Kit SDS Cover Sheet

Document ID: 35000-75: Version AM
Revision Date (year/month/day) 2025/07/05
Last Revision Date (year/month/day) 2024/08/15

Product information

Product name	TOTAL IgE
Part number	35000
Series name	ACCESS

Additional product information

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

Components

Description

Total IgE Magnetic Particles (Compartment R1a)
Total IgE Conjugate (Compartment R1b)

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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SAFETY DATA SHEET

Document ID: 35000-75 Version AM
Revision Date (year/month/day) 2025/07/05
Last Revision Date (year/month/day) 2024/08/15

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

1.1 Product identifier

Product name Total IgE Magnetic Particles (Compartment R1a)

Part number Component of P/N 35000

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

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

UNITED KINGDOM
Beckman Coulter (UK) Ltd.
Amersham Place
Little Chalfont
Buckinghamshire
United Kingdom, HP7 9NA
01494 441181

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

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

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 In vitro diagnostic reagent.

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Section 2 Hazards identification (Continued)

Reddish-brown when particles suspended; Liquid; Odorless

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

Skin Sensitization Category 1, H317

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

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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.

Precautionary statements

Prevention

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
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

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.

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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**
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) 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
1,4-Dioxane CAS # 123-91-1 EINECS # 204-661-8 Index # 603-024-00-5	< 0.01	Carc. 1B, H350 Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H335 EUH019 EUH066	Carc. 1B, H350 Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H335	2, 8

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Section 3 Composition and information on ingredients (Continued)

Ethylene Oxide CAS # 75-21-8 EINECS # 200-849-9 Index # 603-023-00-X	< 0.01	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Flam. Gas 1, H220 Muta. 1B, H340 Press. Gas [CG], H280 Repr. 1B, H360 STOT RE 1, H372 STOT SE 3 , H335, H336 Skin Corr. 1, H314 Acute Toxicity Estimates (ATE) ATE Inhalation - Vapors = 3 mg/L ATE Inhalation - Gases = 700 ppmV ATE Oral = 100 mg/kg	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Flam. Gas 1, H220 Muta. 1B, H340 Press. Gas [CG], H280 Repr. 1B, H360 STOT RE 1, H372 STOT SE 3 , H335, H336 Skin Corr. 1, H314	2, 8

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 immediately and obtain medical attention.

Eye contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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.

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Section 5 Firefighting measures (Continued)

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.

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

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Section 8 Exposure controls and personal protection (Continued)

US OSHA

1,4-Dioxane CAS # 123-91-1	100 ppm TWA; 360 mg/m3 TWA; prevent or reduce skin absorption
Ethylene Oxide CAS # 75-21-8	1 ppm TWA; 5 ppm STEL (see 29 CFR 1910.1047)

ACGIH

1,4-Dioxane CAS # 123-91-1	20 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
Ethylene Oxide CAS # 75-21-8	1 ppm TWA
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)

Ethylene Oxide CAS # 75-21-8	5000 pmol HEV/g globin medium: blood time: not critical parameter: N-(2-Hydroxyethyl)valine (HEV) hemoglobin adducts (applies to workers having representative Ethylene oxide exposure during the previous 120 days); 5 µg HEMA/g creatinine medium: urine time: end of shift parameter: S-(2-Hydroxyethyl)mercapturic acid (HEMA) (nonspecific, population based)

DFG MAK

1,4-Dioxane CAS # 123-91-1	20 ppm Peak; 74 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 37 mg/m3 TWA MAK
Ethylene Oxide CAS # 75-21-8	skin notation
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

1,4-Dioxane CAS # 123-91-1	20 ppm TWA (technical grade); 73 mg/m3 TWA (technical grade); 60 ppm STEL (calculated); 219 mg/m3 STEL (calculated); Potential for cutaneous absorption (technical grade)
Ethylene Oxide CAS # 75-21-8	1 ppm TWA; 1.8 mg/m3 TWA; 3 ppm STEL (calculated); 5.4 mg/m3 STEL (calculated); Potential for cutaneous absorption
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

