

MATERIAL SAFETY DATA SHEET

Toxin B Sepharose

Section 1: Product and Company Identification

Material name	Toxin B Sepharose	
Synonyms	Clostridium difficile Cytotoxin B Sepharose	
Product description	Liquid slurry containing sepharose (highly cross-linked agarose), phosphate buffer, Clostridium difficile cytotoxin B and sodium azide.	
Product use	Intermediate for use in the manufacture of C. difficile in vitro diagnostic kit.	
Emergency Telephone Numbers	Manufacturer/Distributor	Corporate Headquarters
Americas: +1-760-476-3962	Sekisui Diagnostics (UK) Ltd	Sekisui Diagnostics LLC
Europe, Middle East	50 Gibson Drive	31 New York Avenue
& Africa: +1-760-476-3961	Kings Hill, West Malling	Framingham, MA 01701
Asia Pacific: +1-760-476-3960	Kent ME19 4AF UK	USA
Access code: 333512	Phone: 44 (0) 1732 220022	Phone: 508-661-1835

Section 2: Hazards Identification

OSHA regulatory status	This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.
Precautionary statements	CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Contains a small amount of a highly potent toxin produced by the bacteria C. difficile. This preparation does not contain C. difficile and is therefore not infectious. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: white gel in clear, colorless liquid.
Potential health effects:	
Routes of exposure	Occupational exposure routes may include inhalation, eye and skin contact.
Eyes	No data available.
Skin	No data available.
Inhalation	No data available.
Ingestion	Toxins produced from Clostridium difficile cause profuse watery diarrhea, fever, abdominal pain, nausea and dehydration.
Chronic effects	No data available.
Target organs	C. difficile toxin: intestine.
Potential environmental effects	No data available.

Section 3: Composition / Information on Ingredients

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	86 - 87
EC R-Phrases: None	EC Hazard Class: None		
CNBr-activated Sepharose	9012-36-6	232-731-8	12 - 13
EC R-Phrases: None	EC Hazard Class: None		
Sodium chloride	7647-14-5	231-598-3	< 0.5
EC R-Phrases: None	EC Hazard Class: None		
Potassium phosphate dibasic, anhydrous	7758-11-4	231-834-5	< 0.2
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
Clostridium difficile Cytotoxin B	Not Assigned	Not Assigned	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
Potassium phosphate, monobasic	7778-77-0	231-913-4	< 0.1
EC R-Phrases: None	EC Hazard Class: None		

Section 4: First Aid Measures

First aid procedures:	
Eye contact	Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain immediate medical attention.
Skin contact	In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.
Inhalation	If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.
Ingestion	In case of ingestion, contact a poison control center or physician for instructions.

MATERIAL SAFETY DATA SHEET

Toxin B Sepharose

Section 5: Fire Fighting Measures

Flammable properties	Dilute aqueous solution not considered a fire hazard.
Suitable extinguishing media	Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.
Unsuitable extinguishing media	Unknown.
Specific hazards arising from the chemical	None expected.
Standard protective equipment and precautions for firefighters	Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

Section 6: Accidental Release Measures

Personal precautions	Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid aerosol inhalation. After handling, immediately wash any areas of the body that may have been exposed, whether or not known skin contact has occurred.
Environmental 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. Follow proper disposal procedures.
Methods and materials for containment and clean-up	Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Section 7: Handling and Storage

Handling	Follow good work practices. See Section 8, Engineering Controls. Avoid physical contact. Wash hands thoroughly after handling.
Storage	Store at 2 to 8°C (36 to 46°F).

Section 8: Exposure Controls / Personal Protection

Exposure guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium azide	26628-22-8	0.29 mg/m3 Ceiling (as NaN ₃); 0.11 ppm Ceiling (vapor, as hydrazoic acid)
--------------	------------	--

Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium azide	26628-22-8	0.11 ppm Ceiling; 0.3 mg/m3 Ceiling
--------------	------------	-------------------------------------

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - Skin Notations

Sodium azide	26628-22-8	possibility of significant uptake through the skin
--------------	------------	--

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - STELs

Sodium azide	26628-22-8	0.3 mg/m3 STEL
--------------	------------	----------------

EU - Occupational Exposure Directive (2006/15/EC) Indicative Occupational Exposure Limit Values (IOELV) - TWAs

Sodium azide	26628-22-8	0.1 mg/m3 TWA
--------------	------------	---------------

Germany - DFG - Recommended Exposure Limits - Ceilings (Peak Limitations)

Sodium azide	26628-22-8	0.4 mg/m3 Peak (inhalable fraction)
--------------	------------	-------------------------------------

