Safety Data Sheet

Issue Date: 08-Jun-2011 **Revision Date:** 29-Oct-2013 **Version** 1

1. IDENTIFICATION

Product Identifier

Product Name Lyophilized Microorganisms

Other means of identification

SDS # GB-023

Product Code BCC-Kit; POC-PELLETS series; N-GL80; GBS-XX, MRSA-XX, Ce-VRE-XX, VRE-XX; CSXXXX, DPXXXX, CPXXXX, CP+XXXX, CQXXXX, STXXXX, 2PXXXX series, Surveys: Shiga Toxin Survey; Surveys, API (Blood, Dermatophyte, Ear, Eye, Genital, Mycology, Sputum, Stool, Throat, Urine Wound; Surveys (D, D-A, D-B, D-C, BCS, BDP, LPX, MRS, MRS 5, IDO, D8, DEX, VRE, VS1, CAMP, MBT, PNA, BIT); TVS-02; TVS-01; VV-01, CV-01

Synonyms Blood Culture Control Verification Kit (Lyophilized microorganism preparations)
Diagnostic Specimens (Lyophilized microorganism preparations)
Lyophilized microorganism preparations, Custom
Lyophilized microorganism preparations, Special QC Controls
Inocu-Swabs and Inocu-Pellets (Lyophilized microorganism preparations)
Proficiency Materials (Lyophilized microorganism preparations, swabs & pellets)
Escherichia coli, Shiga-like Toxin 1 and 2
Tri-Valent Swabs, Negative Control
Tri-Valent Swabs, Positive Control
Tri-Valent Swabs, Validation & Calibration Set.

UN/ID No UN3373

Recommended use of the chemical and restrictions on use

Recommended Use For laboratory use.

Details of the supplier of the safety data sheet

Manufacturer Address
Gibson Bioscience
1040 Manchester Street
Lexington, KY 40508

Emergency Telephone Number

Company Phone Number Phone: (800) 477-4763
Fax: (859) 253-1476

Emergency Telephone (24 hr) INFOTRAC 1-352-323-3500 (International)
1-800-535-5053 (North America)

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: This material presents a biohazard and risk of infection.

Appearance According to product specification **Physical State** Dry material
Swab containing dry material **Odor** Odorless

Classification

Each lyophilized pellet contains a pure or mixed microorganism population. The microorganisms are classified as either Risk Group 1 or Risk Group 2 by the World Health Organization (WHO). These microorganisms may cause human infection, may pose a hazard to the laboratory personnel, but are unlikely to spread in the community. Exposure to these microorganisms in the laboratory rarely causes infection. Effective prevention and treatment is readily available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms

Blood Culture Control Verification Kit (Lyophilized microorganism preparations)
Diagnostic Specimens (Lyophilized microorganism preparations)
Lyophilized microorganism preparations, Custom
Lyophilized microorganism preparations, Special QC Controls
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Tri-Valent Swabs, Validation & Calibration Set.

Chemical Nature

Each lyophilized pellet contains a pure or mixed microorganism population. The microorganisms are classified as either Risk Group 1 or Risk Group 2 by the World Health Organization (WHO), Tri-Valent Swabs, Validation & Calibration Set: Each swab contains a randomly mixed microorganism population (Trichomonas vaginalis, Gardnerella vaginalis, Candida albicans, and Escherichia coli).

If Chemical Name/CAS No is "proprietary" and/or Weight-% is listed as a range, the specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

First Aid Measures

General Advice Provide this SDS to medical personnel for treatment.

Eye Contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin Contact If skin contact occurs, immediately wash with an appropriate biocide solution.

Inhalation Remove to fresh air. Seek medical advice.

Ingestion Call a physician or poison control center immediately.

Most important symptoms and effects

Symptoms Not determined.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media Not determined.

Specific Hazards Arising from the Chemical

Not applicable.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Immediately notify nearby personnel of the incident.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Clean-Up Decontaminate the spill by flooding and soaking the spilled material with a suitable disinfectant. Allow sufficient time for the biocide activity of the disinfectant. Clean the area and material using disposable towels. Materials used in cleanup should be treated as biohazard material.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Ensure adequate microbiological equipment and facilities to receive, process, maintain, store, and dispose of biohazard material. Proper techniques must be employed to avoid exposure and contact with microorganism growth. The microbiology laboratory personnel using these devices must be trained, experienced, and demonstrate proficiency in processing, maintaining, storing, and disposing of biohazard material. It is recommended that all microbial cultures be handled by qualified microbiologists and to use appropriate safety procedures and precautions when handling these specimens. Caution should be used to prevent the generation of aerosols during the preparation of suspensions.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store devices in their original sealed packaging according to temperature specifications on labeling.

