

1. Product and Company Identification

Material name	C. difficile CONTROL +
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 Positive Control
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 irritation.
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

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

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	When heated to decomposition, may produce hydrazoic acid fumes.
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	Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide.
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	No exposure limits noted for ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Engineering controls	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
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	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not applicable.
Solubility (water)	Soluble.
Specific gravity	Not available.
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	Protect against direct sunlight.
Incompatible materials	Strong oxidizing agents. Acids. Heavy metals.
Hazardous decomposition products	None.
Possibility of hazardous reactions	Contact with acids liberates toxic gas.

11. Toxicological Information

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.
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 irritation.
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.
Aquatic toxicity	Not classified.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulation / Accumulation	Not available.
Mobility in environmental media	The product is soluble in water.

13. Disposal Considerations

Disposal instructions	Dispose in accordance with all applicable regulations. 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. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

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.

All components are on the U.S. EPA TSCA Inventory List.

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)***

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

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

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
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