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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

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.

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description In vitro diagnostic reagent.

Colorless; Transparent; 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

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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	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

^{2 -} Substance with Community workplace exposure 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.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

^{8 -} Present at concentration below the cut-off limits.

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Section 5 Fire Fighting Measures

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

For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture Special Fire and Explosion Hazards

No special hazards determined.

Hazardous Combustion Products

No combustion products posing significant hazards are expected from this

product (an aqueous solution).

5.3 Advice for fire fighters

Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all

chemical fire situations.

5.4 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.

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

DFG MAK

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

Ireland

Sodium Azide 0.1 mg/m3 TWA (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption CAS # 26628-22-8

IOELVs

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

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

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

0, 10 .. 20020 22 0

Exposure controls

8.2

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.



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Section 9 Physical and Chemical Properties

			<u> </u>		
9.1	Information on basic physi	formation on basic physical and chemical properties			
	Physical State	Liquid	Specific Gravity (Water=1.0)	1.002 @20°C	
	Color	Colorless	Solubility		
	Transparency	Transparent	Water	Miscible	
	Odor	Mild odor	Organic	Not determined	
	pH	6.3 - 6.7	Partition coefficient: n-octanol/water	Not determined	
	Freezing Point	Not determined	Auto-ignition Temp.	Not applicable	
	Boiling Point	Not determined	Decomposition Temperature	Not determined	
	Flash Point	Not applicable	Percent Volatiles	Not applicable	
	Evaporation Rate	Not determined	Vapor Pressure	Not determined	
	Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined	
	Flammability Limits	Not applicable	Explosive Properties	Not applicable	
	Vapor Density	Not determined	Oxidizing Properties	Not applicable	
	Odor Threshold	Not applicable			
9.2	Other Information	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 rea	actions	

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 AvoidAvoid 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).

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Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg Sodium Azide CAS # 26628-22-8

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. Not classified based on available data. Skin Corrosion/Irritation Serious eye damage/eye Not classified based on available data.

irritation

Respiratory/skin sensitization Not classified based on available data.

This product does not contain a reportable concentration (≥ 0.1%) of any ingredient Carcinogenicity

listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity Not classified based on available data. **Reproductive Toxicity** Not classified based on available data.

Specific target organ toxicity - single exposure

Not classified based on available data.

Specific target organ toxicity - repeated exposure

Not classified based on available data.

Not classified based on available data. **Aspiration hazard**

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 Ecotoxicity

Fresh Water Species

Sodium Azide 96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: CAS # 26628-22-8

0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]

Microtox No information available. No information available. Water Flea No information available. Fresh Water Algae

12.2 Persistence and degradability Not determined for the product. 12.3 Bioaccumulation Not determined for the product. 12.4 Mobility in soil Not determined for the product.

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Section 12 Ecological Information (Continued)

12.5 Results of PBT and vPvB assessment

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

12.6 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.

13.2 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 Shipping Name: Not regulated for transportation

14.3 Hazard Class: 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 Transport in bulk according to Annex II of MARPOL and the IBC Code: 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 # 75-56-9	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 # 75-21-8 Ethylene Oxide
CAS # 26628-22-8 Sodium Azide
CAS # 75-56-9 Propylene Oxide



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Section 15 Regulatory Information (Continued)

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

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

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

No ingredients listed.

Canada

This product is exempt from WHMIS label and SDS requirements.

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	Removed the classification of EC Directives 1999/45/EC and 67/548/EEC from Sec. 2.1. Sec 3.2 and 15.1	

Updated Section 4, 6, 8, 11 - 16.

Document version and issue/revision date

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Section 16 Other Information (Continued)

Version: 04

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

H300 - Fatal if swallowed. 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

ADR and RID - European Agreement Concerning The International Carriage Of Dangerous Goods By Road and Rail

CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act

CLP - Classification, Labeling and Packaging

DFGMAK - Republic Germany's maximum exposure limit

GHS - Globally Harmonized System 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 IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

SARA - Superfund Amendments and Reauthorization Act

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System US DOT - United States Department of Transportation

WHMIS - Workplace Hazardous Material Information System

vPvB - Very persistent and very bioaccumulative substances

LC50 - Lethal Concentration, 50%

LD50 - Lethal Dose, 50%

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

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