

Classified as hazardous in accordance with the criteria of EPA New Zealand

Section 1 - Identification

Product Identifier

Product Name ProSpecT Clostridium difficile Toxin AB Microplate Assay

Recommended Use Laboratory chemicals.
Uses advised against No Information available

Product Code	R244596
Address	Thermo Fisher Scientific New Zealand Ltd 244 Bush Road, Albany, Auckland, New Zealand
Emergency Tel.	CHEMTREC® 09 980 6780 or +64 9 980 6780
Telephone / Fax Numbers	Tel: 09 980 6700 Fax: 09 980 6788
E-mail address	<u>ANZinfo@thermofisher.com</u>

Section 2 - Hazard(s) Identification

Classification under Work Safe New Zealand

Classified as hazardous in accordance with the criteria of EPA New Zealand

GHS Classification

Physical hazards

Substances/mixtures corrosive to metal Category 1

Health hazards

Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 1
Carcinogenicity	Category 1
Specific target organ toxicity - (repeated exposure)	Category 2

Environmental hazards

Based on available data, the classification criteria are not met

Label Elements



Signal Word

Danger

Hazard Statements

H315 - Causes skin irritation
H318 - Causes serious eye damage
H290 - May be corrosive to metals
H350 - May cause cancer
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements

Prevention

P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor
P362 + P364 - Take off contaminated clothing and wash it before reuse

Storage

P403 - Store in a well-ventilated place

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Other hazards which do not result in classification

Contains a known or suspected endocrine disruptor
Included in the list established in accordance with Article 59(1) for having endocrine disrupting properties

Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
STOP SOLUTION - Sulphuric acid	7664-93-9	4.5
Negative Control & Sample Diluent - Sodium azide	26628-22-8	0.1
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-	9002-93-1	0.1

Section 4 - First Aid Measures

Description of first aid measures

General Advice

If symptoms persist, call a physician.

New Zealand Emergency Tel.

CHEMTREC®
09 980 6780 or +64 9 980 6780

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

Eye Contact	Get medical attention. 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. If skin irritation persists, call a physician.
Ingestion	Clean mouth with water and drink afterwards plenty of water.
Self-Protection of the First Aider	No special precautions required.
First Aid Facilities	Eyewash, safety shower and washroom.
Most important symptoms and effects	Causes eye burns.
Notes to Physician	Treat symptomatically.

Section 5 - Fire Fighting Measures

Suitable Extinguishing Media

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

Extinguishing media which must not be used for safety reasons

No information available.

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

None under normal use conditions.

Special protective equipment and precautions for fire fighters

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

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Emergency procedures

Use personal protective equipment as required. Ensure adequate ventilation.

Environmental Precautions

Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods for Containment and Clean Up

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

Precautions to prevent secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

Section 7 - Handling and Storage

Precautions for Safe Handling

Advice on safe handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions

Keep at temperatures between 2°C and 8 °C.

Incompatible Materials

None known.

AS/NZS 2243.10:2004, Safety in laboratories - Storage of chemicals

Section 8 - Exposure Controls and Personal Protection

Control parameters

Exposure limits

NZ - Workplace Exposure Standards and Biological Exposure Indices (6th edition). New Zealand Department of Labor

AUS - Exposure Standards for Atmospheric Contaminants in the Occupational Environment - Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008(1995)]

Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:1003(1995)] updated in August, 2005. Safe Work Australia

UK - EH40/2005 Work Exposure Limits, Fourth edition. Published 2020.

ACGIH - Threshold Limit Values - Ceiling (TLV-C) guidelines by the American Conference of Governmental Industrial Hygienists (ACGIH) for controlling worker exposure to airborne chemical concentrations in the workplace.

Component	New Zealand WEL	Australia	ACGIH TLV	The United Kingdom
STOP SOLUTION - Sulphuric acid	TWA: 0.1 mg/m ³	STEL: 3 mg/m ³ TWA: 1 mg/m ³	TWA: 0.2 mg/m ³	STEL: 0.15 mg/m ³ 15 min TWA: 0.05 mg/m ³ 8 hr
Negative Control & Sample Diluent - Sodium azide	Ceiling: 0.11 ppm Ceiling: 0.29 mg/m ³	CL 0.11 ppm (0.3 mg/m ³)	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	Skin TWA 0.1 mg/m ³ STEL 0.3 mg/m ³

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Appropriate engineering controls

Engineering Measures

None under normal use conditions.

Individual protection measures, such as personal protective equipment

Eye Protection

If splashes are likely to occur: Wear safety glasses with side shields (or goggles) (Australian/New Zealand Standard AS/NZS 1337 - Eye protectors for Industrial applications)

Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	AUS/NZ Standard	Glove comments
Disposable gloves.	See manufacturers recommendations	-	AS/NZS 2161	(minimum requirement)

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Skin and body protection	Long sleeved clothing
Respiratory Protection	Use an AS/NZS 1716 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained in line with AS/NZS 1715 on the use and maintenance of respiratory protective devices
Recommended Filter type:	Particle filter (or AUS/NZ equivalent)

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

Environmental exposure controls Prevent product from entering drains. Do not allow material to contaminate ground water system.