1,4-Dioxane CAS # 123-91-1	20 ppm TWA; 73 mg/m3 TWA
Ethylene Oxide CAS # 75-21-8	Present (Substantial contribution to the total body burden via dermal exposure possible); 1.8 mg/m3 TWA; 1 ppm TWA
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

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Section 8 Exposure controls and personal protection (Continued)

NIOSH

1,4-Dioxane CAS # 123-91-1	500 ppm IDLH
Ethylene Oxide CAS # 75-21-8	800 ppm IDLH; 0.1 ppm TWA (less than stated value); 0.18 mg/m3 TWA (less than stated value)

China

1,4-Dioxane CAS # 123-91-1	Skin notation; 70 mg/m3 TWA
Ethylene Oxide CAS # 75-21-8	Skin notation; 2 mg/m3 TWA
Sodium Azide CAS # 26628-22-8	0.3 mg/m3 Ceiling MAC

Croatia

1,4-Dioxane CAS # 123-91-1	20 ppm TWA [GVI]; 73 mg/m3 TWA [GVI]
Ethylene Oxide CAS # 75-21-8	Skin Notation (significant contribution to the total body load possible exposure through the skin); 1 ppm TWA [GVI]; 1.8 mg/m3 TWA [GVI]; Carcinogen Category 1B; Mutagen Category 1B
Sodium Azide CAS # 26628-22-8	Skin Notation; 0.1 mg/m3 TWA [GVI]; 0.3 mg/m3 STEL [KGVI]
Acetaldehyde CAS # 75-07-0	20 ppm TWA [GVI]; 37 mg/m3 TWA [GVI]; 50 ppm STEL [KGVI]; 92 mg/m3 STEL [KGVI]

Japan

1,4-Dioxane CAS # 123-91-1	1 ppm OEL; 3.6 mg/m3 OEL
Ethylene Oxide CAS # 75-21-8	1 ppm OEL; 1.8 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

1,4-Dioxane CAS # 123-91-1	10 ppm TLV NGV; 35 mg/m3 TLV NGV; 25 ppm Indicative STEL Vägledande KGV; 90 mg/m3 Indicative STEL Vägledande KGV
Ethylene Oxide CAS # 75-21-8	1 ppm TLV NGV; 1.8 mg/m3 TLV NGV; 5 ppm Binding STEL Bindande KGV; 9 mg/m3 Binding STEL Bindande KGV; Skin notation
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV NGV; 0.3 mg/m3 Binding STEL Bindande KGV

Turkey

1,4-Dioxane CAS # 123-91-1	20 ppm TWA; 73 mg/m3 TWA
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.

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Section 8 Exposure controls and personal protection (Continued)

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	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 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**	1.013 @20°C
Color	Reddish-brown when particles suspended	**Solubility**	
Odor	Odorless	**Water**	Miscible
pH	8.1	**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.

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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

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

1,4-Dioxane CAS # 123-91-1	Dermal LD50 Rabbit 7600 mg/kg (CHEMVIEW); Inhalation LC50 Rat 46 mg/L 2 h (vapor)(JAPAN_GHS); Oral LD50 Rat 5170 mg/kg (JAPAN_GHS)
Ethylene Oxide CAS # 75-21-8	Inhalation LC50 Rat 800 ppm 4 h (gas)(NLM_CIP); Oral LD50 Rat 72 mg/kg (JAPAN_GHS)
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)

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 No data available.

Serious eye damage/irritation No data available.

Respiratory or skin sensitisation May cause sensitization by skin contact.

Germ cell mutagenicity No data available.

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.

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Section 11 Toxicological information (Continued)

Reproductive toxicity No data available.

Specific target organ toxicity (STOT) – single exposure

No data available.

Specific target organ toxicity (STOT) – repeated exposure

No data available.

Aspiration hazard No data available.

