BECKMAN COULTER

SAFETY DATA SHEET

Doc. ID: 468405-75 Rev. AG
Revised (year/month/day) 2015/05/08

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

1.1 Product Identifier

Product Name Calibrator 1

Part Number 468405

Series Name SYNCHRON Systems

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

Yellow; Translucent; Liquid; Musty

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

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

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

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

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)

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Section 2 Hazards Identification (Continued)

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 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:		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**GHS**	
Ethylene Glycol CAS # 107-21-1 EINECS # 203-473-3 Index # 603-027-00-1	5 - 10	Xn;R 22	Acute Tox. Oral 4 H302	Acute Tox. Oral 4 H302	3, 8
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

2 - Substance with Community workplace exposure limits
3 - Health hazard
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 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, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

Ingestion

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

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Section 4 First Aid Measures (Continued)

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

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.

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 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.
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.

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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.

7.2 Conditions for safe storage, including any incompatibilities

Store at -20 to -15°C , as directed on the product label. Keep container closed.

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

Ethylene Glycol CAS # 107-21-1	100 mg/m3 Ceiling (aerosol only)
Sodium Azide CAS # 26628-22-8	0.29 mg/m3 Ceiling (as NaN3); 0.11 ppm Ceiling (as Hydrazoic acid) (vapor)

DFG MAK

Ethylene Glycol CAS # 107-21-1	20 ppm Peak; 52 mg/m3 Peak; skin notation; 10 ppm TWA MAK; 26 mg/m3 TWA MAK
Sodium Azide CAS # 26628-22-8	0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

Ireland

Ethylene Glycol CAS # 107-21-1	10 mg/m3 TWA (particulate); 20 ppm TWA (vapour); 52 mg/m3 TWA (vapour); 40 ppm STEL (vapour); 104 mg/m3 STEL (vapour); Potential for cutaneous absorption
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

Ethylene Glycol CAS # 107-21-1	Possibility of significant uptake through the skin; 20 ppm TWA; 52 mg/m3 TWA; 40 ppm STEL; 104 mg/m3 STEL
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.

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Section 8 Exposure Controls and Personal Protection (Continued)

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.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	Liquid	**Specific Gravity (Water=1.0)**	1.031 @20°C
Color	Yellow	**Solubility**	
Transparency	Translucent	**Water**	Miscible
Odor	Musty	**Organic**	Not determined
pH	6.0 - 8.0	**Partition coefficient: n-octanol/water**	Not determined
Freezing Point	Not determined	**Auto-ignition Temp.**	Not applicable
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 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.

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Section 10 Stability and Reactivity (Continued)

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

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Ethylene Glycol CAS # 107-21-1	Oral LD50 Rat 4000 mg/kg; Dermal LD50 Rabbit 9530 µL/kg
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.

Respiratory/skin sensitization

No data available.

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 materials of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12 Ecological Information

12.1 Ecotoxicity

Fresh Water Species

Ethylene Glycol CAS # 107-21-1	96 h LC50 Oncorhynchus mykiss: 41000 mg/L; 96 h LC50 Oncorhynchus mykiss: 14 - 18 mL/L [static]; 96 h LC50 Lepomis macrochirus: 27540 mg/L [static]; 96 h LC50 Oncorhynchus mykiss: 40761 mg/L [static]; 96 h LC50 Pimephales promelas: 40000 - 60000 mg/L [static]; 96 h LC50 Poecilia reticulata: 16000 mg/L [static]
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

Ethylene Glycol CAS # 107-21-1	48 h EC50 Daphnia magna: 46300 mg/L

Fresh Water Algae

Ethylene Glycol CAS # 107-21-1	96 h EC50 Pseudokirchneriella subcapitata: 6500 - 13000 mg/L

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).
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.

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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, 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	Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration Ethylene Glycol is subject to reporting requirements of Section 313, Title III of SARA. 1.0 % de minimis concentration 1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration 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	Acetaldehyde is listed. Ethylene Glycol is listed. 1,4-Dioxane is listed. Sodium Azide is listed.
California Proposition 65	Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning: **WARNING**: This product contains a chemical known to the State of California to cause cancer. 1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning: **WARNING**: This product contains a chemical known to the State of California to cause cancer.
Massachusetts MSL	Acetaldehyde is listed. Ethylene Glycol is listed. 1,4-Dioxane is listed. Sodium Azide is listed.

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Section 15 Regulatory Information (Continued)

New Jersey Dept. of Health RTK List

Acetaldehyde is listed.
Ethylene Glycol is listed.
1,4-Dioxane is listed.
Sodium Azide is listed.

Pennsylvania RTK

Acetaldehyde is listed.
Ethylene Glycol is listed.
1,4-Dioxane 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)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Ingredients on Ingredient Disclosure List

Acetaldehyde
Ethylene Glycol
1,4-Dioxane
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: 1** **Reactivity with Water: 0** **Contact: 1**	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+ - Very toxic
Xn - Harmful

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Section 16 Other Information (Continued)

R 22 Harmful if swallowed.
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. Oral 2 - Acute Toxicity Oral, Category 2
Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H302 - Harmful if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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 - International 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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