Section 9 - Physical and Chemical Properties

Information on basic physical and chemical properties

Physical State	Liquid	
Appearance	No information available	
Odor	No information available	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	No data available	
Softening Point	No data available	
Boiling Point/Range	Not applicable	
Flammability (liquid)	No data available	
Flammability (solid,gas)	Not applicable	Liquid
Explosion Limits	No data available	
Flash Point	Not applicable	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	No data available	
Water Solubility	Soluble in water	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Component	log Pow	
Poly(oxy-1,2-ethanediyl),	2.7	
.alpha.-[4-(1,1,3,3-tetramethylbutyl)phe		
nyl]-.omega.-hydroxy-		
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	Not applicable	Liquid
Vapor Density	No data available	(Air = 1.0)
Particle characteristics	Not applicable (liquid)	

Other information

Section 10 - Stability and Reactivity

Reactivity None known, based on information available

Stability	Stable under recommended storage conditions.
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available
Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions	None under normal processing.
Conditions to Avoid	Accumulations of product in enclosed spaces and generation of mists.
Incompatible Materials	None known.
Hazardous Decomposition Products	None under normal use conditions.

Section 11 - Toxicological Information

Acute Effects

Information on likely routes of exposure

Product Information	Product does not present an acute toxicity hazard based on known or supplied information
Inhalation	Not an expected route of exposure.
Eyes	Not an expected route of exposure.
Skin	No known effect based on information supplied.
Ingestion	No known effect based on information supplied.

Numerical measures of toxicity

(a) acute toxicity;

Oral	Based on available data, the classification criteria are not met
Dermal	Based on available data, the classification criteria are not met
Inhalation	Based on available data, the classification criteria are not met

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
STOP SOLUTION - Sulphuric acid	LD50 = 2140 mg/kg (Rat)		LC50 = 0.375 mg/L (Rat) 4 h
Negative Control & Sample Diluent - Sodium azide	LD50 = 27 mg/kg (Rat)	LD50 = 20 mg/kg (Rabbit)	LC50 0.054 - 0.52 mg/L (Rat) 4 h
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]- .omega.-hydroxy-	1800 mg/kg (Rat)		

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory	No data available
Skin	No data available

Sensitization No information available

(e) germ cell mutagenicity; No data available

None known

(f) carcinogenicity;

No data available

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

Component	New Zealand	Australia	New South Wales	Western Australia	IARC	EU	UK	Germany
STOP SOLUTION - Sulphuric acid	Confirmed carcinogen				Group 1			

**(g) reproductive toxicity;
Reproductive Effects
Developmental Effects
Neurological Effects**

No data available
None known
None known
None known

(h) STOT-single exposure;

No data available

(i) STOT-repeated exposure;

No data available

Target Organs

No information available.

(j) aspiration hazard;

No data available

Symptoms / effects, both acute and delayed

No information available.

Section 12 - Ecological Information

Ecotoxicity

Aquatic ecotoxicity

The product contains following substances which are hazardous for the environment. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
STOP SOLUTION - Sulphuric acid	LC50: > 500 mg/L, 96h static (Brachydanio rerio)	EC50: 29 mg/L/24h		
Negative Control & Sample Diluent - Sodium azide	LC50: = 0.7 mg/L, 96h (Lepomis macrochirus) LC50: = 0.8 mg/L, 96h (Oncorhynchus mykiss) LC50: = 5.46 mg/L, 96h flow-through (Pimephales promelas)			
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-	LC50 = 8.9 mg/L 96H LC50 = 4.0 mg/l 96H (Pimephales promelas)	EC50 = 26 mg/L 48h	-	-

Terrestrial ecotoxicity

There is no data for this product

Persistence and Degradability

Persistence

Soluble in water, Persistence is unlikely, based on information available.

Component	Degradability
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-9002-93-1 (0.1)	60% >28 days

Bioaccumulative Potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]- .omega.-hydroxy-	2.7	No data available

Mobility The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils

Other adverse effects

Endocrine Disruptor Information

Component	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Japan - Endocrine Disruptor Information
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]- .omega.-hydroxy-	Group III Chemical	-	-

Persistent Organic Pollutant This product does not contain any known or suspected substance

Ozone Depletion Potential This product does not contain any known or suspected substance

Section 13 - Disposal Considerations

Waste treatment methods

Waste from Residues/Unused Products Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes, including emptied containers, are controlled wastes and should be disposed of in accordance with all federal, E.P.A., state and local regulations. Assure conformity with all applicable regulations.

Contaminated Packaging Dispose of in accordance with local regulations.