Germany - DFG - Recommended Exposure Limits - MAK Values

Sodium azide	26628-22-8	0.2 mg/m3 MAK (inhalable fraction)
--------------	------------	------------------------------------

Germany - TRGS 900 - Occupational Exposure Limits - TWAs

Sodium azide	26628-22-8	0.2 mg/m3 TWA (exposure factor 2)
--------------	------------	-----------------------------------

Israel - Occupational Exposure Limits - Ceilings

Sodium azide	26628-22-8	0.29 mg/m3 Ceiling (as NaN ₃); 0.11 ppm Ceiling (vapor, as Hydrazoic acid)
--------------	------------	--

Korea - Occupational Exposure Limits - Ceilings

Sodium azide	26628-22-8	0.1 ppm Ceiling; 0.3 mg/m3 Ceiling
--------------	------------	------------------------------------

MATERIAL SAFETY DATA SHEET

Toxin B Sepharose

Engineering controls

Minimize potential for aerosolization. Handle within a containment system, with local exhaust ventilation, or with dilution ventilation at a minimum. Facilities storing or using this preparation should be equipped with an eyewash fountain and a safety shower.

Personal protective equipment:

Eye / face protection

Wear appropriate protective chemical safety glasses or goggles.

Skin protection

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

Hand protection

Wear chemical resistant protective gloves. Change gloves regularly or immediately if they are contaminated, torn or punctured.

Respiratory protection

A respirator is not required under normal conditions of use.

General

Follow company-specific safety procedures.

Section 9: Physical and Chemical Properties

Appearance	White gel in clear, colorless liquid
Odor	Unknown
pH	Not available
Melting point/Freezing point	Not applicable / Not available
Boiling point	Not available
Flash point	Not available
Flammability/explosivity limits in air, upper	Not available
Flammability/explosivity limits in air, lower	Not available
Vapor pressure	Not available
Vapor density	Not available
Solubility	Water-soluble
Partition coefficient (n-octanol/water)	Not available
Auto-ignition temperature	Not available

Section 10: Chemical Stability and Reactivity Information

Possibility of hazardous reactions	Hazardous polymerization will not occur.
Chemical stability	Stable under ordinary conditions of use and storage. See Section 7.
Conditions to avoid	None known.
Incompatible materials	Sodium azide: Avoid strong oxidizing agents, acids, heavy metals and their salts.
Hazardous decomposition products	None expected under normal conditions of use.

Section 11: Toxicological Information

Acute effects:

Toxicological data - Selected LD50s and LC50s

Potassium phosphate, monobasic	7778-77-0	Dermal LD50 Rabbit: >4640 mg/kg
Sodium azide	26628-22-8	Oral LD50 Rat: 27 mg/kg; Dermal LD50 Rabbit: 20 mg/kg
Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m ³ /1H; Oral LD50 Rat: 3 g/kg;
Water	7732-18-5	Dermal LD50 Rabbit: >10 g/kg
		Oral LD50 Rat: >90 mL/kg

Chronic effects

No data available.

Sensitization

No data available.

Carcinogenicity:

ACGIH - Threshold Limits Values - Carcinogens

Sodium azide	26628-22-8	A4 - Not Classifiable as a Human Carcinogen
Mutagenicity	No data available.	
Reproductive effects	No data available.	
Teratogenicity	No data available.	

MATERIAL SAFETY DATA SHEET

Toxin B Sepharose

Section 12: Ecological Information

Ecotoxicity:

Ecotoxicity - Freshwater Fish Species Data

Sodium azide 26628-22-8

96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 Hr LC50 Lepomis macrochirus: 0.7 mg/L; 96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Sodium chloride 7647-14-5

96 Hr LC50 Lepomis macrochirus: 9675 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7650 mg/L [static]

Ecotoxicity - Water Flea Data

Sodium chloride 7647-14-5

48 Hr EC50 Daphnia magna: 1000 mg/L

Persistence and degradability

No data available.

Bioaccumulation potential

No data available.

Mobility in environmental media

No data available.