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

1,4-Dioxane CAS # 123-91-1	LC50 96 h Lepomis macrochirus: >10000 mg/L [static] (EPA); LC50 96 h Lepomis macrochirus: >10000 mg/L [semi-static] (IUCLID); LC50 96 h Pimephales promelas: 9850 mg/L [flow-through] (EPA); LC50 96 h Pimephales promelas: 10306 - 14742 mg/L [static] (EPA); LC50 96 h Pimephales promelas: 9850 mg/L (IUCLID)
Ethylene Oxide CAS # 75-21-8	LC50 96 h Pimephales promelas: 73 - 96 mg/L (EPA)
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

1,4-Dioxane CAS # 123-91-1	EC50 48 h water flea: 163 mg/L [Static]
Ethylene Oxide CAS # 75-21-8	LC50 48 h Daphnia magna: 137 - 300 mg/L (IUCLID)

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.

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Section 12 Ecological information (Continued)

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 contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

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 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 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 06* - chemicals consisting of or containing dangerous substances. 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

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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
CAS # 75-07-0	Acetaldehyde	0.1% de minimis concentration

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

CAS # 123-91-1	1,4-Dioxane
CAS # 7558-79-4	Sodium Phosphate, Dibasic
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 60-00-4	Edetic Acid
CAS # 75-07-0	Acetaldehyde

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
CAS # 75-07-0	Acetaldehyde

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

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Section 15 Regulatory information (Continued)

Massachusetts Right To Know (RTK) List

CAS # 123-91-1	1,4-Dioxane
CAS # 7558-79-4	Sodium Phosphate, Dibasic
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 60-00-4	Edetic Acid
CAS # 75-07-0	Acetaldehyde

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

CAS # 123-91-1	1,4-Dioxane
CAS # 7558-79-4	Sodium Phosphate, Dibasic
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 60-00-4	Edetic Acid
CAS # 75-07-0	Acetaldehyde

Pennsylvania Right To Know (RTK) List

CAS # 123-91-1	1,4-Dioxane
CAS # 7558-79-4	Sodium Phosphate, Dibasic
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 60-00-4	Edetic Acid
CAS # 75-07-0	Acetaldehyde

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)

Not applicable.

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

Not applicable.

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Section 15 Regulatory information (Continued)

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
CAS # 75-07-0	Acetaldehyde

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

All ingredients are listed or exempted.

Turkey

Türkiye-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: 2** **Reactivity with water: 0** **Physical contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision changes Update supplier addresses in Section 1.3

Document version and issue/revision date

Revision Date (year/month/day) 2025/07/05
Last Revision Date (year/month/day) 2024/08/15

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Section 16 Other information (Continued)

Document ID: 35000-75
Version: AM

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. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Flam. Gas 1 - Flammable Gases (including chemically unstable gases), Category 1
Flam. Liq. 2 - Flammable Liquids, Category 2
Press. Gas [CG] - Gases under pressure, Compressed Gas
Muta. 1B - Germ Cell Mutagenicity Category 1B
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1 - Skin Corrosion Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A
STOT RE 1 - Specific Target Organ Toxicity Repeated Exposure Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
Repr. 1B - Toxic to Reproductive Category 1B
EUH019 - May form explosive peroxides.
EUH032 - Contact with acids liberates very toxic gas.
EUH066 - Repeated exposure may cause skin dryness or cracking.
EUH071 - Corrosive to the respiratory tract.
H220 - Extremely flammable gas.
H225 - Highly flammable liquid and vapour.
H280 - Contains gas under pressure; may explode if heated.
H300 - Fatal if swallowed.
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.
H319 - Causes serious eye irritation.
H330 - Fatal if inhaled.
H331 - Toxic if inhaled.

