MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name	**C. difficile Sample Diluent**
Version #	01
Issue date	09-04-2012
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	173; 173E
Product use	Component of the OSOM® C. difficile Toxin A/B Test kit. Intended for the qualitative detection of Clostridium difficile toxins A and or B in human stool samples. For In Vitro Diagnostic use only.
Synonym(s)	C. difficile Sample Buffer
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042
Emergency Telephone Numbers	Americas 1-760-476-3962 Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazards Identification

Physical state	Liquid.
Appearance	Clear, colorless liquid.
Emergency overview	Health injuries are not known or expected under normal use.
OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	In high concentrations, vapors may be irritating to the respiratory system.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes.
Chronic effects	No data available.
Signs and symptoms	Direct contact with skin and eyes may cause irritiation.
Potential environmental effects	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Sucrose	57-50-1	1 - 5

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion If material is ingested, immediately contact a poison control center.

Notes to physician Provide general supportive measures and treat symptomatically.

5. Fire Fighting Measures

Flammable properties This product is not flammable.

Extinguishing media

Suitable extinguishing media Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media None known.

Protection of firefighters

Specific hazards arising from the chemical None known.

Protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products None known.

6. Accidental Release Measures

Personal precautions Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

Methods for containment Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

ACGIH

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Unspecified.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

Canada - Alberta

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Unspecified.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Total dust.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

Canada - Quebec

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Unspecified.

Exposure guidelines Follow standard monitoring procedures.

Engineering controls Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.

Personal protective equipment

Eye / face protection Wear approved safety glasses or goggles.

Skin protection Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection Under normal conditions, respirator is not normally required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance Clear, colorless liquid.

Physical state Liquid.

Form Liquid.

Color Clear, colorless.

Odor Odorless.

Odor threshold Not available.

pH 8

Vapor pressure Not available.

Vapor density Not available.

Boiling point Not available.

Melting point/Freezing point Not applicable.

Solubility (water) Soluble.

Specific gravity 1

Flash point Not available.

Flammability limits in air, upper, % by volume Not available.

Flammability limits in air, lower, % by volume Not available.

Auto-ignition temperature Not applicable.

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.

Conditions to avoid No data available.

Incompatible materials No data available.

Hazardous decomposition products None known.

Possibility of hazardous reactions Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Sucrose (CAS 57-50-1)		
Acute		
Oral		
LD50	Rat	29700 mg/kg

Sensitization Not classified.

Acute effects May cause discomfort if swallowed.

Local effects Ingestion may cause irritation and malaise.

Chronic effects No data available.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

ACGIH Carcinogens

Sucrose (CAS 57-50-1) A4 Not classifiable as a human carcinogen.

Epidemiology No epidemiological data is available for this product.

Mutagenicity Not classified.

Reproductive effects Not classified.

Symptoms and target organs Direct contact with skin and eyes may cause irritiation.

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Accumulation Not available.

Partition coefficient

Sucrose -3.7

Mobility in environmental media The product is completely soluble in water.

13. Disposal Considerations

Disposal instructions Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions. This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

Waste from residues / unused products Dispose in accordance with all applicable regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A) No

Section 311/312 (40 CFR 370) No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Not controlled

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US. Massachusetts RTK - Substance List

Sucrose (CAS 57-50-1) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Sucrose (CAS 57-50-1) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended use	Component of the OSOM® C. difficile Toxin A/B Test kit. Intended for the qualitative detection of Clostridium difficile toxins A and or B in human stool samples. For In Vitro Diagnostic use only.
Recommended restrictions	Use in accordance with supplier's recommendations.
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 Instability: 0
Disclaimer	The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.