Section 13: Disposal Considerations

Methods of disposal

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. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste classification:

U.S. - California - 22 CCR - Presumed Hazardous Wastes

Sodium azide 26628-22-8

Ignitable; Reactive

U.S. - RCRA (Resource Conservation & Recovery Act) - P Series Wastes - Acutely Toxic Wastes

Sodium azide 26628-22-8

waste number P105

Section 14: Transport Information

Basic shipping description

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

Section 15: Regulatory Information

US Federal Regulations:

This preparation is an intermediate used in the production of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA):

CNBr-activated Sepharose 9012-36-6 XU

Potassium phosphate dibasic, anhydrous 7758-11-4 Present

Potassium phosphate, monobasic 7778-77-0 Present

Sodium azide 26628-22-8 Present

Sodium chloride 7647-14-5 Present

Water 7732-18-5 Present

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Sodium azide 26628-22-8 1000 lb final RQ; 454 kg final RQ

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Sodium azide 26628-22-8 1000 lb EPCRA RQ

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Sodium azide 26628-22-8 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Sodium azide 26628-22-8 1.0 % de minimis concentration

US State Regulations

U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances

Sodium azide 26628-22-8 Present

MATERIAL SAFETY DATA SHEET

Toxin B Sepharose

International Regulations:

This preparation is an intermediate and is exempt from classification under the EU Dangerous Preparations Directive (1999/45/EC).

Canada - WHMIS - Classifications of Substances

CNBr-activated Sepharose	9012-36-6	Uncontrolled product according to WHMIS classification Criteria
Potassium phosphate dibasic, anhydrous	7758-11-4	Uncontrolled product according to WHMIS classification Criteria
Potassium phosphate, monobasic	7778-77-0	Uncontrolled product according to WHMIS classification Criteria
Sodium azide	26628-22-8	D1A
Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification Criteria
Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

Sodium azide	26628-22-8	1 %
--------------	------------	-----

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium azide	26628-22-8	T+;R28_R32_N;R50-53
--------------	------------	---------------------

EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium azide	26628-22-8	S:1/2-28-45-60-61
--------------	------------	-------------------

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium azide	26628-22-8	ID Number 636, hazard class 2 - hazard to waters
Sodium chloride	7647-14-5	ID Number 270, hazard class 1 - low hazard to waters

Inventory - Australia - Inventory of Chemical Substances (AICS)

CNBr-activated Sepharose	9012-36-6	Present
Potassium phosphate dibasic, anhydrous	7758-11-4	Present
Potassium phosphate, monobasic	7778-77-0	Present
Sodium azide	26628-22-8	Present
Sodium chloride	7647-14-5	Present
Water	7732-18-5	Present

Inventory - Canada - Domestic Substances List (DSL)

CNBr-activated Sepharose	9012-36-6	Present
Potassium phosphate dibasic, anhydrous	7758-11-4	Present
Potassium phosphate, monobasic	7778-77-0	Present
Sodium azide	26628-22-8	Present
Sodium chloride	7647-14-5	Present
Water	7732-18-5	Present

Inventory - China

CNBr-activated Sepharose	9012-36-6	Present
Potassium phosphate dibasic, anhydrous	7758-11-4	Present
Potassium phosphate, monobasic	7778-77-0	Present
Sodium azide	26628-22-8	Present
Sodium chloride	7647-14-5	Present
Water	7732-18-5	Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

CNBr-activated Sepharose	9012-36-6	232-731-8
Potassium phosphate dibasic, anhydrous	7758-11-4	231-834-5
Potassium phosphate, monobasic	7778-77-0	231-913-4
Sodium azide	26628-22-8	247-852-1
Sodium chloride	7647-14-5	231-598-3
Water	7732-18-5	231-791-2

Inventory - Japan Existing and New Chemical Substances (ENCS)

Potassium phosphate dibasic, anhydrous	7758-11-4	1-452
Potassium phosphate, monobasic	7778-77-0	1-452
Sodium azide	26628-22-8	1-482
Sodium chloride	7647-14-5	1-236

MATERIAL SAFETY DATA SHEET

Toxin B Sepharose

Inventory - Korea - Existing and Evaluated Chemical Substances

CNBr-activated Sepharose	9012-36-6	KE-00278
Potassium phosphate dibasic, anhydrous	7758-11-4	KE-12167
Potassium phosphate, monobasic	7778-77-0	KE-28622
Sodium azide	26628-22-8	KE-31357
Sodium chloride	7647-14-5	KE-31387
Water	7732-18-5	KE-35400

Canadian Hazardous Products

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations

EC Hazard Class Exempt

Risk Phrases None

Safety Phrases None

Section 16: Other Information

Further Information:

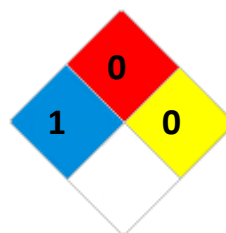
This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using a Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks. Chronic (long-term) health effects are indicated in the HMIS® by an asterisk (*). HMIS® is a registered trade and service mark of the NPCA. For details on HMIS® ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

HMIS® RATINGS

HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0

NFPA RATINGS



MSDS Origination Date: 30 October, 2008

Version #: 2

Revision Date: 04 December, 2012

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 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 has been advised of the possibility of such damages.