs.

AUTOPSY OR BIOPSY SPECIMEN

- Collect fresh tissue from appropriate site using a separate sterile instrument to cut and remove each sample. Each specimen need not be more than 1-2 cm in diameter.
- Place each sample into an individual leakproof container and cover with sufficient transport medium to prevent drying of specimen.
- Tissue specimens should not be formalinized or fixed. 3

CEREBROSPINAL FLUID (CSF)

- Collect cerebrospinal fluid (CSF) in the usual manner.
- Transfer up to 2 ml, equal to the amount of transport medium, into the vial.
- If less than 1 ml of CSF is available, consult your laboratory for transport recommendations.

CERVIX FOR CHLAMYDIA CULTURE

- Wipe the cervix prior to collection to remove WBC and mucus debris. Insert a sterile, largetipped swab into the endocervix, rotate and remove. Discard this swab.
- Insert a second, sterile swab into the cervical os to collect cells from the transitional zone. Rotate the swab vigorously in firm contact with cervical surface to facilitate the collection of columnar epithelial cells.
- 3 Withdraw swab without contacting vaginal surfaces
- 4. Place swab into transport medium.

CERVIX FOR HERPES SIMPLEX CUI TURE

- Remove exocervical mucus with swab, and discard swab.
- Insert fresh swab at least 1 cm into cervical canal, and rotate swab for 10 seconds.
- Place swab into transport medium.
- For detection of HSV shedding, collection of a vulvar sample may increase recovery.

CUTANFOUS/VESICULAR LESION

- Gently cleanse vesicle using a swab moistened with sterile saline.
 Aspirate fluid with a tuberculin syringe or collect lanced vesicle onto a swab.
- If vesicle is absent, vigorously swab base of lesion.
- Transfer fluid or swab into transport medium.

FYF

- Gently swab the lower conjunctiva with a sterile, fine-tipped swab, collecting patient mucous membrane cells.
- 2. Place swab into transport medium.

NASOPHARYNX

- Gently insert a sterile nasopharyngeal swab into one or both anterior nares to the posterior pharynx, rotate to collect mucous membrane cells and withdraw.
- Place swab into transport medium.

RECTAL SWAB

- Insert a sterile swab 1 cm past the anal sphincter, rotate in firm contact with the mucosal surface and withdraw.
- Place swab into transport medium.

RESPIRATORY ASPIRATE

(The quantity and quality of respiratory specimens to be tested can be improved by aspiration).

- Collect aspirates from nose, nasopharynx and/or oropharynx.
- Aspirates may be collected using a plastic disposable premature infant feeding tube attached to a 10 ml syringe. Alternately, a suction catheter with a mucous trap may be utilized
- 3. Transfer up to 3 ml of aspirate into transport medium.

STOOL

- Collect specimen in a clean, dry container.
- 2 Transfer sufficient faeces into transport medium to make a 20-40% suspension.

THROAT

- Swab the posterior pharynx and tonsillar crypts vigorously with a largetipped, sterile swab.
- Place swab into transport medium.

URETHRA (PATIENT SHOULD NOT HAVE URINATED WITHIN ONE HOUR OF COLLECTION).

- Insert a sterile, fine-tipped swab 2-4 cm into the male urethra, or 1 cm into the female urethra and hold in place for 5 seconds.
- 2. Rotate the swab several times to obtain columnar epithelial cells and withdraw.
- 3. Place swab into transport medium.

URINE

- Collect a fresh, clean-catch specimen in a sterile container.
- Transfer 2 ml into transport medium.

TRANSPORT AND STORAGE

After collection, store specimen tubes at 2-8°C. All collected specimens should be transported on wet ice to the laboratory immediately after collection. Failure to transport and store specimens at 2-8°C may lead to loss of viral or chlamydial infectivity. If the specimen cannot be processed within 2 days, freeze it at -70°C; however, freezing should be avoided if at all possible. Specific requirements for shipping specimens should follow recommendations found in Titles 42 and 49 of the Code of Federal Regulations for Interstate Transport of Etiologic Agents.

PROCESSING

FOR CHLAMYDIA CULTURE

- Rotate the swab in the transport medium, then press against the inside of the tube to allow excess fluid to drain back into the transport medium. Discard the swab into an appropriate disinfectant, such as 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).
- Disrupt cellular material in the transport medium by vortexing with sterile glass beads for 30-60 seconds, or sonicating at 10 kc/sec for the same length of time. This will enhance the release of cell-associated chlamydiae into the medium.
- To remove bacterial, fungal and cellular debris, centrifuge the transport medium at 900xg for 5 minutes. Supernatant is then used as the cell culture inoculum. Futher clarification of heavily contaminated specimens may be accomplished by passing the specimen through a low retention 0.45 micron filter. The filtrate is then used as the inoculum.

FOR VIRAL EXAMINATION

If the transport tube contains a swab, it should be handled with sterile forceps. The swab should be rotated in the transport medium, then pressed against the inside of the tube to allow excess fluid to drain back into the transport medium. If specimens are to be used for both direct detection and culture isolation/confirmation, half of the cells should be removed by centrifugation at 300 to 500xg and used for the direct specimen for cell culture isolation. Discard the swab into an appropriate disinfectant, such as 0.5% sodium hypochlorite solution (1:10 dilution of household bleach).

DIRECT DETECTION

- Add 2 ml of phosphate buffered saline (PBS) to the specimen. Resuspend cells and add an additional 6 ml of PBS.
- Centrifuge specimen at 300 to 500xg for 10 minutes to pellet patient cells. If the specimen contains mucous, it will be observed as a hazy layer immediately above the
- cell pellet. Using a sterile Pasteur pipette, remove all of the supernatant, including any mucous layer, and discard into sodium hypochlorite solution.
- Add 2 ml of PBS to the specimen to re-suspend cell pellet. Add an additional 6 ml of PBS.
- 5. Centrifuge specimen at 300 to 500xg for 10 minutes.
- Remove supernatant, including any mucous and discard into sodium hypochlorite solution. 6.
- 7 Repeat steps 4-6 until cells are free of mucous.

Page 1 of 3 - EN B1029-90-29 Rev B

- Add 2-8 drops of PBS to make a slightly cloudy cell suspension. 8
- Using a Pasteur pipette, spot cells onto acetone-cleaned glass slides.
- 10. Air-dry slides completely.
- Fix slides in acetone and allow to air-dry. 11.
- After fixation, slides may be held for several days at 2-8°C before staining. 12.

CELL CULTURE INOCULATION

- Disrupt cellular material in the transport medium or supernatant by vortexing with sterile glass beads for 30-60 seconds, sonicating at 10 kc/second for the same length of time, or by other methods determined by the laboratory to be effective in disrupting cellular material. This will enhance the release of cell associated virus into the medium.
- To remove bacterial, fungal and cellular debris, centrifuge the transport medium at 2000xg for 10 minutes. Supernatant is then used as the cell culture inoculum.

FOR ELISA TESTING

Follow ELISA kit manufacturer's instructions for specimen processing.

QUALITY ASSURANCE

FlexTrans™ is tested for microbiological contamination, toxicity to host cell culture, and the ability to maintain viability of desired agents. Quality assurance information is available upon request. Individuals may evaluate the ability of FlexTrans™ to support viral and/or chlamydial agents by inoculating FlexTrans™ with an individual agents of choice. After 72 hours at 2-8°C, using appropriate isolation procedures for the selected agent, positive growth should be obtained. Verify isolation by methodology appropriate to the selected agent.

