BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 33606-75 Rev. AE
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Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name CORTISOL CALIBRATOR S0

Part Number 33606

Series Name ACCESS®

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 Eurocenter S.A.
22, rue Juste-Oliver, Case Postale 1044,
CH-1260 Nyon 1, Switzerland.
Telephone +41 (0)22 365 36 11
Monday through Friday, 9:00 am to 7:00pm)

e-mail address SDSNT@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

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 Mixture

For full text of R- phrases: see Section 16.

Amber; Clear; Liquid; Musty

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

Skin Sensitization Category 1

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Xi;R43

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

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Section 2 Hazards Identification (Continued)

2.2 Label Elements

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

Hazardous Ingredients

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1)

Pictogram



Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

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 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.

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:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	2, 8

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Section 3 Composition and Information on Ingredients (Continued)

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # Not available	< 0.05	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	9

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of ProClin 300.

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

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 immediately and obtain medical attention.

Eye Contact — If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Skin Contact — In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

Ingestion — If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5 Fire Fighting Measures

Flammable Properties — Nonflammable solution.

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.

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Section 5 Fire Fighting Measures (Continued)

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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 10°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

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Section 8 Exposure Controls and Personal Protection (Continued)

ACGIH

Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 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 (as NaN3); 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
Japan	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	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 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	Liquid	**Specific Gravity (Water=1.0)**	1.021 @20°C
Color	Amber	**Solubility**	
Transparency	Clear	**Water**	Miscible
Odor	Musty	**Organic**	Not determined
pH	7.2	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable

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Section 9 Physical and Chemical Properties (Continued)

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 determined	**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

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

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	Oral LD50 Rat 27 mg/kg; Dermal LD50 Rat 50 mg/kg; Dermal LD50 Rabbit 20 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.

Skin Corrosion/Irritation No data available.

Serious eye damage/eye irritation No data available.

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Section 11 Toxicological Information (Continued)

Respiratory/skin sensitization May cause an allergic skin reaction.

Carcinogenicity No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity No data available.

Reproductive Toxicity No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard No data available.

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 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.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

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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.

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.

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, IMDG, US DOT, European ADR or Canadian TDG.

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

Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Edetic Acid is listed.
Sodium Azide is listed.

California Proposition 65

No ingredients listed.

Massachusetts MSL

Edetic Acid is listed.
Sodium Azide is listed.

New Jersey Dept. of Health RTK List

Edetic Acid is listed.
Sodium Azide is listed.

Pennsylvania RTK

Edetic Acid is listed.
Sodium Azide is listed.

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.

According to EC Directives (1999/45/EC and 67/548 EEC)

Irritant
Xi



Risk and Safety Phrases

R43 May cause sensitization by skin contact.
S37 Wear suitable gloves.
S28 After contact with skin, wash immediately with plenty of soap and water.

Canada

This product is exempt from WHMIS label and SDS requirements.

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Section 15 Regulatory Information (Continued)

PIN Not applicable

Ingredients on Ingredient Disclosure List

Sodium Azide

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Beckman Coulter Safety Rating	**Flammability: 0** **Health: 2** **Reactivity with Water: 0** **Contact: 2**	Code 0=None 1=Slight 2=Caution 3=Severe

Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

N - Dangerous for the environment
T - Toxic
T+ - Very toxic
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R43 May cause sensitization by skin contact.
R28 Very toxic if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Sens. 1 - Skin Sensitization Category 1
H300 - Fatal if swallowed.
H301 - Toxic if swallowed.
H311 - Toxic in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H331 - Toxic if inhaled.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
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 - Internal Agency for Research on Cancer
IATA - International Air Transport Association
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%

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