Kit SDS Cover Sheet

Document ID: A16953-75: Version AN
Revision Date (year/month/day) 2023/12/22
Last Revision Date (year/month/day) 2023/05/23

Product information

Product name	PTH Calibrators
Part number	A16953
Series name	ACCESS

Components

Description	**Calibrators** Reconstitution Buffer

Transport information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

BECKMAN COULTER

SAFETY DATA SHEET

Document ID: A16953-75 Version AN
Revision Date (year/month/day) 2023/12/22
Last Revision Date (year/month/day) 2023/05/23

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name **Calibrators**

Part number Component of P/N A16953

Series name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

Supplier

CANADA
Beckman Coulter Canada LP
7075 Financial Drive
Mississauga, ON L5N 6V8
Canada
1-800-463-7828

UNITED KINGDOM
Beckman Coulter (UK) Ltd.
Oakley Court
Kingsmead Business Park, London Road
High Wycombe
United Kingdom HP11 1JU
01494 441181

AUSTRALIA
Beckman Coulter Australia Pty Ltd
23-27 Chaplin Drive
Lane Cove NSW 2066
Australia
ABN 81 002 011 672
24 Hour emergency contact phone number:
1800 060 881

SWITZERLAND
Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

Section 1 Identification of the substance/mixture and of the company/undertaking (Continued)

NEW ZEALAND
Beckman Coulter NZ
Unit J, 33 Walmsley Road, Otahuhu,
Auckland 1062, New Zealand
Hours available: 08:30 - 17:00

ICELAND / ÍSLAND
Beckman Coulter AB
Ekbacksvägen 28
168 69 Bromma
Sweden
Phone No.: +46 80564 85 900
Hours available: 08.00-16.30

MALTA
DX Distributor:
Cherubino Ltd
DELF Building, Sliema Road, Gzira,
GZR 1637
Telephone: +356 21343270
Hours available: 08:30 – 17:00

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and emergency phone no.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

UNITED STATES - Emergency Phone (24h): Chemtrec (800) 424-9300, International (001) 703-527-3887

CANADA - Poison Centre: 1-844-764-7669; Centre antipoison du Québec: 1-800-463-5060

UNITED KINGDOM - For UK and Scotland: Emergency Call 999

IRELAND - National Poisons Information Centre Phone No.: Members of Public: +353 (01) 809 2166 (8:00 am to 10:00 pm 7 days a week); Healthcare Professionals: +353 (01) 809 2566 (24 hour service)

AUSTRALIA - 24 Hour emergency contact phone number: 1800 060 881

NEW ZEALAND - 24 Hour emergency number: 0800 446 109

Section 2 Hazards identification

2.1 Classification of the substance or mixture

Product description Mixture

Section 2 Hazards identification (Continued)

White; Lyophilized Powder; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

2.2 Label elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous ingredients

Ethoxylated alkyl alcohol

Pictogram

None

Signal word

None

Hazard statements

H402 Harmful to aquatic life.

Precautionary statements

Prevention
P273 Avoid release to the environment.
Response
None
Storage
None
Disposal
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and information on ingredients

3.2 Mixtures

Hazardous ingredients:		Hazard classification of pure ingredients		
Chemical name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**

Section 3 Composition and information on ingredients (Continued)

Ethoxylated alkyl alcohol CAS # 68439-49-6 EINECS # Not available Index # Not available	0.1 - 0.5	Acute Tox. Oral 4, H302 Aquatic Acute 1, H400 Eye Dam. 1, H318 Acute Toxicity Estimates (ATE) ATE Oral = 1260 mg/kg	Acute Tox. Oral 4, H302 Aquatic Acute 1, H400 Eye Dam. 1, H318	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 EUH032 Acute Toxicity Estimates (ATE) ATE Oral = 27 mg/kg	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First aid measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin contact — In case of skin contact, rinse with water as a precaution.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Firefighting measures

5.1 Extinguishing media

For large fires use extinguishing media suitable for surrounding fire.
In case of fire use carbon dioxide (CO_2), dry chemical, water spray or foam.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards

No special hazards determined.

