

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

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

1.1 Product Identifier

Product Name COULTER CLENZ CLEANING AGENT

Part Number 8546930

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 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
Blue; Clear; Liquid; Odorless

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

Skin Sensitization Category 1
Respiratory Sensitization Category 1

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

Skin Sensitization Category 1
Respiratory Sensitization Category 1

2.2 Label Elements

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

Diazolidinyl Urea
Subtilisin

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



SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

Section 2 Hazards Identification (Continued)

Signal Word

DANGER

Hazard Statements

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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.

P284 In case of inadequate ventilation, wear respiratory protection.

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

P304+P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

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

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

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

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
Diazolidinyl Urea CAS # 78491-02-8 EINECS # 278-928-2 Index # Not available	< 1	Skin Sens. 1, H317	Acute Tox. Dermal 5, H313 Acute Tox. Oral 5, H303 Skin Sens. 1, H317	
Subtilisin CAS # 9014-01-1 EINECS # 232-752-2 Index # 647-012-00-8	< 1	Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Skin Irrit. 2, H315	Acute Tox. Oral 5, H303 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Skin Irrit. 2, H315	
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	< 0.0015	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Skin Corr. 1B, H314 Skin Sens. 1, H317	Acute Tox. Dermal 3, H311 Acute Tox. Inhal. 3, H331 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Skin Corr. 1B, H314 Skin Sens. 1, H317	15, 8

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

Section 3 Composition and Information on Ingredients (Continued)

15 - May produce an allergic reaction.
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 plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

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

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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. Refer to Section 4.1.

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 (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.

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions

Observe general safety guidelines for protection; avoid eye and skin contact.
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

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 Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 25°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

Subtilisin
CAS # 9014-01-1

0.00006 mg/m³ Ceiling (as crystalline active enzyme) (listed under Subtilisins)

DFG MAK

None established

Ireland

Subtilisin
CAS # 9014-01-1

0.00006 mg/m³ TWA (proteolytic enzymes) (as 100% pure crystalline enzyme);
0.00006 mg/m³ STEL

IOELVs

None established

NIOSH

Subtilisin
CAS # 9014-01-1

0.00006 mg/m³ STEL (60 min) (listed under Subtilisins)

Japan

None established

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

Section 8 Exposure Controls and Personal Protection (Continued)

Sweden (AFS 2015:7 and amendments)

Subtilisin
CAS # 9014-01-1

1 glycine unit/m³ TLV; 3 glycine unit/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	Liquid	Specific Gravity (Water=1.0)	1.04 @20°C
Color	Blue	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	8.5 - 8.9	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.

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

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

Diazolidinyl Urea CAS # 78491-02-8	Oral LD50 Rat 2600 mg/kg
Subtilisin CAS # 9014-01-1	Oral LD50 Rat 3700 mg/kg
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	Oral LD50 Rat 53 mg/kg

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	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Carcinogenicity	This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen 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.

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

Section 11 Toxicological Information (Continued)

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.

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.

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)

CAS # 123-91-1	1,4-Dioxane	0.1% de minimis concentration
CAS # 75-21-8	Ethylene Oxide	0.1% de minimis concentration

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

CAS # 7664-38-2	Phosphoric Acid
CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide

California Proposition 65

 **WARNING** This product can expose you to chemical which is known to the State of California to cause cancer and/or reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical which is known to the State of California to cause cancer

CAS # 123-91-1	1,4-Dioxane
CAS # 75-21-8	Ethylene Oxide

Chemical which is known to the State of California to cause development toxicity

CAS # 75-21-8	Ethylene Oxide
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Chemical which is known to the State of California to cause male reproductive toxicity

CAS # 75-21-8	Ethylene Oxide
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Chemical which is known to the State of California to cause female reproductive toxicity

CAS # 75-21-8	Ethylene Oxide
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Section 15 Regulatory Information (Continued)

Massachusetts Right To Know (RTK) List

CAS # 7664-38-2	Phosphoric Acid
CAS # 123-91-1	1,4-Dioxane
CAS # 10377-60-3	Magnesium Nitrate
CAS # 111-76-2	Ethylene Glycol Monobutyl Ether
CAS # 75-21-8	Ethylene Oxide

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

CAS # 7664-38-2	Phosphoric Acid
CAS # 123-91-1	1,4-Dioxane
CAS # 10377-60-3	Magnesium Nitrate
CAS # 111-76-2	Ethylene Glycol Monobutyl Ether
CAS # 75-21-8	Ethylene Oxide
CAS # 129-17-9	Patent Blue VF
CAS # 57-55-6	Propylene Glycol

Pennsylvania Right To Know (RTK) List

CAS # 7664-38-2	Phosphoric Acid
CAS # 123-91-1	1,4-Dioxane
CAS # 10377-60-3	Magnesium Nitrate
CAS # 111-76-2	Ethylene Glycol Monobutyl Ether
CAS # 75-21-8	Ethylene Oxide
CAS # 57-55-6	Propylene Glycol

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

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

Section 16 Other Information

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

Updated Section 3.
Updated Section 4.
Updated Section 6.
Updated Section 8.
Updated Section 11.
Updated Section 14.
Updated Section 15.
Updated Section 16.

Document version and issue/revision date

Revision Date (year/month/day) 2018/07/27
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Description of hazard Class and hazard statements from Section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Dermal 3 - Acute Toxicity Dermal, Category 3
Acute Tox. Dermal 5 - Acute Toxicity Dermal, Category 5
Acute Tox. Inhal. 3 - Acute Toxicity Inhalation, Category 3
Acute Tox. Oral 3 - Acute Toxicity Oral, Category 3
Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5
Eye Dam. 1 - Eye Damage Category 1
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Resp. Sens. 1 - Respiratory Sensitization Category 1
Skin Corr. 1B - Skin Corrosion Category 1B
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1 - Skin Sensitization Category 1
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H301 - Toxic if swallowed.
H303 - May be harmful if swallowed.
H311 - Toxic in contact with skin.
H313 - May be harmful in contact with skin
H314 - Causes severe skin burns and eye damage.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H331 - Toxic if inhaled.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 - May cause respiratory irritation.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

SAFETY DATA SHEET

Document ID: 8546930-75 Version AG
Revision Date (year/month/day) 2018/07/27
Last Revision Date (year/month/day) 2015/04/01

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
LD50 - Lethal Dose, 50%

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