LIMITATIONS

- Do not use FlexTrans™ if leakage, evaporation, pH change or signs of contamination are apparent.
- 2 Improper storage of FlexTrans™ may lead to decreased antibacterial and antimycotic activity.
- Freezing of specimens should be avoided; freezing may decrease recovery of viruses
- When performing a direct immunofluorescent test, do not freeze or vortex FlexTrans™ prior to slide preparation, as this can result in cellular disruption.

EXPECTED VALUES

From December 1992 through November 1993, 4,455 clinical cultures were processed using FlexTrans™ Virus was isolated in 7.0% (325) of these cultures, and chlamydiae was isolated in 3.5% (34). The viruses are listed below

| Virus | Number of Isolates |
|-------------|--------------------|
| HSV 1 | 114 |
| HSV 2 | 57 |
| CMV | 38 |
| Adenovirus | 23 |
| Enterovirus | 76 |
| Influenza A | 13 |
| Influenza B | 3 |
| RSV | 1 |

Specimens were transported under a variety of conditions: cool packs, refrigerated, frozen (dry ice) and ambient temperature. The patient population and demographics were diverse: newborn to elderly of both sexes were evaluated. Specimens were not selected for a particular disease, but were those submitted to the laboratory for routine screening. This lack of selection may account for the isolation rates observed.

PERFORMANCE CHARACTERISTICS

Sterility and toxicity of FlexTrans™ were determined by inoculation of the indicated cell lines. Transports were held at both ambient temperature and 2-8°C for 5 days prior to inoculation of cells. Cell cultures were held at 34-37°C in a CO2 environment for 8 days.

| Cell Line | # wells examined | # shell vials examined | Sterility | Toxicity |
|-----------|------------------|------------------------|-----------|----------|
| McCoy | 24 | 10 | All | None |
| MRC-5 | 24 | 10 | All | None |
| HF | 24 | 10 | All | None |
| Vero | 24 | 10 | All | None |

FlexTrans™ inhibits the following organisms for at least 10 days after a log phase inoculation: E. coli, Ps. aeruginosa, Legionella pneumophilia, Enterococcus faecalis, Staphylococcus aureus, Mycoplasma hominis, Ureaplasma ureolyticus, Klebsiella oxytoca, Micrococcus luteus. In comparative studies with other commercially available transports, FlexTrans™ was found to be equivalent for the recovery of viral agents and suitable for the satisfactory survival and transport of chlamydia FlexTrans™ and other commercially available transports were each inoculated with 10 TCID50 of an HSV-2 stock virus strain. After 48 hours of refrigeration at 2-8°C, 0.2 ml of each transport was inoculated into duplicate MRC-5 shell vials. After 48 hours incubation at 35°C, the shell vials were stained with HSV-2 typing reagent. Equal growth was seen in all transports. Negative control vials were negative for growth and toxicity. Following refrigeration at 2-8°C, one MRC-5 shell vial was inoculated every other day for 14 days with 0.2 ml from each transport. Shell vials were then incubated for 48 hours and then stained. FlexTrans™ showed growth in all transports, indicating that FlexTrans™ can maintain the viability of viruses when stored at 2-8°C for 14 days. Five clinical specimens containing either CMV strain AD 169 or CMV strain Towne were inoculated into FlexTrans™ previously stored at either room temperature or 2-8°C and another commerically available transport, and stored for 24 hours at 2-8°C. Transports were then subcultured into cell culture vials and incubated at 34-37°C for 48 hours. Cell culture vials were subcultied into cert culture vials and includated at 34-37 c link of hours. Cert culture vials were then fixed and stained with Bartels CMV Immediate Early Antigen Direct Fluorescent Antibody. All vials inoculated with CMV showed growth with negative control vials from both storage conditions showing no growth. In addition, the effectiveness of FlexTrans™ for the transport of respiratory

viruses was determined by comparing FlexTrans™ with another commecially available transport media. Eight of each transport were inoculated with 0.2 ml stock influenza A culture material (105/ 0.2 ml). Four (each) of the two transports were either refrigerated or maintained at room temperature. At 24, 48, 72 and 96 hours, 0.2 ml of each transport was inoculated onto A-549 shell vials and incubated for 48 hours. Detection of infection was determined following staining with the Bartels Influenza A Indirect Fluorescent Antibody. A 2+ or greater immunofluorescence was considered positive. Positive growth was seen in all FlexTrans™ transports, whereas the other commercially available transport showed negative growth in all vials held at room temperature and inoculated at 96 hours.

| Transport | 24 Hours | 48 Hours | 72 Hours | 96 Hours |
|------------------|----------|----------|----------|----------|
| FlexTrans™ RT | 4/4 | 4/4 | 4/4 | 4/4 |
| FlexTrans™ 2-8°C | 4/4 | 4/4 | 4/4 | 4/4 |

FlexTrans™ is also effective for the transport of chlamydiae. Chlamydia trachomatis was inoculated into both FlexTrans™ and another commercially available transport and left at ambient temperature for three days. Each day, 0.2 ml was removed from each transport and inoculated into shell vials containing McCoy cells. All shell vials were treated similarly according to standard shell vial isolation procedures. After 48 hour incubation, the cells were fixed and stained with the Bartels Chlamydia Culture Confirmation Reagent. Equivalent growth was seen in shell vials inoculated on day one and day three

FlexTrans™ can also be used for the transport of virus and chlamydiae for direct fluorescent antibody (DFA) and enzyme immunoassay (EIA) testing. When performing DFA or EIA, follow package insert instructions, paying particular attention to instructions for sample preparation, such as sample dilution prior to beginning testing. When performing a DFA test, **do not** vortex FlexTrans™ prior to slide preparation. Clinical specimens containing RSV, influenza A or chlamydiae, and stock cultures of Chlamydia pneumoniae and Chlamydia psittaci were inoculated into FlexTrans™ and stored at 2-8°C or room temperature for 24 hours.

Transports were then tested in the appropriate Bartels ELISA, i.e., the Bartels RSV ELISA, the Bartels influenza A ELISA or the Bartels Chlamydiae ELISA. Transports were also inoculated into cell culture and confirmed via fluorescent antibody testing. All transports that tested positive in ELISA also tested positive in fluorescent antibody testing.

| Clinical Samples | Replicates | ELISA Result | Culture Result |
|-------------------------|------------|--------------|----------------|
| RSV-10 samples | 90 | All positive | All positive |
| Chlamydiae-10 samples | 90 | All positive | 6/10 positive* |
| Influenza A-6 samples** | 54 | 45 positive | All positive |

*Four out of ten clinicals showed elementary bodies when stained with DFA, with no inclusions. **Influenza A samples were tested 7 days after inoculation with FlexTrans™ Titer levels in some clinical samples were below the detection limit of the Bartels Influenza A ELISA.

| Stock Cultures | Replicates | ELISA Result | Culture Result |
|------------------------|------------|--------------|----------------|
| Chlamydia pneumoniae | 15 | All positive | All positive |
| Chlamydia psittaci | 15 | All positive | All positive |
| Chlamydia trachomatis | 15 | All positive | All positive |
| Chlamydia trachomatis, | 15 | All positive | All positive |
| I GV strain | | · | |