Section 5 Firefighting measures (Continued)

Hazardous combustion products

No combustion products posing significant hazards are expected from this product.

5.3 Advice for firefighters

Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

Additional information No further relevant information available.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental precautions Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and leak procedures If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.

If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses No further relevant information available.

Section 8 Exposure controls and personal protection

8.1 Control parameters

Exposure limits

US OSHA

None established

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

ACGIH Biological Exposure Indices (BEI)

None established

DFG MAK

Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

China

Sodium Azide CAS # 26628-22-8	0.3 mg/m3 Ceiling MAC

Croatia

Sodium Azide CAS # 26628-22-8	Skin Notation; 0.1 mg/m3 TWA [GVI]; 0.3 mg/m3 STEL [KGVI]

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV NGV; 0.3 mg/m3 Binding STEL Bindande KGV

Turkey

Sodium Azide CAS # 26628-22-8	0.3 mg/m3 STEL; Skin notation; 0.1 mg/m3 TWA

8.2 Exposure controls

Engineering controls

No special engineering controls are required. Use with good general ventilation.

Eye protection

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Section 8 Exposure controls and personal protection (Continued)

Skin protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Lyophilized Powder	**Density and/or relative density**	Not determined
Color	White	**Solubility**	
Odor	Odorless	**Water**	Miscible
pH	Not applicable	**Organic**	Not determined
Melting Point	Not determined	**Partition coefficient n-octanol/water (log value)**	Not applicable
Boiling point or initial boiling point and boiling range	Not applicable	**Auto-ignition temp.**	Not determined
Flash point	Not applicable	**Decomposition temperature**	Not determined
Flammability	Not determined	**Vapor pressure**	Not applicable
		Kinematic viscosity	Not applicable
Lower and upper explosion limit	Not determined		
Relative vapor density	Not applicable		
Particle characteristics	Not determined		

9.2 Other information

Information with regard to physical hazard classes

Not applicable
No further relevant information available.

Other safety characteristics

No further relevant information available.

Section 10 Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to avoid Avoid contact with incompatible materials.
Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials Metals and metallic compounds

10.6 Hazardous decomposition products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological information

11.1 Information on hazard classes

Toxicity data for hazardous ingredients

Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg (NLM_HSDB); Inhalation LC50 Rat 0.054 - 0.52 mg/L 4 h (dust)(ECHA_API); Oral LD50 Rat 27 mg/kg (NZ_CCID)
Ethoxylated alkyl alcohol CAS # 68439-49-6	Oral LD50 Rat 1260 mg/kg (NLM_CIP)

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute toxicity Not classified based on available data.

Skin corrosion/irritation Not classified based on available data.

Serious eye damage/irritation Not classified based on available data.

Respiratory or skin sensitisation Not classified based on available data.

Germ cell mutagenicity Not classified based on available data.

Carcinogenicity This product does not contain a reportable concentration (≥ 0.1%) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Reproductive toxicity Not classified based on available data.

Specific target organ toxicity (STOT) – single exposure

Not classified based on available data.

Section 11 Toxicological information (Continued)

Specific target organ toxicity (STOT) – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

11.2 Information on other hazards

Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f).