Incompatible Materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines No exposure limits noted for ingredient(s)

Appropriate engineering controls

Engineering Controls Biological Safety Cabinet.

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses.

Skin and Body Protection Wear suitable gloves. Protective work clothing (lab coat).

Respiratory Protection Ensure adequate ventilation, especially in confined areas.

General Hygiene Considerations Keep away from food, drink and animal feeding stuffs. Immediately remove all soiled and contaminated clothing. Wash hands thoroughly after handling. Avoid contact with skin, eyes or clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Dry material Swab containing dry material		
Appearance	According to product specification	**Odor**	Odorless
Color	According to product specification	**Odor Threshold**	Not determined

Property	Values	Remarks • Method
pH	Not determined	
Melting Point/Freezing Point	Not determined	
Boiling Point/Boiling Range	Not determined	
Flash Point	Not determined	
Evaporation Rate	Not determined	
Flammability (Solid, Gas)	Not determined	
Upper Flammability Limits	Not determined	
Lower Flammability Limit	Not determined	
Vapor Pressure	Not determined	
Vapor Density	Not determined	
Specific Gravity	Not determined	
Water Solubility	Soluble in water	
Solubility in other solvents	Not determined	
Partition Coefficient	Not determined	
Auto-ignition Temperature	Product is not self-igniting	
Decomposition Temperature	Not determined	
Kinematic Viscosity	Not determined	
Dynamic Viscosity	Not determined	
Explosive Properties	Not an explosive	
Oxidizing Properties	Not determined	

10. STABILITY AND REACTIVITY

Reactivity
Not reactive under normal conditions.

Chemical Stability
Stable under recommended storage conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to Avoid
Keep out of reach of children.

Incompatible Materials
None known based on information supplied.

Hazardous Decomposition Products
No decomposition if used according to specifications.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	Shiga Toxin Survey: Shiga-toxigenic E coli produce verotoxins (VTs) (verocytotoxins) that result in human disease. These toxins produce profound cytopathic effects in vero cells, and they show a high degree of homology to the Shiga-toxin (Stx) of Shigella dysenteriae type 1. Clinical symptoms may include bloody diarrhea and hemorrhagic colitis, along with complications associated with HUS, acute and chronic kidney disease, thrombotic thrombocytopenic purpura (TTP), neurological sequelae and death
Eye Contact	Avoid contact with eyes.
Skin Contact	Not expected to be a skin irritant during prescribed use.
Inhalation	Avoid the production of aerosols.
Ingestion	Avoid hand to mouth contact.

Component Information

Information on physical, chemical and toxicological effects

Symptoms	Please see section 4 of this SDS for symptoms.

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

Carcinogenicity	Carcinogenic potential is unknown.

Numerical measures of toxicity
Not determined

12. ECOLOGICAL INFORMATION

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

Persistence/Degradability
Not determined.

Bioaccumulation
Not determined.

Mobility
Not determined

Other Adverse Effects
Not determined

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Disposal of Wastes The lyophilized microorganisms and subsequent growth of these microorganisms on culture media are considered to be biohazard material. Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of and comply with the proper disposal of biohazard materials.

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

Note Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

DOT

UN/ID No	UN3373
Proper Shipping Name	Biological substance, Category B
Hazard Class	6.2

IATA

UN/ID No	UN3373
Proper Shipping Name	Biological substance, Category B
Hazard Class	6.2

IMDG

UN/ID No	UN3373
Proper Shipping Name	Biological substance, Category B
Hazard Class	6.2

15. REGULATORY INFORMATION

International Inventories

Not determined

Legend:

TSCA *- United States Toxic Substances Control Act Section 8(b) Inventory*

DSL/NDSL *- Canadian Domestic Substances List/Non-Domestic Substances List*

EINECS/ELINCS *- European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances*

ENCS *- Japan Existing and New Chemical Substances*

IECSC *- China Inventory of Existing Chemical Substances*

KECL *- Korean Existing and Evaluated Chemical Substances*

PICCS *- Philippines Inventory of Chemicals and Chemical Substances*

AICS *- Australian Inventory of Chemical Substances*

US Federal Regulations

SARA 313

Not determined

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations
Not determined

16. OTHER INFORMATION

NFPA	**Health Hazards**	**Flammability**	**Instability**	**Special Hazards**
	Not determined	Not determined	Not determined	Not determined
HMIS	**Health Hazards**	**Flammability**	**Physical Hazards**	**Personal Protection**
	Not determined	Not determined	Not determined	Not determined

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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 Safety Data Sheet