REFERENCES

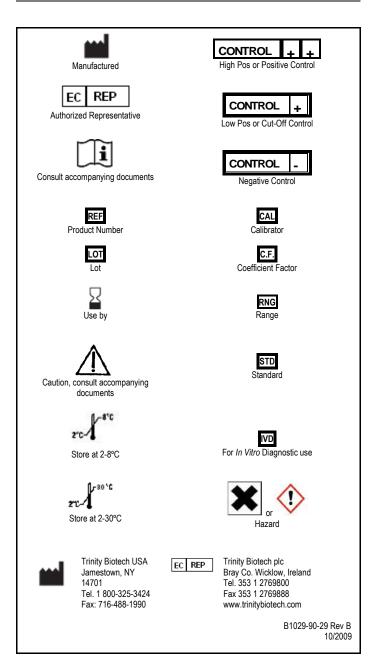
- Bartels, P.A. et al. 1988, Clinical Applications of Cell Culture Systems and Direct Antigen Detection. Baxter Healthcare, Bellevue, WA.
- Chernesky, M.A., Ray C.G., and Smith T.F. 1982, Cumitech 15, Laboratory Diagnosis Of Viral Infection. *Am. Soc. Microbiology*, Washington, D.C. 2
- 3. Clyde, W.A., Jr., Kenny G.E. and Schachter J. 1984, Cumitech 19, Laboratory Diagnosis of Chlamydial and Mycoplasmal Infections. Am. Soc. Microbiology, Washington, D.C.
- Fields, B.N., Knipe D.M. 1990, Fields Virology, Raven, N.Y.
- 5. Isenberg, H.D. 1992, Clinical Microbiology Procedures Handbook, Am. Soc. Microbiology, Washington, D.C.
- Washington, D.C. Lennette, E.H., Schmidt N.J. 1979, Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections, Am. Public Health Assoc., Washington, D.C. 6.
- 7.
- Lycke, E., Norrby E. 1983, Medical Virology, *Butterworths*, London.
 Rose, N.R., DeMacario E.C., Fahey J.L., Friedman H., and Penn G.M. 1992, Manual of Clinical Laboratory Immunology, *Am. Soc. Microbiology*, Washington, D.C. Specter, S., and Lancz G.J. 1986, *Clinical Virology Manual*, Elsevier, N.Y.
- 9

TECHNICAL INFORMATION

For further information or assistance, contact Technical Services.

Page 2 of 3 - EN B1029-90-29 Rev B

| ORDERING INFORMATION | | | | |
|----------------------|--------------------|--------------------|--|--|
| KIT | | Bartels FlexTrans™ | | |
| | | Medium | | |
| Catalog No. | Item | Quantity | | |
| B1029-90C | Bartels FlexTrans™ | 25 Vials | | |
| B1029-90D | Medium | 50 vials | | |
| | Bartels FlexTrans™ | | | |
| | Medium | | | |



Page 3 of 3 – EN B1029-90-29 Rev B



SAFETY DATA SHEET

Revision Date 23-May-2017 Revision Number 7

1. Identification

Product Name Saline

Cat No.: R064430, R064432, R064434, R064436, R064438, R064442, R064444,

R064446, R064448, R064450, R064462, R064464, R064466, R064468,

R07140, R07141, R07142, R07143, R08756, R112560, R112572,

R112576, R112584, R116602, R117672, R118520, R119750, R119751,

R20123, R92023, R92024

Synonyms No information available

Recommended Use Laboratory chemicals.

Uses advised against Not for food, drug, pesticide or biocidal product use

Details of the supplier of the safety data sheet

Company

Remel

12076 Santa Fe Drive

Lenexa, KS 66215 United States Telephone: 1-800-255-6730

Fax:1-800-621-8251

Emergency Telephone Number

INFOTRAC 1-352-323-3500 (International)

1-800-535-5053 (North America)

2. Hazard(s) identification

Classification

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Based on available data, the classification criteria are not met

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition / information on ingredients

| Component | CAS-No | Weight % |
|--------------|--------|----------|
| NONHAZARDOUS | NA | 100 |

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Obtain medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Inhalation Move to fresh air. Get medical attention immediately if symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms/effects None reasonably foreseeable. Symptoms of allergic reaction may include rash, itching,

swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest

pain, muscle pain or flushing

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media No information available

Flash Point No information available Method - No information available

Autoignition Temperature

Explosion Limits

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

None known

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

| Health | Flammability | Instability | Physical hazards |
|--------|--------------|-------------|------------------|
| 1 | 0 | 0 | N/A |

6. Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment.

Environmental Precautions Should not be released into the environment. See Section 12 for additional ecological

information.

Methods for Containment and Clean Provide adequate ventilation. Soak up with inert absorbent material (e.g. sand, silica gel, up acid binder, universal binder, sawdust).

7. Handling and storage

Handling Wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin,

eyes and clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures Ensure adequate ventilation, especially in confined areas.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard

EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene MeasuresHandle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State Liquid

Appearance
Odor
No information available

Melting Point/Range

Boiling Point/Range

Flash Point

Evaporation Rate

Flammability (solid,gas)

No data available
No information available
No information available
No information available

Flammability or explosive limits

Upper
Lower
No data available
No data available
No data available
No information available
Vapor Density
No information available
Specific Gravity
No information available
No information available
No information available
No information available
No data available

Autoignition Temperature

Partition Coefficient, Proctation/water

No information available

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products. Excess heat. Avoid dust formation.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products None under normal use conditions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous ReactionsNone under normal processing.

11. Toxicological information

Acute Toxicity

Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. Oral LD50 Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. **Dermal LD50** Based on ATE data, the classification criteria are not met. ATE > 20 mg/l. Vapor LC50

Component Information Toxicologically Synergistic

No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

No information available Irritation

Sensitization No information available

The table below indicates whether each agency has listed any ingredient as a carcinogen. Carcinogenicity

| Component | CAS-No | IARC | NTP | ACGIH | OSHA | Mexico |
|--------------|--------|------------|------------|------------|------------|------------|
| NONHAZARDOUS | NA | Not listed |

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental Effects No information available.

No information available. **Teratogenicity**

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

delayed

Symptoms / effects, both acute and Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability No information available **Bioaccumulation/ Accumulation** No information available.

Mobility No information available.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

| | 14. Transport information | |
|------------|---------------------------|--|
| DOT | Not regulated | |
| DOT TDG | Not regulated | |
| IATA | Not regulated | |

IMDG/IMO Not regulated

15. Regulatory information

All of the components in the product are on the following Inventory lists: X = listed

International Inventories

Legend:

X - Listed

- E Indicates a substance that is the subject of a Section 5(e) Consent order under TSCA.
- F Indicates a substance that is the subject of a Section 5(f) Rule under TSCA.
- N Indicates a polymeric substance containing no free-radical initiator in its inventory name but is considered to cover the designated polymer made with any free-radical initiator regardless of the amount used.
- P Indicates a commenced PMN substance
- R Indicates a substance that is the subject of a Section 6 risk management rule under TSCA.
- S Indicates a substance that is identified in a proposed or final Significant New Use Rule
- T Indicates a substance that is the subject of a Section 4 test rule under TSCA.
- XU Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(B).
- Y1 Indicates an exempt polymer that has a number-average molecular weight of 1,000 or greater.
- Y2 Indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

U.S. Federal Regulations

TSCA 12(b) Not applicable

SARA 313 Not applicable

SARA 311/312 Hazard Categories

Acute Health Hazard

Chronic Health Hazard

No
Fire Hazard

Sudden Release of Pressure Hazard

No
Reactive Hazard

No

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA Occupational Safety and Health Administration

Not applicable

CERCLA

Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know

Not applicable

Regulations

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland Security

This product does not contain any DHS chemicals.