Other information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological information

12.1 Toxicity

Fresh water species

Sodium Azide CAS # 26628-22-8	LC50 96 h Oncorhynchus mykiss: 0.8 mg/L; LC50 96 h Lepomis macrochirus: 0.7 mg/L; LC50 96 h Pimephales promelas: 5.46 mg/L [flow-through]
Microtox/organisms	No information available.
Water flea	No information available.
Fresh water algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulative potential Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal considerations

13.1 Waste treatment methods

Product waste disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country

concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Package disposal Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Additional information Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID number: Not regulated for transportation

14.2 UN proper shipping name: Not regulated for transportation

14.3 Transport hazard class(es): Not regulated for transportation

14.4 Packing group: Not regulated for transportation

14.5 Environmental hazards: Not regulated for transportation

14.6 Special precautions for user: None

14.7 Maritime transport in bulk according to IMO instruments: Not applicable

Section 15 Regulatory information

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

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

CAS # 123-91-1	1,4-Dioxane	0.1% de minimis concentration
CAS # 75-21-8	Ethylene Oxide	0.1% de minimis concentration
CAS # 26628-22-8	Sodium Azide	1.0% de minimis concentration

Section 15 Regulatory information (Continued)

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

California Proposition 65

⚠ **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause development toxicity

CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause male reproductive toxicity

CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause female reproductive toxicity

CAS # 75-21-8	Ethylene Oxide

Massachusetts Right To Know (RTK) List

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

New Jersey Dept. of Health Right To Know (RTK) List

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

Section 15 Regulatory information (Continued)

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - Substances Subject to Suspicious Transactions Reporting

No ingredients listed.

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - Restricted Explosives Precursors

No ingredients listed.

REACH 1907/2006 EC - Candidate List of Substances of Very High Concern (SVHC)

Not applicable.

REACH 1907/2006 EC - Annex XVII – Restrictions on Certain Dangerous Substances

Not applicable.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorisation

No ingredients listed.

Refer to Section 3

UK Regulations

UK REACH Regulation (as Amended) - List of substances subject to authorisation

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

China

Catalog of Hazardous Chemicals - Hazardous Chemicals

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide

Inventory - China - Inventory of Existing Chemical Substances (IECSC)

All ingredients are listed or exempted.

Turkey

Turkey-REACH - KKDIK Regulation - Annex 17 – Restrictions

Not applicable.

International

UN/FAO/Rotterdam Convention - Chemicals Subject to Prior Informed Consent (PIC)

CAS # 75-21-8	Ethylene Oxide

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other information

Beckman Coulter safety rating	**Flammability: 0** **Health: 1** **Reactivity with water: 0** **Physical contact: 1**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision changes

Updated sections 1, 2, 3, 4, 8 and 15

Document version and issue/revision date

Revision Date (year/month/day) 2023/12/22
Last Revision Date (year/month/day) 2023/05/23
Document ID: A16953-75
Version: AN

Hazard Classification Procedure

This mixture was classified using the calculation method for human health and environmental hazards. Physical hazards were determined based on the specification.

Description of hazard class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
EUH032 - Contact with acids liberates very toxic gas.
H300 - Fatal if swallowed.
H302 - Harmful if swallowed.
H318 - Causes serious eye damage.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

ACGIH - American Conference of Governmental Industrial Hygienists (ACGIH)
ADR and RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road and Rail
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
EC50 - Concentration of a substance in an environmental medium expected to produce a certain effect in 50% of test organisms
GHS - Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IDLH - Immediately Dangerous to Life or Health
IMDG - International Maritime Dangerous Goods
IMO - International Maritime Organization

Section 16 Other information (Continued)

IOELVs - European Unions' Indicative Occupational Exposure Limit Values
LC50 - Concentration of a substance in water causing death (50% of the tested population) to aquatic life
LD50 - Lethal Dose 50%
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent Bioaccumulative and Toxic substances
PEL - Permissible Exposure Limit
SARA - Superfund Amendments and Reauthorization Act
STEL – Short Term Exposure Limit
STLV - Short Term Limit Value
STV - Short Term Value
TDG - Canadian Transportation of Dangerous Goods Regulations
TLV - Threshold Limit Value
TWA – Time Weighted Average
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
US OSHA - United States Occupational Safety and Health Administration
vPvB - very Persistent and very Bioaccumulative substances
WHMIS - Workplace Hazardous Material Information System

For further information, please contact your local Beckman Coulter, Inc. representative.