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Section 16 Other information (Continued)

H335 - May cause respiratory irritation.
H336 - May cause drowsiness or dizziness.
H340 - May cause genetic defects.
H350 - May cause cancer.
H360 - May damage fertility or the unborn child.
H372 - Causes damage to organs through prolonged or repeated exposure.
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

TWA – Time Weighted Average

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Section 16 Other information (Continued)

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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BECKMAN COULTER

SAFETY DATA SHEET

Document ID: 35000-75 Version AM
Revision Date (year/month/day) 2025/07/05
Last Revision Date (year/month/day) 2024/08/15

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

1.1 Product identifier

Product name Total IgE Conjugate (Compartment R1b)

Part number Component of P/N 35000

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

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

UNITED KINGDOM
Beckman Coulter (UK) Ltd.
Amersham Place
Little Chalfont
Buckinghamshire
United Kingdom, HP7 9NA
01494 441181

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

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland
Tel: 353 (0)65 6831100

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 In vitro diagnostic reagent.

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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

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

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

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.

Precautionary statements

Prevention

P261 Avoid breathing vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
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

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.

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SAFETY DATA SHEET

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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**
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) 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
1,4-Dioxane CAS # 123-91-1 EINECS # 204-661-8 Index # 603-024-00-5	< 0.01	Carc. 1B, H350 Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H335 EUH019 EUH066	Carc. 1B, H350 Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H335	2, 8

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Section 3 Composition and information on ingredients (Continued)

Ethylene Oxide CAS # 75-21-8 EINECS # 200-849-9 Index # 603-023-00-X	< 0.01	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Flam. Gas 1, H220 Muta. 1B, H340 Press. Gas [CG], H280 Repr. 1B, H360 STOT RE 1, H372 STOT SE 3 , H335, H336 Skin Corr. 1, H314 Acute Toxicity Estimates (ATE) ATE Inhalation - Vapors = 3 mg/L ATE Inhalation - Gases = 700 ppmV ATE Oral = 100 mg/kg	Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Carc. 1B, H350 Eye Dam. 1, H318 Flam. Gas 1, H220 Muta. 1B, H340 Press. Gas [CG], H280 Repr. 1B, H360 STOT RE 1, H372 STOT SE 3 , H335, H336 Skin Corr. 1, H314	2, 8

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 immediately and obtain medical attention.

Eye contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May produce an allergic reaction in some people.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

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.

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Section 5 Firefighting measures (Continued)

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.

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

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Section 8 Exposure controls and personal protection (Continued)

US OSHA

1,4-Dioxane CAS # 123-91-1	100 ppm TWA; 360 mg/m3 TWA; prevent or reduce skin absorption
Ethylene Oxide CAS # 75-21-8	1 ppm TWA; 5 ppm STEL (see 29 CFR 1910.1047)

ACGIH

1,4-Dioxane CAS # 123-91-1	20 ppm TWA; Skin - potential significant contribution to overall exposure by the cutaneous route
Ethylene Oxide CAS # 75-21-8	1 ppm TWA
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)

Ethylene Oxide CAS # 75-21-8	5000 pmol HEV/g globin medium: blood time: not critical parameter: N-(2-Hydroxyethyl)valine (HEV) hemoglobin adducts (applies to workers having representative Ethylene oxide exposure during the previous 120 days); 5 µg HEMA/g creatinine medium: urine time: end of shift parameter: S-(2-Hydroxyethyl)mercapturic acid (HEMA) (nonspecific, population based)

DFG MAK

1,4-Dioxane CAS # 123-91-1	20 ppm Peak; 74 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 37 mg/m3 TWA MAK
Ethylene Oxide CAS # 75-21-8	skin notation
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

1,4-Dioxane CAS # 123-91-1	20 ppm TWA (technical grade); 73 mg/m3 TWA (technical grade); 60 ppm STEL (calculated); 219 mg/m3 STEL (calculated); Potential for cutaneous absorption (technical grade)
Ethylene Oxide CAS # 75-21-8	1 ppm TWA; 1.8 mg/m3 TWA; 3 ppm STEL (calculated); 5.4 mg/m3 STEL (calculated); Potential for cutaneous absorption
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