Other Information Disposal agencies or waste contractors must comply with the New Zealand Hazardous Substances (Disposal) Regulations. Do not flush to sewer. Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. Do not let this chemical enter the environment.

Section 14 - Transport Information

Component	Hazchem Code
STOP SOLUTION - Sulphuric acid 7664-93-9 (4.5)	2P 4WE 2W 2R
Negative Control & Sample Diluent - Sodium azide 26628-22-8 (0.1)	2XE

NZS 5433:2020 Not regulated

IATA Not regulated

IMDG/IMO Not regulated

Environmental hazards	Dangerous for the environment Product is a marine pollutant according to the criteria set by IMDG/IMO
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable, packaged goods
Special Precautions	No special precautions required. Please refer to the applicable dangerous goods regulations for additional information.
Additional information	None known

Section 15 - Regulatory Information

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

National Regulations

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information. Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information.

Prohibition or notification/licensing requirements

Shown below are details of specific prohibition/notifications or licencing requirements when they apply.

Component	New Zealand
STOP SOLUTION - Sulphuric acid	Confirmed carcinogen

International Regulations

Ozone Depletion Potential This product does not contain any known or suspected substance

Persistent Organic Pollutant This product does not contain any known or suspected substance

Rotterdam Convention (PIC) Not applicable

Authorisation/Restrictions according to EU REACH

Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
STOP SOLUTION - Sulphuric acid	-	Use restricted. See item 75. (see link for restriction details)	-
Poly(oxy-1,2-ethanediyl), alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-	Endocrine disrupting properties (Article 57(f) - environment) Application date: July 4, 2019 Sunset date: January 4, 2021 Exemption - extended latest application and sunset date for the research, development and production of medicinal products or medical devices in view of their use for the diagnosis, treatment or	-	SVHC Candidate list - Equivalent level of concern having probable serious effects to the environment (Article 57f - environment)

	prevention of the coronavirus disease (COVID-19)		
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After the sunset date the use of this substance requires either an authorization or can only be used for exempted uses, e.g. use in scientific research and development which includes routine analytics or use as intermediate.

<https://echa.europa.eu/authorisation-list>
<https://echa.europa.eu/substances-restricted-under-reach>
<https://echa.europa.eu/candidate-list-table>

International Inventories

New Zealand (NZIoC), Australia (AICS), Europe (EINECS/ELINCS/NLP), Korea (KECL), China (IECSC), Taiwan (TCSI), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
STOP SOLUTION - Sulphuric acid	7664-93-9	X	X	231-639-5	-	-	KE-32570	X	X
Negative Control & Sample Diluent - Sodium azide	26628-22-8	X	X	247-852-1	-	-	KE-31357	X	X
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-	9002-93-1	X	X	-	-	-	KE-33568	X	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	PICCS	ISHL	ENCS
STOP SOLUTION - Sulphuric acid	7664-93-9	X	ACTIVE	X	-	X	X	X
Negative Control & Sample Diluent - Sodium azide	26628-22-8	X	ACTIVE	X	-	X	X	X
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-	9002-93-1	X	ACTIVE	X	-	X	X	X

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

Section 16 - Other Information

This safety data sheet complies with the requirements of the EPA Hazardous Substances (Hazard Classification) Notice 2020 and WorkSafe New Zealand Regulations

Legend

NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
IECSC - Chinese Inventory of Existing Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
TWA - Time Weighted Average
IARC - International Agency for Research on Cancer
NZS 5433:2020 - Transport of Dangerous Goods on Land
ICAO/IATA - International Civil Aviation Organization/International Air Transport Association
MARPOL - International Convention for the Prevention of Pollution from Ships
LD50 - Lethal Dose 50%
EC50 - Effective Concentration 50%
WEL - Workplace Exposure Limit
DNEL - Derived No Effect Level
POW - Partition coefficient Octanol:Water
vPvB - very Persistent, very Bioaccumulative

AICS - Australian Inventory of Chemical Substances
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
ENCS - Japanese Existing and New Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
CAS - Chemical Abstracts Service
ACGIH - American Conference of Governmental Industrial Hygienists
PNEC - Predicted No Effect Concentration
OECD - Organisation for Economic Co-operation and Development
IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code
ADG - Australian Code for the Transport of Dangerous Goods by Road and Rail
LC50 - Lethal Concentration 50%
ATE - Acute Toxicity Estimate
RPE - Respiratory Protective Equipment
NOEC - No Observed Effect Concentration
BCF - Bioconcentration factor
PBT - Persistent, Bioaccumulative, Toxic

VOC - (Volatile Organic Compound)

Key literature references and sources for data

HSNO classifications provided in the New Zealand Chemical Classification Information Database (CCID).

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

EPA Guide to classifying hazardous substances in New Zealand

EPA - Assigning a product to an existing HSNO approval guide

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data

Health Hazards Calculation method

Environmental hazards Calculation method

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Revision Date 30-Jun-2023

Revision Summary Update to CLP Format

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