BECKMAN COULTER

SAFETY DATA SHEET

Document ID: A16953-75 Version AN
Revision Date (year/month/day) 2023/12/22
Last Revision Date (year/month/day) 2023/05/23

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Reconstitution Buffer

Part number Component of P/N A16953

Series name ACCESS

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Beckman Coulter, Inc.
250 S. Kraemer Blvd
Brea, CA 92821, U.S.A.
Tel: 800-854-3633

Supplier

CANADA
Beckman Coulter Canada LP
7075 Financial Drive
Mississauga, ON L5N 6V8
Canada
1-800-463-7828

UNITED KINGDOM
Beckman Coulter (UK) Ltd.
Oakley Court
Kingsmead Business Park, London Road
High Wycombe
United Kingdom HP11 1JU
01494 441181

AUSTRALIA
Beckman Coulter Australia Pty Ltd
23-27 Chaplin Drive
Lane Cove NSW 2066
Australia
ABN 81 002 011 672
24 Hour emergency contact phone number:
1800 060 881

SWITZERLAND
Beckman Coulter Eurocenter SA
22, rue Juste-Olivier, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone: +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

Section 1 Identification of the substance/mixture and of the company/undertaking (Continued)

NEW ZEALAND
Beckman Coulter NZ
Unit J, 33 Walmsley Road, Otahuhu,
Auckland 1062, New Zealand
Hours available: 08:30 - 17:00

ICELAND / ÍSLAND
Beckman Coulter AB
Ekbacksvägen 28
168 69 Bromma
Sweden
Phone No.: +46 80564 85 900
Hours available: 08.00-16.30

MALTA
DX Distributor:
Cherubino Ltd
DELF Building, Sliema Road, Gzira,
GZR 1637
Telephone: +356 21343270
Hours available: 08:30 – 17:00

e-mail address SDSNT@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and emergency phone no.

Refer to attached list, Document ID: 472050, for local distributor and emergency phone numbers.

UNITED STATES - Emergency Phone (24h): Chemtrec (800) 424-9300, International (001) 703-527-3887

CANADA - Poison Centre: 1-844-764-7669; Centre antipoison du Québec: 1-800-463-5060

UNITED KINGDOM - For UK and Scotland: Emergency Call 999

IRELAND - National Poisons Information Centre Phone No.: Members of Public: +353 (01) 809 2166 (8:00 am to 10:00 pm 7 days a week); Healthcare Professionals: +353 (01) 809 2566 (24 hour service)

AUSTRALIA - 24 Hour emergency contact phone number: 1800 060 881

NEW ZEALAND - 24 Hour emergency number: 0800 446 109

Section 2 Hazards identification

2.1 Classification of the substance or mixture

Product description Mixture

Section 2 Hazards identification (Continued)

Slightly milky; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Skin Sensitization Category 1, H317

Aquatic Hazard Long term, Category 3, H412

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

2.2 Label elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram

Signal word

WARNING

Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing and eye/face protection.

Response

P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before use.

Storage

None

Disposal

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.
1% of product contains ingredients of unknown hazards to the aquatic environment.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and information on ingredients

3.2 Mixtures

Hazardous ingredients:		Hazard classification of pure ingredients		
Chemical name	**% by wt.**	**EU 1272/2008 CLP/GHS**	**GHS**	**Note**
reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # 613-167-00-5	< 0.05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 M-factor Acute=100 M-factor Chronic=100 Skin Corr. 1C, H314 Skin Sens. 1A, H317 EUH071 Specific Concentration Limit (SCL) Skin Irrit. 2 H315 >= 0.06% - < 0.6% Eye Dam. 1 H318 >= 0.6% Skin Corr. 1C H314 >= 0.6% Eye Irrit. 2 H319 >= 0.06% - < 0.6% Skin Sens. 1A H317 >= 0.0015% Acute Toxicity Estimates (ATE) ATE Dermal = 87.12 mg/kg ATE Inhalation - Vapors = 0.5 mg/L ATE Oral = 53 mg/kg	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317	9

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

See section 8 for available Occupational exposure limits
See Section 15 for additional regulatory information
See Section 16 for description of hazard class and hazard statements

Section 4 First aid measures

4.1 Description of first aid measures

Inhalation — If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

Eye contact — If product enters eyes, rinse eyes gently with water as a precaution.