Other International Regulations

Revision Date 23-May-2017

Mexico - Grade No information available

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

Revision Date 23-May-2017 Print Date 23-May-2017

Revision Summary This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx Page 1 of 8

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Urine Monovette® 10 ml with stabiliser/Set

Further trade names

10.253 - Urine Monovette® 10 ml with stabiliser 10.253.001 - Urine Monovette® 10 ml with stabiliser 10.253.020 - Urine Monovette® 10 ml with stabiliser 51.253.041 - Urine Monovette® 10 ml with stabiliser - Set

CAS No: 10043-35-3 Index No: 005-007-00-2 EC No: 233-139-2

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Microbiological urine analysis

1.3. Details of the supplier of the safety data sheet

Company name: SARSTEDT AG & Co.
Street: Sarstedtstraße 1
Place: D-51588 Nümbrecht

Post-office box: 1220

D-51582 Nümbrecht

Telephone: +49 (0)2293 / 305 - 0 Telefax: +49 (0)2293 / 305 - 2470

e-mail: info@sarstedt.com

Contact person: Dr. Dagmar Flach Telephone: +49 (0)2293 / 305 - 4500

Jochen Hoffmann

e-mail: sicherheitsdatenblatt@sarstedt.com

Internet: www.sarstedt.com
Responsible Department: R & D Center

1.4. Emergency telephone Poison Center in Bonn (Germany): +49 (0)228 / 19240

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: R2 - Repr. Cat. 2

R phrases:

May impair fertility.

May cause harm to the unborn child.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:

Reproductive toxicity: Repr. 1B

Hazard Statements:

May damage fertility. May damage the unborn child.

2.2. Label elements

Hazardous components which must be listed on the label

Boric acid

Signal word: Danger Pictograms: GHS08



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx

Page 2 of 8



Hazard statements

H360FD May damage fertility. May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical characterization

The L-Monovette® with stabiliser contains boric acid (< 210 mg).

Hazardous components

| EC No | Chemical name | Quantity |
|--------------|---|----------|
| CAS No | Classification according to Directive 67/548/EEC | |
| Index No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | |
| REACH No | | |
| 233-139-2 | Boric acid | 100 % |
| 10043-35-3 | Repr. Cat. 2 R60-61 | |
| 005-007-00-2 | Repr. 1B; H360FD | |

Full text of R-, H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

After inhalation

Provide fresh air. Medical treatment necessary.

After contact with skin

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink water (max. 2 glasses). Consult physician.

4.2. Most important symptoms and effects, both acute and delayed

Drop in temperature, excitation, spasm, diarrhea, sickness, vomiting, tiredness, ataxia (disturbed coordination of movements).

4.3. Indication of any immediate medical attention and special treatment needed

No information available.



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx

Page 3 of 8

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media

none

5.2. Special hazards arising from the substance or mixture

Non-flammable.

Surrounding fire may cause hazardous vapour.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Do not breathe dust. Avoid contact with substance. Call an expert. Provide adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Avoid generation of dust. Take up carefully when dry. Dispose of waste according to applicable legislation. Re-clean.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

See also section 10. Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid generation of dust. Do not breathe dust.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Avoid contact with substance. Store at room temperature. Store in a dry place. Store in a place accessible by authorized persons only.

Advice on storage compatibility

No special measures are necessary.

7.3. Specific end use(s)

Microbiological urine analysis

SECTION 8: Exposure controls/personal protection



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx Page 4 of 8

8.1. Control parameters

8.2. Exposure controls



Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

Respiratory protection

Required in case of formation of dust. Recommended filter type: filter P 2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid
Colour: white
Odour: odourless

Test method

pH-Value: not determined

Changes in the physical state

Melting point: >1000 °C OECD 102

Initial boiling point and boiling range:

Flash point:

not determined

not applicable

Flammability

Solid: not determined Gas: not applicable

Lower explosion limits: not determined Upper explosion limits: not determined Ignition temperature: Non-flammable.

Auto-ignition temperature

Solid: not determined
Gas: not applicable



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx Page 5 of 8

Decomposition temperature: 184,9 °C

Oxidizing properties

Not oxidizing.

 Vapour pressure:
 <0,0000001 hPa</td>
 OECD 104

 Density (at 23 °C):
 1,489 g/cm³
 OECD 109

Bulk density: ca. 400 - 600 kg/m³

Water solubility: 49,2 g/L OECD 105

(at 20 °C)

Solubility in other solvents

not determined

Partition coefficient:

Vapour density:

Evaporation rate:

-1,09

not determined

not determined

9.2. Other information

Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

See section 10.3.

10.2. Chemical stability

Hygroscopic.

10.3. Possibility of hazardous reactions

Exothermic reactions with:

Acetic anhydride

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

| CAS No | Chemical name | | | | | | |
|------------|-----------------|--------|-------------|---------|----------|--|--|
| | Exposure routes | Method | Dose | Species | Source | | |
| 10043-35-3 | Boric acid | | | | | | |
| | oral | LD50 | >2660 mg/kg | Rat | OECD 401 | | |
| | dermal | LD50 | >2000 mg/kg | Rat | (ECHA) | | |

STOT-single exposure

No information available.

Severe effects after repeated or prolonged exposure

No information available.

Carcinogenic/mutagenic/toxic effects for reproduction

May damage the unborn child. May damage fertility.



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx

Page 6 of 8

Aspiration hazard

No information available.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

Further information

After resorbing big quantities:

Drop in temperature, excitation, spasm, diarrhea, sickness, vomiting, tiredness, ataxia (disturbed coordination of movements).

The usual precautions are to be adhered to when handling chemicals.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity: The classification criteria for this hazard class are not met by definition.

| CAS No | Chemical name | | | | | | |
|------------|--------------------------|--------|---------------|-----------|--|-------------------|--|
| | Aquatic toxicity | Method | Dose | [h] [d] | Species | Source | |
| 10043-35-3 | Boric acid | | | | | | |
| | Acute fish toxicity | LC50 | 50 - 100 mg/l | | Oncorhynchus mykiss (Rainbow trout) | (ECOTOX Database) | |
| | Acute crustacea toxicity | EC50 | 133 mg/l | | Daphnia magna (Big water flea) | (ECOTOX Database) | |

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

Bioaccumulation is not to be expected.

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|------------|---------------|---------|
| 10043-35-3 | Boric acid | -1,09 |

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

not applicable

12.6. Other adverse effects

No information available.

Further information

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)

14.2. UN proper shipping name:

Not a hazardous material with respect to transportation regulations.

Inland waterways transport (ADN)



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx Page 7 of 8

14.2. UN proper shipping name: Not a hazardous material with respect to transportation regulations.

Marine transport (IMDG)

14.2. UN proper shipping name: Not a hazardous material with respect to transportation regulations.

Air transport (ICAO)

14.2. UN proper shipping name: Not a hazardous material with respect to transportation regulations.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No information available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment

restrictions for child bearing mothers and nursing.

