SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name HDL-Cholesterol Calibrator

Part Number ODC0023

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

EC REP Address

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.

Light yellow; Opaque; Lyophilized Powder; Odorless

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

Aquatic Hazard Long term, Category 3

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

Aquatic Hazard Acute, Category 3

Aquatic Hazard Long term, Category 3

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Hazardous Ingredients

Sodium Azide

Pictogram

None

Section 2 Hazards Identification (Continued)

Signal Word

None

Hazard Statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements

P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

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 Sodium azide 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 - 0.5	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	

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.

Section 4 First Aid Measures (Continued)

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.

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

Section 6 Accidental Release Measures (Continued)

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

Sodium Azide
CAS # 26628-22-8

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

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 (as NaN3); 0.3 mg/m3 STEL; Potential for cutaneous absorption

IOELVs

Sodium Azide
CAS # 26628-22-8

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

NIOSH

None established

Japan

None established

Section 8 Exposure Controls and Personal Protection (Continued)

Sweden (AFS 2015:7 and amendments)

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

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 impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 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	Lyophilized Powder	**Specific Gravity (Water=1.0)**	Not determined
Color	Light yellow	**Solubility**	
Transparency	Opaque	**Water**	Not miscible
Odor	Odorless	**Organic**	Not determined
pH	Not determined	**Partition coefficient: n-octanol/water**	Not determined
Melting Point	Not determined	**Auto-ignition Temp.**	Product is not selfigniting
Boiling Point	Similar to water, approximately 100°C	**Decomposition Temperature**	Not determined
Flash Point	Not applicable	**Percent Volatiles**	Not applicable
Evaporation Rate	Not determined	**Vapor Pressure**	Similar to water, approximately 23 hPa
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 reactions

This product contains Sodium azide 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.

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

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

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

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.

Specific target organ toxicity – repeated exposure

Not classified based on available data.

Section 11 Toxicological Information (Continued)

Aspiration hazard Not classified based on available data.

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 CAS # 26628-22-8	96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50 Pimephales promelas: 5.46 mg/L [flow-through]
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 Harmful to aquatic life with long lasting effects.

This product is classified as environmentally hazardous. Do not allow undiluted product to enter sewer/surface or ground water. Dispose of contents/container to in accordance with local/national regulations

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

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 # 26628-22-8	Sodium Azide	1.0% de minimis concentration

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

CAS # 26628-22-8	Sodium Azide

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.

Section 15 Regulatory Information (Continued)

Massachusetts Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

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

CAS # 26628-22-8 Sodium Azide

Pennsylvania Right To Know (RTK) List

CAS # 26628-22-8 Sodium Azide

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.

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

Document version and issue/revision date

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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.

Section 16 Other Information (Continued)

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.