1,4-Dioxane CAS # 123-91-1	20 ppm TWA; 73 mg/m3 TWA
Ethylene Oxide CAS # 75-21-8	Present (Substantial contribution to the total body burden via dermal exposure possible); 1.8 mg/m3 TWA; 1 ppm TWA
Sodium Azide CAS # 26628-22-8	Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

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Section 8 Exposure controls and personal protection (Continued)

NIOSH

1,4-Dioxane CAS # 123-91-1	500 ppm IDLH
Ethylene Oxide CAS # 75-21-8	800 ppm IDLH; 0.1 ppm TWA (less than stated value); 0.18 mg/m3 TWA (less than stated value)

China

1,4-Dioxane CAS # 123-91-1	Skin notation; 70 mg/m3 TWA
Ethylene Oxide CAS # 75-21-8	Skin notation; 2 mg/m3 TWA
Sodium Azide CAS # 26628-22-8	0.3 mg/m3 Ceiling MAC

Croatia

1,4-Dioxane CAS # 123-91-1	20 ppm TWA [GVI]; 73 mg/m3 TWA [GVI]
Ethylene Oxide CAS # 75-21-8	Skin Notation (significant contribution to the total body load possible exposure through the skin); 1 ppm TWA [GVI]; 1.8 mg/m3 TWA [GVI]; Carcinogen Category 1B; Mutagen Category 1B
Sodium Azide CAS # 26628-22-8	Skin Notation; 0.1 mg/m3 TWA [GVI]; 0.3 mg/m3 STEL [KGVI]
Zinc Chloride CAS # 7646-85-7	1 mg/m3 TWA [GVI] (fume); 2 mg/m3 STEL [KGVI] (fume)
Acetaldehyde CAS # 75-07-0	20 ppm TWA [GVI]; 37 mg/m3 TWA [GVI]; 50 ppm STEL [KGVI]; 92 mg/m3 STEL [KGVI]

Japan

1,4-Dioxane CAS # 123-91-1	1 ppm OEL; 3.6 mg/m3 OEL
Ethylene Oxide CAS # 75-21-8	1 ppm OEL; 1.8 mg/m3 OEL

Sweden (AFS 2015:7 and amendments)

1,4-Dioxane CAS # 123-91-1	10 ppm TLV NGV; 35 mg/m3 TLV NGV; 25 ppm Indicative STEL Vägledande KGV; 90 mg/m3 Indicative STEL Vägledande KGV
Ethylene Oxide CAS # 75-21-8	1 ppm TLV NGV; 1.8 mg/m3 TLV NGV; 5 ppm Binding STEL Bindande KGV; 9 mg/m3 Binding STEL Bindande KGV; Skin notation
Sodium Azide CAS # 26628-22-8	0.1 mg/m3 TLV NGV; 0.3 mg/m3 Binding STEL Bindande KGV

Turkey

1,4-Dioxane CAS # 123-91-1	20 ppm TWA; 73 mg/m3 TWA
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.

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Section 8 Exposure controls and personal protection (Continued)

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	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 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**	1.01 @20°C
Color	Colorless	**Solubility**	
Odor	Odorless	**Water**	Miscible
pH	8.1	**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.

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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

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

1,4-Dioxane CAS # 123-91-1	Dermal LD50 Rabbit 7600 mg/kg (CHEMVIEW); Inhalation LC50 Rat 46 mg/L 2 h (vapor)(JAPAN_GHS); Oral LD50 Rat 5170 mg/kg (JAPAN_GHS)
Ethylene Oxide CAS # 75-21-8	Inhalation LC50 Rat 800 ppm 4 h (gas)(NLM_CIP); Oral LD50 Rat 72 mg/kg (JAPAN_GHS)
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)

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 No data available.

Serious eye damage/irritation No data available.

Respiratory or skin sensitisation May cause sensitization by skin contact.

Germ cell mutagenicity No data available.

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.

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Section 11 Toxicological information (Continued)

Reproductive toxicity No data available.

Specific target organ toxicity (STOT) – single exposure

No data available.

