

Kit SDS Cover Sheet

Document ID: DR0070-2-75: Version AF
Revision Date (year/month/day) 2022/07/20
Last Revision Date (year/month/day) 2018/06/29

Product information

Product name Lyophilized Chemistry Calibrator Level 2

Part number DR0070-2

Series name AU/DxC AU US

Additional product information

For In Vitro Diagnostic Use. See product literature for details.

Components

Description Lyophilized Chemistry Calibrator Level 2
Beckman Coulter Calibrator Diluent

Transport information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.



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

1.1 Product identifier

Product name Lyophilized Chemistry Calibrator Level 2
Part number Component of P/N DR0070-2
Series name AU/DxC AU US

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

Manufactured for
 Beckman Coulter, Inc.
 250 S. Kraemer Blvd
 Brea, CA 92821, U.S.A.
 Tel: 800-854-3633

EC REP Address

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)

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
 Light yellow; Clear; Lyophilized - Liquid after reconstitution.; Slight odor

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

Section 5 Fire fighting measures (Continued)

Hazardous combustion products

No combustion products posing significant hazards are expected from this product (an aqueous solution).

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

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	None established
DFG MAK	None established
Ireland	None established
IOELVs	None established
NIOSH	None established
Japan	None established

Sweden (AFS 2015:7 and amendments)

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 - Liquid after reconstitution.	Specific gravity (water=1.0)	≈ 1.0
Color	Light yellow	Solubility	
Transparency	Clear	Water	Miscible
Odor	Slight odor	Organic	Not determined
pH	7.0 - 8.5	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

Section 9 Physical and chemical properties (Continued)

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	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	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	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.
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.

Section 11 Toxicological information (Continued)

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.
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	No information available.
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	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.
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)

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.

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Section 15 Regulatory information (Continued)

Pennsylvania Right To Know (RTK) List

No ingredients 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.

Refer to Section 3

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
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Revision changes

Reviewed for three-years cycle.

Document version and issue/revision date

Revision Date (year/month/day) 2022/07/20
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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

Section 16 Other information (Continued)

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

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

1.1 Product identifier

Product name Beckman Coulter Calibrator Diluent
Part number Component of P/N DR0070-2
Series name AU/DxC AU US

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

Manufactured for
 Beckman Coulter, Inc.
 250 S. Kraemer Blvd
 Brea, CA 92821, U.S.A.
 Tel: 800-854-3633

EC REP Address

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)

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
 Colorless; Clear; Liquid; Odorless

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

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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
Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS
- 2.3 Other hazards** 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 | Not applicable |
| Eye contact | Not applicable |
| Skin contact | Not applicable |
| Ingestion | Not applicable |
- 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** Not applicable
- 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 (an aqueous solution).
- 5.3 Advice for fire fighters**
- | | |
|-----------------------------|----------------|
| Protective equipment | Not applicable |
|-----------------------------|----------------|
- 5.4 Additional information** No further relevant information available.

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Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions No special precautions are necessary. Use good laboratory procedures.

6.2 Environmental precautions Contain spill to prevent migration.

6.3 Methods and material for containment and cleaning up

Spill and leak procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections Refer sections 8 and 13.

Section 7 Handling and storage

7.1 Precautions for safe handling No special precautions are necessary; use good laboratory procedures.

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 None established

DFG MAK None established

Ireland None established

IOELVs None established

NIOSH None established

Japan None established

Sweden (AFS 2015:7 and amendments)

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.

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Section 8 Exposure controls and personal protection (Continued)

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	Specific gravity (water=1.0)	1.00 @20°C
Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	7.8 - 8.6	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 None

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.

Section 10 Stability and reactivity (Continued)

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

Not applicable

Primary routes of exposure Eye contact, ingestion, inhalation, and skin contact.

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.

Aspiration hazard Not classified based on available data.

Other information No further relevant information available.

Section 12 Ecological information

12.1 Ecotoxicity

Fresh water species No information available.

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.

Section 12 Ecological information (Continued)

- 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** 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.
- 13.2 Additional information** Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. 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)

No ingredients listed.

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

Section 15 Regulatory information (Continued)

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.

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

Refer to Section 3

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.

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Section 16 Other information

Beckman Coulter safety rating	Flammability: 0 Health: 0 Reactivity with water: 0 Physical contact: 0	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision changes Reviewed for three-years cycle.

Document version and issue/revision date

Revision Date (year/month/day) 2022/07/20
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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

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