Water contaminating class (D): 1 - slightly water contaminating

Additional information

Substances of Very High Concern (SVHC): This product contains substances of very high concern according to REACH guideline EC No. 1907/2006 Art. 57 above the legal concentration limit of ≥ 0.1

% (w/w).

Instructions of BG RCI (Germany):

M039 Damage to the unborn child - protection at the workplace -

M050 handling of hazardous materials

15.2. Chemical safety assessment

For this substance a chemical safety assessment has been carried out.

SECTION 16: Other information

Changes

General revision. The telephone and fax numbers of the company have been updated.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

SVHC: Substances of Very High Concern

Relevant R-phrases (Number and full text)

60 May impair fertility.

61 May cause harm to the unborn child.



according to Regulation (EC) No 1907/2006

Urine Monovette® 10 ml with stabiliser/Set

Art. no. xx.253.xxx Page 8 of 8

Relevant H- and EUH-phrases (Number and full text)

H360FD May damage fertility. May damage the unborn child.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.



SAFETY DATA SHEET

Creation Date 01-Apr-2021 Revision Date 01-Apr-2021 Revision Number 7

1. Identification

Product Name M4RT Transport Medium

Cat No.: R12505, R12506, R12552, R12565, R12566, R12567, R12575, R12576,

R12578, R12587, R12588, R12591, R12592, R12611, R12617, R12618, R12619, R12620, R12621, R12625, R12626, R12629, R12630,R12631, R12632, R12687, R12688, R12699, R12708, R12593, R12596, R12700,

R12701, R12705, R12720, R12900, R12901, 444079

Synonyms No information available

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

CompanyOxoid Ltd.RemelWade Road

12076 Santa Fe Drive Basingstoke, Hants, UK

Lenexa, KS 66215 United States RG24 8PW

Telephone: 1-800-255-6730 Telephone: +44 (0) 1256 841144 Fax:1-800-621-8251

Emergency Telephone Number

INFOTRAC - 24 Hour Number: 1-800-535-5053

Outside of the United States, call 24 Hour Number: 001-352-323-3500 (Call Collect)

2. Hazard(s) identification

Classification

Classification under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements

None required

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

| Component | CAS-No | Weight % |
|----------------------------|-----------|----------|
| Sucrose | 57-50-1 | 6.32 |
| Gentamicin, sulfate (salt) | 1405-41-0 | Trace |

4. First-aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes.

Inhalation Remove to fresh air.

Ingestion Do NOT induce vomiting.

Most important symptoms and

effects

Notes to Physician

No information available.

Treat symptomatically

Fire-fighting measures

Unsuitable Extinguishing Media No information available

Flash Point No information available No information available Method -

Autoignition Temperature

Explosion Limits

No information available

Upper No data available Lower No data available Sensitivity to Mechanical Impact No information available Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

None known.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Physical hazards Health **Flammability** Instability N/A 0 0 1

Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required.

Environmental Precautions See Section 12 for additional Ecological Information.

Methods for Containment and Clean Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder,

Up sawdust). Keep in suitable, closed containers for disposal.

7. Handling and storage

Ensure adequate ventilation. Handling

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls / personal protection

Exposure Guidelines

| Component | ACGIH TLV | OSHA PEL | NIOSH IDLH | Mexico OEL (TWA) |
|-----------|---------------------------|--|-------------------------------|------------------|
| Sucrose | TWA: 10 mg/m ³ | (Vacated) TWA: 15 mg/m³ (Vacated) TWA: 5 mg/m³ TWA: 15 mg/m³ TWA: 5 mg/m³ | TWA: 10 mg/m³ TWA: 5 mg/m³ | TWA: 10 mg/m³ |

Legend

ACGIH - American Conference of Governmental Industrial Hygienists OSHA - Occupational Safety and Health Administration

NIOSH IDLH: NIOSH - National Institute for Occupational Safety and Health

None under normal use conditions. **Engineering Measures**

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No protective equipment is needed under normal use conditions.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State Liquid

No information available **Appearance** Odor No information available **Odor Threshold** No information available

No information available pН

Melting Point/Range No data available **Boiling Point/Range** No information available

Flash Point No information available No information available **Evaporation Rate**

Flammability (solid,gas) Not applicable

Flammability or explosive limits

No data available Upper No data available Lower

Vapor Pressure No information available **Vapor Density** No information available **Specific Gravity** No information available Solubility No information available

Partition coefficient; n-octanol/water No data available **Autoignition Temperature**

No information available **Decomposition Temperature** No information available **Viscosity** No information available

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products None under normal use conditions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Oral LD50

Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg.

Dermal LD50

Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg.

Vapor LC50

Based on ATE data, the classification criteria are not met. ATE > 20 mg/l.

Component Information

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|----------------------------|--------------------------|-------------|-----------------|
| Sucrose | LD50 = 29700 mg/kg (Rat) | Not listed | Not listed |
| Gentamicin, sulfate (salt) | >5 g/kg (Rat) | Not listed | Not listed |

Toxicologically Synergistic

Products

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

| Component | CAS-No | IARC | NTP | ACGIH | OSHA | Mexico |
|----------------------------|-----------|------------|------------|------------|------------|------------|
| Sucrose | 57-50-1 | Not listed |
| Gentamicin, sulfate (salt) | 1405-41-0 | Not listed |

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental EffectsNo information available.

Teratogenicity No information available.

STOT - single exposureSTOT - repeated exposure
None known
None known

Aspiration hazardNo information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability No information available

Bioaccumulation/ AccumulationNo information available.

Mobility

| Component | log Pow |
|-----------|---------|
| Sucrose | -3.67 |

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOTNot regulatedTDGNot regulatedIATANot regulatedIMDG/IMONot regulated

15. Regulatory information

United States of America Inventory

| Component | CAS-No | TSCA | TSCA Inventory notification - Active/Inactive | TSCA - EPA Regulatory Flags |
|----------------------------|-----------|------|---|-----------------------------|
| Sucrose | 57-50-1 | X | ACTIVE | - |
| Gentamicin, sulfate (salt) | 1405-41-0 | = | - | - |

Legend:

TSCA - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

XU - Indicates a substance exempt from reporting under the Inventory Update Rule, i.e. Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(B)

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Australia (AICS), China (IECSC), Korea (ECL).

| Component | CAS-No | DSL | NDSL | EINECS | PICCS | ENCS | AICS | IECSC | KECL |
|----------------------------|-----------|-----|------|-----------|-------|------|------|-------|----------|
| Sucrose | 57-50-1 | X | - | 200-334-9 | Χ | - | Χ | Χ | KE-17258 |
| Gentamicin, sulfate (salt) | 1405-41-0 | - | - | 215-778-9 | Х | X | - | Х | KE-17593 |

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA Not applicable

California Proposition 65 This product contains the following Proposition 65 chemicals.

| Component | CAS-No | California Prop. 65 | Prop 65 NSRL | Category |
|----------------------------|-----------|---------------------|--------------|---------------|
| Gentamicin, sulfate (salt) | 1405-41-0 | Developmental | - | Developmental |

U.S. State Right-to-Know

Regulations

| Component | Massachusetts | New Jersey | Pennsylvania | Illinois | Rhode Island |
|-----------|---------------|------------|--------------|----------|--------------|
| Sucrose | X | <u> </u> | Χ | • | X |