Skin contact — In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

Ingestion — If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

Section 4 First aid measures (Continued)

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available. Refer to Section 4.1.

Section 5 Firefighting measures

5.1 Extinguishing media

In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards

No special hazards determined.

Hazardous combustion products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters

Protective equipment

Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

Additional information

No further relevant information available.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental precautions

Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

Spill and leak procedures

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°C, as directed on the product label.

To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure controls and personal protection

8.1 Control parameters

Exposure limits

US OSHA None established

ACGIH None established

ACGIH Biological Exposure Indices (BEI)

None established

DFG MAK None established

Ireland None established

IOELVs

None established

NIOSH None established

China None established

Croatia None established

Japan None established

Sweden (AFS 2015:7 and amendments)

None established

Turkey None established

8.2 Exposure controls

Engineering controls No special engineering controls are required. Use with good general ventilation.

Eye protection Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Section 8 Exposure controls and personal protection (Continued)

Skin protection	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
Respiratory protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid	**Density and/or relative density**	≈ 1 @20°C
Color	Slightly milky	**Solubility**	
Odor	Odorless	**Water**	Miscible
pH	7.2	**Organic**	Not determined
Freezing point	Not determined	**Partition coefficient n-octanol/water (log value)**	Not determined
Boiling point or initial boiling point and boiling range	Not determined	**Auto-ignition temp.**	Not applicable
Flash point	Not applicable	**Decomposition temperature**	Not determined
Flammability	Not applicable	**Vapor pressure**	Not determined
		Kinematic viscosity	Not determined
Lower and upper explosion limit	Not applicable		
Relative vapor density	Not determined		
Particle characteristics	Not applicable		

9.2 Other information

Information with regard to physical hazard classes

Not applicable
No further relevant information available.

Other safety characteristics

No further relevant information available.

Section 10 Stability and reactivity

10.1 Reactivity — No further relevant information available.

10.2 Chemical stability — The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No further relevant information available.

10.4 Conditions to avoid — To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials — No further relevant information available.

10.6 Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological information

11.1 Information on hazard classes

Toxicity data for hazardous ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9	Dermal LD50 Rabbit 87.12 mg/kg (ECHA_API); Oral LD50 Rat 53 mg/kg (NLM_CIP)

Primary routes of exposure — Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Acute toxicity — Not classified based on available data.

Skin corrosion/irritation — Not classified based on available data.

Serious eye damage/irritation — Not classified based on available data.

Respiratory or skin sensitisation — May cause sensitization by skin contact.

Germ cell mutagenicity — Not classified based on available data.

Carcinogenicity — No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Reproductive toxicity — Not classified based on available data.

Specific target organ toxicity (STOT) – single exposure

Not classified based on available data.

Section 11 Toxicological information (Continued)

Specific target organ toxicity (STOT) – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

11.2 Information on other hazards

Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f).

Other information This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

Section 12 Ecological information

12.1 Toxicity

Fresh water species	No information available.
Microtox/organisms	No information available.
Water flea	No information available.
Fresh water algae	No information available.

12.2 Persistence and degradability Not determined for the product.

12.3 Bioaccumulative potential Not determined for the product.

12.4 Mobility in soil Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

Section 13 Disposal considerations

13.1 Waste treatment methods

Product waste disposal Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

	Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
Package disposal	Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.
Additional information	Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID number: Not regulated for transportation

14.2 UN proper shipping name: Not regulated for transportation

14.3 Transport hazard class(es): Not regulated for transportation

14.4 Packing group: Not regulated for transportation

14.5 Environmental hazards: Not regulated for transportation

14.6 Special precautions for user: None

14.7 Maritime transport in bulk according to IMO instruments: Not applicable

Section 15 Regulatory information

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

US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4

No ingredients listed.

