

SAFETY DATA SHEET

Document ID: ODC0005-75 Version 06
Revision Date (year/month/day) 2023/12/22
Last Revision Date (year/month/day) 2023/05/23

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

1.1 Product identifier

Product name HDL/LDL-Cholesterol Control Serum

Part number ODC0005

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

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
DELFI Building, Sliema Road, Gzira,
GZR 1637

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

e-mail address

Telephone: +356 21343270
Hours available: 08:30 – 17:00
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.
Yellow; Lyophilized Powder; Light

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.

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 Firefighting measures

5.1 Extinguishing media

In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards

No special hazards determined.

Hazardous combustion products

No combustion products posing significant hazards are expected from this product.

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Section 5 Firefighting measures (Continued)

5.3 Advice for firefighters

Protective equipment	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
Additional information	No further relevant information available.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	This product contains 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.
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6.2 Environmental precautions	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
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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.
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6.4 Reference to other sections	Refer sections 8 and 13.
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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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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.
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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)

ACGIH Biological Exposure Indices (BEI)

None established

DFG MAK

None established

Ireland

None established

IOELVs

None established

NIOSH

None established

China

None established

Croatia

None established

Japan

None established

Sweden (AFS 2015:7 and amendments)

None established

Turkey

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	Density and/or relative density	Not determined
Color	Yellow	Solubility	
Odor	Light	Water	Miscible
pH	Not applicable	Organic	Not determined
Melting Point	Not determined	Partition coefficient n-octanol/water (log value)	Not applicable
Boiling point or initial boiling point and boiling range	Not applicable	Auto-ignition temp.	Not determined
Flash point	Not applicable	Decomposition temperature	Not determined

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Section 9 Physical and chemical properties (Continued)

Flammability	Not determined	Vapor pressure	Not applicable
		Kinematic viscosity	Not applicable
Lower and upper explosion limit	Not determined		
Relative vapor density	Not applicable		
Particle characteristics	Not determined		
9.2 Other information			
Information with regard to physical hazard classes	No further relevant information available.		
Other safety characteristics	No further relevant information available.		

Section 10 Stability and reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical stability	The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions	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 hazard classes	
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.

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Section 11 Toxicological information (Continued)

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	No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Reproductive toxicity	Not classified based on available data.
Specific target organ toxicity (STOT) – single exposure	Not classified based on available data.
Specific target organ toxicity (STOT) – repeated exposure	Not classified based on available data.
Aspiration hazard	Not classified based on available data.
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	No information available.
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.

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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

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.

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

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Section 15 Regulatory information (Continued)

SARA 313 (Section 313, Title III reporting requirements)

No ingredients listed.

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

No ingredients listed.

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

No ingredients listed.

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

No ingredients listed.

Pennsylvania Right To Know (RTK) List

No ingredients listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

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)

No ingredients listed.

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

No ingredients listed.

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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

No ingredients listed.

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

All ingredients are listed or exempted.

Turkey

Turkey-REACH - KKDIK Regulation - Annex 17 – Restrictions

No ingredients listed.

International

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

No ingredients listed.

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 Updated sections 1, 2, 3, 4, 8 and 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.
Abbreviations and acronyms	<p>ACGIH - American Conference of Governmental Industrial Hygienists (ACGIH)</p> <p>ADR and RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road and Rail</p> <p>CLP - Classification, Labeling and Packaging</p> <p>DFGMAK - Republic Germany's maximum exposure limit</p> <p>EC50 - Concentration of a substance in an environmental medium expected to produce a certain effect in 50% of test organisms</p> <p>GHS - Globally Harmonized System of Classification and Labelling of Chemicals (GHS)</p> <p>HCS - Hazard Communication Standard</p> <p>IARC - International Agency for Research on Cancer</p> <p>IATA DGR - International Air Transport Association Dangerous Goods Regulation</p> <p>ICAO - International Civil Aviation Organization</p> <p>IDLH - Immediately Dangerous to Life or Health</p> <p>IMDG - International Maritime Dangerous Goods</p> <p>IMO - International Maritime Organization</p> <p>IOELVs - European Unions' Indicative Occupational Exposure Limit Values</p> <p>LC50 - Concentration of a substance in water causing death (50% of the tested population) to aquatic life</p> <p>LD50 - Lethal Dose 50%</p> <p>NIOSH - National Institute for Occupational Safety and Health</p> <p>NTP - National Toxicology Program</p> <p>OSHA - Occupational Safety and Health Administration</p> <p>PBT - Persistent Bioaccumulative and Toxic substances</p> <p>PEL - Permissible Exposure Limit</p> <p>SARA - Superfund Amendments and Reauthorization Act</p> <p>STEL – Short Term Exposure Limit</p> <p>STLV - Short Term Limit Value</p> <p>STV - Short Term Value</p> <p>TDG - Canadian Transportation of Dangerous Goods Regulations</p> <p>TLV - Threshold Limit Value</p> <p>TWA – Time Weighted Average</p> <p>UN GHS - United Nations Globally Harmonized System</p> <p>US DOT - United States Department of Transportation</p> <p>US OSHA - United States Occupational Safety and Health Administration</p> <p>vPvB - very Persistent and very Bioaccumulative substances</p>

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Section 16 Other information (Continued)

WHMIS - Workplace Hazardous Material Information System

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

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