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

16. Other information

Prepared By Regulatory Affairs

Thermo Fisher Scientific

Email: EMSDS.RA@thermofisher.com

 Creation Date
 01-Apr-2021

 Revision Date
 01-Apr-2021

 Print Date
 01-Apr-2021

Revision Summary

This document has been updated to comply with the US OSHA HazCom 2012 Standard

replacing the current legislation under 29 CFR 1910.1200 to align with the Globally

Harmonized System of Classification and Labeling of Chemicals (GHS).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS

PURITAN MEDICAL PRODUCTS COMPANY LLC

Safety Data Sheet Rev. 03 March 23, 2015

1. Product and company identification

Product name: PurFlock® Ultra swab with Polystyrene handle

Product numbers: 3306-U SERIES (Sterile and Non-sterile items)

Company identification: Contact numbers:

Puritan Medical Products Company LLC Tel: +1 207-876-3311 P.O. Box 149, 31 School Street Fax: +1 207-876-3130

Guilford, Maine 04443-0149 U.S.A.

2. Hazards identification

Hazardous ingredients:

Skin contact: None

3. Composition/information on ingredients

Product consists of a PurFlock® Ultra tip with a polystyrene handle. Non hazardous materials.

None

4. First-aid measures

Skin contact: N/A

Eye contact: N/A
Inhalation: N/A

Swallowing: Immediately call a doctor.

5. Fire-fighting measures

Extinguishing media: CO2, extinguishing powder or water spray. Fight larger

fires with water or alcohol resistant foam

Protective Equipment:No protective equipment required

6. Accidental release measures

Personal precautions: No personal protective equipment required.

Environmental precautions: N/A
Methods for cleaning up: N/A

7. Handling and storage

Handling: No special handling procedures required

Storage: Store away from oxidizing agents

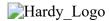
Store in dry conditions.

8. Exposure controls/personal protection

Respiratory protection: N/A
Hand protection: N/A
Eye protection: N/A
Skin and body protection: N/A

| 9. Physical and chemical properties | | | | |
|--|--|--|--|--|
| Odor: | Odorless | | | |
| рН: | Not applicable | | | |
| Density: | Not determined | | | |
| Boiling point, °C: | Not determined | | | |
| Melting point, °C | Not determined | | | |
| Flash point, °C: | Not applicable | | | |
| Solubility: | Insoluble | | | |
| 10. Stability and reactivity | | | | |
| Materials and conditions to avoid: | No decomposition if used according to specifications | | | |
| Hazardous decomposition products: | No dangerous decomposition products known | | | |
| 11. Toxicology information | | | | |
| Acute effects: | None | | | |
| Chronic effects: | None | | | |
| Exposure limits: | None | | | |
| Carcinogenicity (to humans): | None | | | |
| 12. Ecological Information | | | | |
| Ecology: | The ecological effects have not been thoroughly investigated, but currently none have been identified. Not known to be hazardous to water. | | | |
| 13. Disposal considerations | | | | |
| Recommendation: | Dispose used devices that have been processed with human samples as if biohazardous. Wastes containing these products should be disposed of in a manner consistant with state, federal, and local regulations. | | | |
| 14. Transport information | | | | |
| No special transportation needed. Non-haza | rdous material. | | | |
| 15. Regulatory information | | | | |
| Not classified as a hazardous material. | | | | |
| 16. Other information | | | | |
| Duritan Medical Products Company LLC provi | ides the information in this document in good faith and | | | |

Puritan Medical Products Company LLC 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. Puritan Medical 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.



| Product Name: | Viral Transport Medium, 31 | mL |
|-----------------|----------------------------|----|
| Catalog Number: | R99 | |

Dear Customer:

This product does not require a Safety Data Sheet under the Occupational Health and Safety Administration standard entitled "Hazardous Communication" 29 CFR 1910.1200 for the United States, and Regulation (EC) No 1272/2008 for Europe.

Additionally, the product does not meet the criteria for W.H.M.I.S. classification as a controlled product. As a result, a W.H.M.I.S. Safety Data Sheet is not required (in Canada) for this product.

If you have any questions, please contact us at (800) 266-2222 option 2 or via email at TechService@HardyDiagnostics.com.

Sincerely,

Quality Assurance Department Hardy Diagnostics

SDS-002457[A]

Hardy Diagnostics ~ 1430 West McCoy Lane ~ Santa Maria, CA 93455 ~ USA ~ (805)346-2766 Sales@HardyDiagnostics.com ~ www.HardyDiagnostics.com

Distribution Centers: California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

SOP-4277A [B]



Page 1 / 6

SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

VACUETTE® FE Sodium Fluoride / K3EDTA Blood Collection Tube

greiner bio-one A AN SOP 04.03.02-061

A AN SOP 04.03.02-061 Rev.01 Valid from: Sept 12, 2016

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: VACUETTE[®] FE Sodium Fluoride / K3EDTA Blood Collection Tube

Manufacturer/Supplier:

AUSTRIA

Greiner Bio-One GmbH Bad Haller Strasse 32 4550 Kremsmünster

Austria

Tel: (+43) 7583 6791-0 Fax: (+43) 7583 114 Email: office@at.gbo.com

Emergency phone number: (+43) 7583 6791-0

USA

Greiner Bio-One North America Inc. 4238 Capital Drive Monroe, NC 28110

USA

Tel: (+1) 888-286-3883 FAX: (+1) 800-726-0052 Email: info@us.gbo.com

Emergency phone number: (+1) 888-286-3883

BRASIL

Greiner Bio-One Brasil Produtos Médicos Hospitalares Ltda. Av. Affonso Pansan no. 1.967 13473-620 Vila Bertini Americana, São Paulo - Brasil

Tel: +55 (19) 3468-9600 Fax: +55 (19) 3468-9601 Email: info@br.gbo.com

Emergency phone number+55 (19) 3468-9600

· Recommended use / restrictions of use :

To collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. To be used only by trained healthcare professionals according to instructions of use.

SECTION 2: HAZARDS IDENTIFICATION

Classification according to NFPA 704 (Possible Rating 0-4):

K3EDTA:

Health Rating: 1 Flammability Rating: 1 Reactivity Rating: 0

Sodium Fluoride: Health Rating: 3 Flammability Rating: 0 Reactivity Rating: 0





• Classification according to Regulation (EC) No. 1272/2008 [EU-GHS/CLP]:

K3EDTA:

Skin irritation: Category 2 Eye irritation: Category 2A Acute toxicity: Category 4 (Oral)

Specific target organ toxicity: Category 3 (Respiratory tract irritation)

Sodium Fluoride:

Acute Toxicity: Category 3 (Oral)

Eye Irritation: Category 2 **Skin irritation:** Category 2



Page 2 / 6

SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

VACUETTE® FE Sodium Fluoride / K3EDTA **Blood Collection Tube**

areiner bio-one A AN SOP 04.03.02-061

Rev.01 Valid from: Sept 12, 2016

Classification according to EU Directives 67/548/EEC or 1999/45/EC:

K3EDTA: Irritating to eyes, respiratory system and skin

Sodium Fluoride: Toxic if swallowed, contact with acids liberates very toxic gas, irritating to eyes and

skin

Signal Word:

K3EDTA: Warning

Sodium Fluoride: Danger





Hazard Statements:

K3EDTA:

H315 Causes Skin irritation

H319 Causes serious eye irritation

H335 May cause respiratory irritation

Sodium Fluoride:

H301 Toxic if swallowed

H315 Causes Skin irritation

H319 Causes serious eye irritation

Precautionary Statements:

K3EDTA:

Avoid breathing dust/fume/gas/mist/vapors/spray

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Sodium Fluoride:

P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA

Sodium Fluoride

CAS No. Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA 65501-24-8

Sodium Fluoride 7691-49-4

Quantity of substances: < 1%

Because of trade secrets, not all components and their percentages are listed.