Specific target organ toxicity (STOT) – repeated exposure

No data available.

Aspiration hazard No data available.

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

1,4-Dioxane CAS # 123-91-1	LC50 96 h Lepomis macrochirus: >10000 mg/L [static] (EPA); LC50 96 h Lepomis macrochirus: >10000 mg/L [semi-static] (IUCLID); LC50 96 h Pimephales promelas: 9850 mg/L [flow-through] (EPA); LC50 96 h Pimephales promelas: 10306 - 14742 mg/L [static] (EPA); LC50 96 h Pimephales promelas: 9850 mg/L (IUCLID)
Ethylene Oxide CAS # 75-21-8	LC50 96 h Pimephales promelas: 73 - 96 mg/L (EPA)
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

1,4-Dioxane CAS # 123-91-1	EC50 48 h water flea: 163 mg/L [Static]
Ethylene Oxide CAS # 75-21-8	LC50 48 h Daphnia magna: 137 - 300 mg/L (IUCLID)

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.

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Section 12 Ecological information (Continued)

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 contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

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 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 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 06* - chemicals consisting of or containing dangerous substances. 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

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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
CAS # 75-07-0	Acetaldehyde	0.1% 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
CAS # 7646-85-7	Zinc Chloride
CAS # 75-07-0	Acetaldehyde

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
CAS # 75-07-0	Acetaldehyde

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
CAS # 7646-85-7	Zinc Chloride
CAS # 75-07-0	Acetaldehyde

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Section 15 Regulatory information (Continued)

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
CAS # 7646-85-7	Zinc Chloride
CAS # 75-07-0	Acetaldehyde

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
CAS # 7646-85-7	Zinc Chloride
CAS # 75-07-0	Acetaldehyde

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)

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.

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Section 15 Regulatory information (Continued)

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
CAS # 7646-85-7	Zinc Chloride
CAS # 75-07-0	Acetaldehyde

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

All ingredients are listed or exempted.

Turkey

Türkiye-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: 2** **Reactivity with water: 0** **Physical contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision changes

Update supplier addresses in Section 1.3

Document version and issue/revision date

Revision Date (year/month/day) 2025/07/05
Last Revision Date (year/month/day) 2024/08/15
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Section 16 Other information (Continued)

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. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Carc. 1B - Carcinogenicity Category 1B
Eye Dam. 1 - Eye Damage Category 1
Eye Irrit. 2 - Eye Irritation Category 2
Flam. Gas 1 - Flammable Gases (including chemically unstable gases), Category 1
Flam. Liq. 2 - Flammable Liquids, Category 2
Press. Gas [CG] - Gases under pressure, Compressed Gas
Muta. 1B - Germ Cell Mutagenicity Category 1B
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1 - Skin Corrosion Category 1
Skin Corr. 1C - Skin Corrosion Category 1C
Skin Sens. 1A - Skin Sensitization Category 1A
STOT RE 1 - Specific Target Organ Toxicity Repeated Exposure Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
Repr. 1B - Toxic to Reproductive Category 1B
EUH019 - May form explosive peroxides.
EUH032 - Contact with acids liberates very toxic gas.
EUH066 - Repeated exposure may cause skin dryness or cracking.
EUH071 - Corrosive to the respiratory tract.
H220 - Extremely flammable gas.
H225 - Highly flammable liquid and vapour.
H280 - Contains gas under pressure; may explode if heated.
H300 - Fatal if swallowed.
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.
H319 - Causes serious eye irritation.
H330 - Fatal if inhaled.
H331 - Toxic if inhaled.
H335 - May cause respiratory irritation.
H336 - May cause drowsiness or dizziness.

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Section 16 Other information (Continued)

H340 - May cause genetic defects.
H350 - May cause cancer.
H360 - May damage fertility or the unborn child.
H372 - Causes damage to organs through prolonged or repeated exposure.
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
TWA – Time Weighted Average
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation

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Section 16 Other information (Continued)

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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