

SAFETY DATA SHEET

Document ID: 33556-75 Version AK
Revision Date (year/month/day) 2023/12/21
Last Revision Date (year/month/day) 2023/05/22

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

1.1 Product identifier

Product name PROGESTERONE CALIBRATOR S0
Part number 33556
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

Supplier

CANADA
Beckman Coulter Canada LP
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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

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)

NEW ZEALAND
Beckman Coulter NZ
Unit J, 33 Walmsley Road, Otahuhu,
Auckland 1062, New Zealand
Hours available: 08:30 - 17:00

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

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

	DELFI Building, Sliema Road, Gzira, GZR 1637 Telephone: +356 21343270 Hours available: 08:30 – 17:00
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. 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	Mixture Amber; Liquid; Musty
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

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

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.

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 EUH032 Acute Toxicity Estimates (ATE) ATE Oral = 27 mg/kg	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2, 8

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off 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.

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Section 4 First aid measures (Continued)

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.

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.

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 below -20°C.

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)

ACGIH Biological Exposure Indices (BEI)

None established

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; 0.3 mg/m³ STEL; 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

China

Sodium Azide
CAS # 26628-22-8

0.3 mg/m³ Ceiling MAC

Croatia

Sodium Azide
CAS # 26628-22-8

Skin Notation; 0.1 mg/m³ TWA [GVI]; 0.3 mg/m³ STEL [KGV]

Japan

None established

Sweden (AFS 2015:7 and amendments)

Sodium Azide
CAS # 26628-22-8

0.1 mg/m³ TLV NGV; 0.3 mg/m³ Binding STEL Bindande KGV

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Section 8 Exposure controls and personal protection (Continued)

Turkey

Sodium Azide
CAS # 26628-22-8

0.3 mg/m3 STEL; Skin notation; 0.1 mg/m3 TWA

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	Liquid	Density and/or relative density	1.017 @20°C
Color	Amber	Solubility	
Odor	Musty	Water	Miscible
pH	7.4	Organic	Not determined
Freezing point	Not determined	Partition coefficient n-octanol/water (log value)	Not determined
Boiling point or initial boiling point and boiling range	Not determined	Auto-ignition temp.	Not applicable
Flash point	Not applicable	Decomposition temperature	Not determined
Flammability	Not applicable	Vapor pressure	Not determined
		Kinematic viscosity	Not determined
Lower and upper explosion limit	Not applicable		
Relative vapor density	Not determined		
Particle characteristics	Not applicable		

9.2 Other information

Information with regard to physical hazard classes

No further relevant information available.

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Section 9 Physical and chemical properties (Continued)

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	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 hazard classes	
Toxicity data for hazardous ingredients	
Sodium Azide CAS # 26628-22-8	Dermal LD50 Rabbit 20 mg/kg (NLM_HSDB); Inhalation LC50 Rat 0.054 - 0.52 mg/L 4 h (dust)(ECHA_API); Oral LD50 Rat 27 mg/kg (NZ_CCID)
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/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.

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Section 11 Toxicological information (Continued)

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

Sodium Azide
CAS # 26628-22-8

LC50 96 h Oncorhynchus mykiss: 0.8 mg/L; LC50 96 h Lepomis macrochirus: 0.7 mg/L; LC50 96 h Pimephales promelas: 5.46 mg/L [flow-through]

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.

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

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.

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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). 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 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

SARA 313 (Section 313, Title III reporting requirements)

CAS # 26628-22-8

Sodium Azide

1.0% de minimis concentration

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Section 15 Regulatory information (Continued)

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.

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.

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

Not applicable.

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

No ingredients listed.

Refer to Section 3

UK Regulations

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Section 15 Regulatory information (Continued)

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

CAS # 26628-22-8 Sodium Azide

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

Document version and issue/revision date

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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.
Description of hazard class and hazard statements from Section 3	<p>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 EUH032 - Contact with acids liberates very toxic gas. H300 - Fatal if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.</p>
Abbreviations and acronyms	<p>ACGIH - American Conference of Governmental Industrial Hygienists (ACGIH) ADR and RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road and Rail CLP - Classification, Labeling and Packaging DFGMAK - Republic Germany's maximum exposure limit EC50 - Concentration of a substance in an environmental medium expected to produce a certain effect in 50% of test organisms GHS - Globally Harmonized System of Classification and Labelling of Chemicals (GHS) 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 IDLH - Immediately Dangerous to Life or Health IMDG - International Maritime Dangerous Goods IMO - International Maritime Organization IOELVs - European Unions' Indicative Occupational Exposure Limit Values LC50 - Concentration of a substance in water causing death (50% of the tested population) to aquatic life LD50 - Lethal Dose 50% NIOSH - National Institute for Occupational Safety and Health NTP - National Toxicology Program OSHA - Occupational Safety and Health Administration PBT - Persistent Bioaccumulative and Toxic substances PEL - Permissible Exposure Limit SARA - Superfund Amendments and Reauthorization Act STEL – Short Term Exposure Limit STLV - Short Term Limit Value STV - Short Term Value TDG - Canadian Transportation of Dangerous Goods Regulations TLV - Threshold Limit Value</p>

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Section 16 Other information (Continued)

TWA – Time Weighted Average
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
US OSHA - United States Occupational Safety and Health Administration
vPvB - very Persistent and very Bioaccumulative substances
WHMIS - Workplace Hazardous Material Information System

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