FIRST AID MEASURES SECTION 4:

Hazard description: Contact causes eye and skin irritation and may cause burns. May cause severe irritation of the respiratory tract with possible burns. Aspiration may lead to pulmonary edema. Prolonged exposure to dusts or vapors may result in perforation of the nasal septum. Ingestion is harmful and may be fatal. Symptoms may include salivation, nausea, vomiting, abdominal pain, fever and labored breathing. May cause respiratory paralysis and cardiac arrest. May cause systemic effects on heart, liver and kidneys.

Repeated exposure can also lead to fluoride poisoning (fluorosis) characterized by weight loss, weakness, anemia, brittle bones, and stiff joints. Skeletal effects may include increased bone density, calcium deposits in ligaments, and mottled tooth enamel. May cause developmental and fetal effects, which may be delayed. Animal studies have reported development of tumors. Avoid contact with skin and eyes. Do not inhale or swallow.

Primary route of entry: Dermal, eyes, inhalation, and ingestion.



Page 3 / 6

SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

VACUETTE® FE Sodium Fluoride / K3EDTA Blood Collection Tube

greiner bio-one A AN SOP 04.03.02-061

Rev.01 Valid from: Sept 12, 2016

Health effects:

Acute exposure effect:

Skin: Causes severe irritation. May cause rash and cold, clammy skin with bluish or pale color (milder cases). May cause burns, especially if skin is wet or moist.

Eyes: Causes severe irritation and may cause burns. May cause chemical conjunctivitis and eye damage.

Inhalation: May cause severe irritation of the respiratory tract and may cause burns.

Ingestion: Harmful if swallowed and may be fatal. Symptoms may include salivation, nausea, vomiting, abdominal pain, fever and labored breathing. May cause respiratory paralysis and cardiac arrest.

Repeated Exposure Effects:

Repeated ingestion may cause systemic effects on heart, liver and kidneys. Repeated ingestion may also result in depleted calcium levels in the body leading to hypocalcemia and death. Chronic inhalation and ingestion can also lead to fluoride poisoning (fluorosis) characterized by weight loss, weakness, anemia, brittle bones, and stiff joints. Skeletal effects may include increased bone density, calcium deposits in ligaments, and mottled tooth enamel. May cause developmental and fetal effects, which may be delayed. Animal studies have reported development of tumors.

Medical conditions which might be aggravated:

Pre-existing diabetes insipidus or renal impairment.

• Skin: Wash with soap and copious amounts of water. Remove contaminated clothing. Wash

clothing and thoroughly clean shoes before reuse. Get medical attention.

Eyes: Flush eyes with copious amounts of water for at least 15 minutes. Get medical

attention.

• **Inhalation:** Remove to fresh air. If breathing is difficult, give oxygen.

• **Ingestion:** Victim should drink copious amounts of water to dilute. Get medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

- Personal precautions: Avoid overexposure. Wear suitable protective clothing.
- Methods for cleaning up: Carefully sweep up and remove.
- Methods of containment: Dispose as of hazardous waste. Keep in suitable, closed containers for disposal
- **Emergency procedures:** Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- Personal precautions: Avoid overexposure. Wear suitable protective clothing.
- Methods for cleaning up: Carefully sweep up and remove.
- Methods of containment: Dispose as of hazardous waste. Keep in suitable, closed containers for disposal
- **Emergency procedures:** Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

SECTION 7: HANDLING AND STORAGE

- Handling: Advice for safe handling: Keep container tightly closed. Suitable for any general chemical storage area.
- Information about protection against explosions and fires: Avoid contact with incompatible material, minimize dust generation and accumulation. Material must be handled with adequate ventilation.
- Storage: Requirements to be met by storerooms and receptacles: Keep container closed when not in use. Store in a cool, dry, well-ventilated area. Store away from incompatible substances. Information about storage in one common storage facility: Keep container closed when not in use. Do not store in glass. Store in a cool, dry, well-ventilated area. Store protected from moisture. Store away from incompatible substances, such as strong acids and alkalies.



Page 4 / 6

SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

VACUETTE® FE Sodium Fluoride / K3EDTA Blood Collection Tube

greiner bio-one A AN SOP 04.03.02-061

Rev.01 Valid from: Sept 12, 2016

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

OSHA PEL: Sodium Fluoride: TWA 2.5 mg/m³ ACGIH TLV: Sodium Fluoride : 2.5 mg/m³TWA

Other recommended limits: N/A

 Additional information about design of technical systems: Use general or local exhaust ventilation to reduce exposure.

Personal protective equipment:

General protective and hygienic measures: Wash thoroughly after handling. Remove contaminated and wash before reuse. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Use with adequate ventilation. Provide eye bath and safety shower.

Breathing equipment: None required, where adequate ventilation conditions exist. For conditions where dust is apparent and engineering controls are not feasible, a NIOSH/MSHA approved respirator is recommended. If concentration exceeds capacity of respirator, a self-contained breathing apparatus is recommended.

Hand protection: Wear appropriate protective gloves to prevent skin exposure.

Eye protection: Use chemical safety goggles

Body protection: Wear appropriate protective clothing to prevent skin exposure.

Special requirements for PPE: N/A

• Hygiene measures: N/A

• Appropriate engineering controls: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

General information

Form: Crystalline powder

Color: White Odor: Odorless Odor Threshold: N/A

PH-value: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA: N/A

Sodium Fluoride: 10,2 (4%, 20 °C)

Change in condition

Melting point/Melting range: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate K3EDTA: N/A

Sodium Fluoride: 993 °C

Boiling point/Boiling range: not determined

Flash point: N/A

Flammability (solid, gaseous): N/A

Danger of explosion: Product does not present an explosion hazard

• Vapor pressure: Not determined

Density: Ethylendiaminetetraacetic Acid Tripotassium Dihydrate EDTA K₃: N/A

Sodium Fluoride: 2,8 g/cm³

• Solubility in/Miscibility w/H2O: Soluble

Organic solvents: N/A
Solids content: N/A

Partition coefficient: n-octanol/water: N/A

Auto-ignition temperature: N/A
 Decomposition temperature: N/A

Viscosity: N/A

Oxidizing properties: N/A



Page 5 / 6

SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

VACUETTE® FE Sodium Fluoride / K3EDTA Blood Collection Tube

greiner bio-one A AN SOP 04.03.02-061

Rev.01 Valid from: Sept 12, 2016

SECTION 10: STABILITY AND REACTIVITY

- Reactivity: No data available
- Chemical Stability: No data available
- Possibility of hazardous reactions: No data available
- Conditions to avoid: Avoid generation and accumulation of dusts.
- Incompatible materials: Moisture, acids, alkalies, oxidizing agents, and glass.
- Hazardous decomposition products: Hydrogen fluoride, sodium oxide. May form under fire conditions: nitrogen oxides (NOx), carbon oxides, potassium oxides

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity (LD 50 oral rat > 200 mg/kg)

Eye: Severely irritating to the eyes.

