

Kit SDS Cover Sheet

Document ID: 33535-75: Version AM
Revision Date (year/month/day) 2023/12/21
Last Revision Date (year/month/day) 2023/05/23

Product information

Product name	PROLACTIN CALIBRATORS
Part number	33535
Series name	ACCESS

Components

Description	PROLACTIN CALIBRATOR S0 PROLACTIN CALIBRATORS S1, S2, S3, S4, S5
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Transport information

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



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

1.1 Product identifier

Product name PROLACTIN CALIBRATOR S0
Part number Component of P/N 33535
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)

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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
DELFI 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

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Section 2 Hazards identification (Continued)

Colorless; 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)

Ethoxylated alkyl alcohol

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.

2.5% of product contains ingredients of unknown hazards to aquatic environment.

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Section 2 Hazards identification (Continued)

2.3 Other hazards

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.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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
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
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)	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

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Section 3 Composition and information on ingredients (Continued)

	ATE Dermal = 87.12 mg/kg ATE Inhalation - Vapors = 0.5 mg/L ATE Oral = 53 mg/kg	
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2 - Substance with Community workplace exposure limits

8 - Present at concentration below the cut-off limits.

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 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

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).

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Section 5 Firefighting measures (Continued)

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 below -20°C.

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)

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Section 8 Exposure controls and personal protection (Continued)

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 [KGV]

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.

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.

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Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid	Density and/or relative density	1.036
Color	Colorless	Solubility	
Odor	Odorless	Water	Miscible
pH	7.7	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

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.

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Section 10 Stability and reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

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

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)
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)
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 May cause sensitization by skin contact.

Germ cell mutagenicity Not classified based on available data.

Carcinogenicity This product does not contain a reportable concentration ($\geq 0.1\%$) 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.

Specific target organ toxicity (STOT) – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

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Section 11 Toxicological information (Continued)

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. 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

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	undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. 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 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)

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

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

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Section 15 Regulatory information (Continued)

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

CAS # 75-21-8	Ethylene Oxide
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Chemical which is known to the State of California to cause female reproductive toxicity

CAS # 75-21-8	Ethylene Oxide
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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

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.

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Section 15 Regulatory information (Continued)

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
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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.

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

Document version and issue/revision date

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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 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
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
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A
EUH032 - Contact with acids liberates very toxic gas.
EUH071 - Corrosive to the respiratory tract.
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H302 - Harmful 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.

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Section 16 Other information (Continued)

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
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

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Section 16 Other information (Continued)

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

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

1.1 Product identifier

Product name PROLACTIN CALIBRATORS S1, S2, S3, S4, S5
Part number Component of P/N 33535
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)

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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
DELFI 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

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Section 2 Hazards identification (Continued)

Colorless; 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)

Ethoxylated alkyl alcohol

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.

2.5% of product contains ingredients of unknown hazards to aquatic environment.

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Section 2 Hazards identification (Continued)

2.3 Other hazards

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.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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
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
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)	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

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Section 3 Composition and information on ingredients (Continued)

	ATE Dermal = 87.12 mg/kg ATE Inhalation - Vapors = 0.5 mg/L ATE Oral = 53 mg/kg	
--	--	--

2 - Substance with Community workplace exposure limits

8 - Present at concentration below the cut-off limits.

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 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

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).

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Section 5 Firefighting measures (Continued)

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 below -20°C.
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 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
CAS # 26628-22-8

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Section 8 Exposure controls and personal protection (Continued)

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 [KGV]

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.

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.

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Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid	Density and/or relative density	1.036
Color	Colorless	Solubility	
Odor	Odorless	Water	Miscible
pH	7.7	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

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.

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Section 10 Stability and reactivity (Continued)

10.5 Incompatible materials Metals and metallic compounds

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

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)
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)
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 May cause sensitization by skin contact.

Germ cell mutagenicity Not classified based on available data.

Carcinogenicity This product does not contain a reportable concentration ($\geq 0.1\%$) 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.

Specific target organ toxicity (STOT) – repeated exposure

Not classified based on available data.

Aspiration hazard Not classified based on available data.

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Section 11 Toxicological information (Continued)

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. 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

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	undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. 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 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)

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

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

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Section 15 Regulatory information (Continued)

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
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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

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.

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Section 15 Regulatory information (Continued)

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.

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

Document version and issue/revision date

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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 2 - Acute Toxicity Oral, Category 2
 Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
 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
 Skin Corr. 1C - Skin Corrosion Category 1C
 Skin Sens. 1A - Skin Sensitization Category 1A
 EUH032 - Contact with acids liberates very toxic gas.
 EUH071 - Corrosive to the respiratory tract.
 H300 - Fatal if swallowed.
 H301 - Toxic if swallowed.
 H302 - Harmful 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.

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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
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

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Section 16 Other information (Continued)

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