

SAFETY DATA SHEET

Document ID: ODC0003-75 Version 05
Revision Date (year/month/day) 2019/08/07
Last Revision Date (year/month/day) 2016/10/21

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Control Serum Level 1

Part Number ODC0003

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.

This safety data sheet is provided for information only, not required by regulations

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.

Yellow-brown; Opaque; Lyophilized Powder; Light 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 materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

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: None

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.

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.

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Section 5 Fire Fighting Measures (Continued)

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 and animal 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.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.
If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
Dispose of all waste material in accordance with local guidelines.

6.4 **Reference to other sections** Refer sections 8 and 13.

Section 7 Handling and Storage

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

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 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 None established

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Section 8 Exposure Controls and Personal Protection (Continued)

DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established
Sweden (AFS 2015:7 and amendments)	None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
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	Lyophilized Powder	Specific Gravity (Water=1.0)	Not determined
Color	Yellow-brown	Solubility	
Transparency	Opaque	Water	Miscible
Odor	Light odor	Organic	Not determined
pH	Not applicable	Partition coefficient: n-octanol/water	Not applicable
Melting Point	Not determined	Auto-ignition Temp.	Not determined
Boiling Point	Not applicable	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not applicable	Vapor Pressure	Not applicable
Flammability (Solid, Gas)	Not determined	Viscosity	Not applicable
Flammability Limits	Not determined	Explosive Properties	Not applicable
Vapor Density	Not applicable	Oxidizing Properties	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

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 reactions	No further relevant information available.
10.4 Conditions to Avoid	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5 Incompatible materials	No further relevant information available.
10.6 Hazardous Decomposition Products	When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

Section 11 Toxicological Information

11.1 Information on toxicological effects	
Toxicity Data for Hazardous Ingredients	Not applicable
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/eye irritation	Not classified based on available data.
Respiratory/skin sensitization	Not classified based on available data.
Carcinogenicity	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
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.

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Section 11 Toxicological Information (Continued)

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Aspiration hazard

Not classified based on available data.

Other Information

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

No information available.

Microtox

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 Bioaccumulation 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 Other Adverse Effects No further relevant information available.

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 an 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.

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

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
US Federal and State Regulations

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

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

CAS # 7646-85-7 Zinc Chloride

California Proposition 65

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

No ingredients listed.

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

No ingredients listed.

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

No ingredients listed.

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

No ingredients listed.

Massachusetts Right To Know (RTK) List

CAS # 7757-82-6 Sodium Sulfate

CAS # 7646-85-7 Zinc Chloride

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

CAS # 7646-85-7 Zinc Chloride

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Section 15 Regulatory Information (Continued)

Pennsylvania Right To Know (RTK) List

CAS # 7757-82-6 Sodium Sulfate
CAS # 7646-85-7 Zinc Chloride

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
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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 1, 2, 5, 6, 8, 9, 11, 15, 16.

Document version and issue/revision date

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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

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Section 16 Other Information (Continued)

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

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

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