Skin: Severely irritating to the skin.

Inhalation: Harmful if inhaled and may be fatal.

Ingestion: Toxic if swallowed. May be fatal.

Primary irritant effect:

On the skin: Severely irritating to the skin.
On the eye: Severely irritating to the eyes.

Sensitization: Not established

Additional toxicological information:

Chronic: Repeated ingestion may cause systemic effects on heart, liver and kidneys. Repeated ingestion may also result in depleted calcium levels in the body leading to hypocalcemia and death. Chronic inhalation and ingestion can also lead to fluoride poisoning (fluorosis) characterized by weight loss, weakness, anemia, brittle bones, and stiff joints. Skeletal effects may include increased bone density, calcium deposits in ligaments, and mottled tooth enamel. May cause developmental and fetal effects, which may be delayed. Animal studies have reported development of tumors.

SECTION 12: ECOLOGICAL INFORMATION

- **Ecotoxilogical effects:** Unspecified. No data is available on the adverse effects of this material on the environment.
- Other information: The ecological effects have not been thoroughly investigated, but currently none
 have been identified.
- **General notes:** Dangerous to aquatic life in high concentrations. Soil can bind fluorides tightly if pH is greater than 6.5. Fluorides can be damaging to plants when present in acid soils.

SECTION 13: DISPOSAL CONSIDERATION

• Product: Recommendation

Disposal should be done in accordance with all federal, state and local environmental regulations. Disposal must be made according to the regulations found in 40 CFR 261. This product is not a hazardous waste according to local regulations.

• Packaging: Recommendation

Disposal should be done in accordance with all federal, state and local environmental regulations. Disposal must be made according to the regulations found in 40 CFR 261. This product is not a hazardous waste according to local regulations.

Recommended cleansing agent

Water, if necessary with cleansing agents



Page 6 / 6

SAFETY DATA SHEET

acc. to ISO 11014, 29 CFR 1910.1200

VACUETTE® FE Sodium Fluoride / K3EDTA Blood Collection Tube

greiner bio-one A AN SOP 04.03.02-061

Rev.01 Valid from: Sept 12, 2016

SECTION 14: TRANSPORT INFORMATION

• DOT regulations: Not regulated

Land transport ADR/RID: Not regulated
 Maritime transport IMDG: Not regulated

• Air transport ICAO-TI and IATA-DGR: Not regulated

SECTION 15: REGULATORY INFORMATION

- OSHA, 29 CFR 1910.1200(g) and Appendix D. United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), third revised edition, United Nations, 2009
- EC directives: 91/155/EEC, 93/112/EC, 88/379/EEC
- Water hazard class: N/A
- **Note:** Please note that there may be additional legal provisions to be observed. We recommend that you keep yourself informed about all applicable international, national and local regulations.

SECTION 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, neither Greiner Bio-One nor any of its subcontractors or suppliers assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



Reviewed On: 04/22/2016 Date Prepared: 05/10/2016

1 Identification

- · Product Identifier:
- · Product Name: BD Universal Viral Transport Combo Swab Kit
- · Catalog Number: 220222
- · Application of the substance / the mixture Laboratory Chemicals
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

BD Diagnostic Systems

7 Loveton Circle Sparks, MD 21152

Telephone: (410) 771 - 0100 or (800) 638 - 8663 Email Address: Technical_Services@bd.com · Information Department: Technical Service

- · Emergency telephone number:
- In case of a chemical emergency, spill, fire, exposure, or accident, contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Hazard(s) identification

- · Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS).
- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · NFPA ratings (scale 0-4)



Health = 0Flammability = 0Reactivity = 0

· HMIS ratings (scale 0-4)



 \bigcirc Health = 0 \bigcirc Flammability = 0 REACTIVITY \bigcirc Reactivity = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.



Date Prepared: 05/10/2016 Reviewed On: 04/22/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 1)

3 Composition/information on ingredients

· Chemical characterization: Mixture

- · **Description**: Mixture consisting of the following components.
- · Dangerous Components: Void
- · Additional information Risk phrases refer to section 15.

4 First-aid measures

- · Description of first aid measures
- · General information No special measures required.
- · After inhalation Seek medical treatment in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing If symptoms persist consult doctor.
- · Information for doctor Show this product label or this SDS.
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents

CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.

· Special hazards arising from the substance or mixture

No further relevant information available.

- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: Wipe up with damp sponge or mop.
- · Methods and material for containment and cleaning up: No special measures required.

(Contd. on page 3)



Date Prepared: 05/10/2016 Reviewed On: 04/22/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 2)

· Reference to other sections No dangerous substances are released.

7 Handling and storage

- · Handling
- · Precautions for safe handling No special measures required.
- Information about protection against explosions and fires:
 No special measures required.
- · Conditions for safe storage, including any incompatibilities
- Storage
- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Store away from oxidizing agents.
- Further information about storage conditions: Store in cool, dry conditions in well sealed containers.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see Section 7.
- · Control parameters
- Components with limit values that require monitoring at the workplace:

 The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal Protective Equipment
- · General protective and hygienic measures

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:





Chemical resistant gloves (i.e. nitrile, or equivalent).

- · Eye protection: Safety glasses
- · Body protection: Protective work clothing (lab coat).

US



Date Prepared: 05/10/2016 Reviewed On: 04/22/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 3)

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Liquid

Color: Light orange Characteristic

• **pH-value:** 7.3 +/- 0.2

Change in condition
 Melting point/Melting range:
 Boiling point/Boiling range:
 Not determined

· Flash point: Not applicable

• **Auto igniting:** Product is not self igniting.

• **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· Solubility in / Miscibility with

Water: Soluble

• Other information No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: Incompatible material: strong oxidizers.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin: No irritating effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.

(Contd. on page 5)



Date Prepared: 05/10/2016 Reviewed On: 04/22/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 4)

· Additional toxicological information:

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 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.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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.

(Contd. on page 6)



Date Prepared: 05/10/2016 Reviewed On: 04/22/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 5)

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to state and federal regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

| 4 Transport information | |
|--|---|
| · UN-Number | |
| · DOT, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, IMDG, IATA | Void |
| · Environmental hazards: · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex I MARPOL73/78 and the IBC Code | II of Not applicable. |
| · Transport/Additional information: | If "void" appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · 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.

(Contd. on page 7)



Reviewed On: 04/22/2016 Date Prepared: 05/10/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 6)

· TSCA (Toxic Substances Control Act)

All ingredients are listed.

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

- GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

Department issuing SDS:

Environmental, Health & Safety Created by Michael J. Spinazzola

- · Contact: Technical Service Representative
- · Date of preparation / last revision 05/10/2016 / -
- · Abbreviations and acronvms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

(Contd. on page 8)



Reviewed On: 04/22/2016 Date Prepared: 05/10/2016

Product Name: BD Universal Viral Transport Combo Swab Kit

(Contd. of page 7)

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement

concerning the International Carriage of Dangerous Goods by Road) LC50: Lethal concentration, 50 percent

BEI: Biological Exposure Limit

US