California Proposition 65

Chemical which is known to the State of California to cause cancer

No ingredients listed.

Chemical which is known to the State of California to cause development toxicity

No ingredients listed.

Section 15 Regulatory information (Continued)

Chemical which is known to the State of California to cause male reproductive toxicity

No ingredients listed.

Chemical which is known to the State of California to cause female reproductive toxicity

No ingredients listed.

Massachusetts Right To Know (RTK) List

No ingredients listed.

New Jersey Dept. of Health Right To Know (RTK) List

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany)

WGK 1, low water endangering

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - Substances Subject to Suspicious Transactions Reporting

No ingredients listed.

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - Restricted Explosives Precursors

No ingredients listed.

REACH 1907/2006 EC - Candidate List of Substances of Very High Concern (SVHC)

No ingredients listed.

REACH 1907/2006 EC - Annex XVII – Restrictions on Certain Dangerous Substances

Not applicable.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorisation

No ingredients listed.

Refer to Section 3

UK Regulations

UK REACH Regulation (as Amended) - List of substances subject to authorisation

Refer to Section 3

Canada

This product is exempt from WHMIS label and SDS requirements.

Section 15 Regulatory information (Continued)

China

Catalog of Hazardous Chemicals - Hazardous Chemicals

No ingredients listed.

Inventory - China - Inventory of Existing Chemical Substances (IECSC)

All ingredients are listed or exempted.

Turkey

Turkey-REACH - KKDIK Regulation - Annex 17 – Restrictions

No ingredients listed.

International

UN/FAO/Rotterdam Convention - Chemicals Subject to Prior Informed Consent (PIC)

No ingredients listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

Section 16 Other information

Beckman Coulter safety rating	**Flammability: 0** **Health: 2** **Reactivity with water: 0** **Physical contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision changes

Updated sections 1, 2, 3, 4, 8 and 15

Document version and issue/revision date

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Version: AN

Hazard Classification Procedure

This mixture was classified using the calculation method for human health and environmental hazards. Physical hazards were determined based on the specification.

Description of hazard class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 2 - Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2 - Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1C - Skin Corrosion Category 1C

Section 16 Other information (Continued)

Skin Sens. 1A - Skin Sensitization Category 1A
EUH071 - Corrosive to the respiratory tract.
H301 - Toxic if swallowed.
H310 - Fatal in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

ACGIH - American Conference of Governmental Industrial Hygienists (ACGIH)
ADR and RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road and Rail
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
EC50 - Concentration of a substance in an environmental medium expected to produce a certain effect in 50% of test organisms
GHS - Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA DGR - International Air Transport Association Dangerous Goods Regulation
ICAO - International Civil Aviation Organization
IDLH - Immediately Dangerous to Life or Health
IMDG - International Maritime Dangerous Goods
IMO - International Maritime Organization
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
LC50 - Concentration of a substance in water causing death (50% of the tested population) to aquatic life
LD50 - Lethal Dose 50%
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent Bioaccumulative and Toxic substances
PEL - Permissible Exposure Limit
SARA - Superfund Amendments and Reauthorization Act
STEL – Short Term Exposure Limit
STLV - Short Term Limit Value
STV - Short Term Value
TDG - Canadian Transportation of Dangerous Goods Regulations
TLV - Threshold Limit Value

SAFETY DATA SHEET

Section 16 Other information (Continued)

TWA – Time Weighted Average
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
US OSHA - United States Occupational Safety and Health Administration
vPvB - very Persistent and very Bioaccumulative substances
WHMIS - Workplace Hazardous Material Information System

For further information, please contact your local Beckman Coulter, Inc. representative.