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

1.1 Product identifier

Product name Urine/CSF Albumin Calibrator Levels 1-5

Part number B38859

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

Supplier

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

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

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

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)

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

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

e-mail address

SDSNT@beckman.com
Further information Contact:
Customer support Unit, Beckman Coulter Ireland Inc.
Technical Service Department Tel. +001-800-854-3633 (PST)
E-mail CC_Support.ie@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
Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

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.
Colorless; Liquid; Mild odor

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

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

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

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS

Section 2 Hazards identification (Continued)

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

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.

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**
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 EUH032 Acute Toxicity Estimates (ATE) ATE Oral = 27 mg/kg	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

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

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

Section 4 First aid measures

4.1 Description of first aid measures

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

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

Section 4 First aid measures (Continued)

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 (CO_2), dry chemical, water spray or foam.

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards

No special hazards determined.

Hazardous combustion products

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

5.3 Advice for firefighters

Protective equipment

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

Additional information

No further relevant information available.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. 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.

Section 7 Handling and storage (Continued)

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°C, as directed on the product label.

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

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

7.3 Specific end uses

No further relevant information available.

Section 8 Exposure controls and personal protection

8.1 Control parameters

Exposure limits

US OSHA

None established

ACGIH

Sodium Azide
CAS # 26628-22-8

0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

ACGIH Biological Exposure Indices (BEI)

None established

DFG MAK

Sodium Azide
CAS # 26628-22-8

0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL

NIOSH

None established

China

Sodium Azide
CAS # 26628-22-8

0.3 mg/m3 Ceiling MAC

Croatia

Sodium Azide
CAS # 26628-22-8

Skin Notation; 0.1 mg/m3 TWA [GVI]; 0.3 mg/m3 STEL [KGVI]

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8

0.1 mg/m3 TLV NGV; 0.3 mg/m3 Binding STEL Bindande KGV

Section 8 Exposure controls and personal protection (Continued)

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 protective clothing and impervious gloves, as appropriate.
Respiratory protection	Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid	**Density and/or relative density**	1.002 @20°C
Color	Colorless	**Solubility**	
Odor	Mild odor	**Water**	Miscible
pH	6.3 - 6.7	**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.

Section 9 Physical and chemical properties (Continued)

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

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)

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

Acute toxicity — Not classified based on available data.

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

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

Respiratory or skin sensitisation — Not classified based on available data.

Germ cell mutagenicity — Not classified based on available data.

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

Reproductive toxicity — Not classified based on available data.

Section 11 Toxicological information (Continued)

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.

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 of human origin and should be considered as potentially capable of transmitting infectious diseases.

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 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.

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

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

Package disposal

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

Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. 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

Section 15 Regulatory information (Continued)

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 # 75-56-9	Propylene Oxide	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 # 75-56-9	Propylene Oxide

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 # 75-56-9	Propylene Oxide

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

CAS # 75-21-8	Ethylene Oxide

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

CAS # 75-21-8	Ethylene Oxide

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

CAS # 75-21-8	Ethylene Oxide

Massachusetts Right To Know (RTK) List

CAS # 128-37-0	Butylated Hydroxytoluene
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

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

CAS # 128-37-0	Butylated Hydroxytoluene
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

Section 15 Regulatory information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 128-37-0	Butylated Hydroxytoluene
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide
CAS # 26628-22-8	Sodium Azide
CAS # 75-56-9	Propylene Oxide

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.

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 # 75-56-9	Propylene Oxide

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

Section 15 Regulatory information (Continued)

All ingredients are listed or exempted.

Turkey

Turkey-REACH - KKDIK Regulation - Annex 17 – Restrictions

Not applicable.

International

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

CAS # 75-21-8 Ethylene Oxide

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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

Section 16 Other information

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

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

Document version and issue/revision date

Revision Date (year/month/day) 2023/12/22
Last Revision Date (year/month/day) 2023/05/23
Document ID: B38859-75
Version: 06

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

Description of hazard class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
EUH032 - Contact with acids liberates very toxic gas.
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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

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