



SAFETY DATA SHEET

Doc. ID: 8546929-75 Rev. AF
Revised (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®

Part Number 8546929

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

Blue; Clear; Liquid; Odorless

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

Respiratory Sensitization Category 1

Skin Sensitization Category 1

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

Skin Sensitization Category 1

Respiratory Sensitization Category 1

Section 2 Hazards Identification (Continued)

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



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-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	

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Section 3 Composition and Information on Ingredients (Continued)

Diazolidinyl Urea CAS # 78491-02-8 EINECS # 278-928-2 Index # Not available	< 1	Xi;R43	Skin Sens. 1 H317	Acute Tox. Dermal 5 Acute Tox. Oral 5 Skin Sens. 1 H303; H313; H317	
Subtilisin CAS # 9014-01-1 EINECS # 232-752-2 Index # 647-012-00-8	< 1	Xn;R37/38-41-42	Eye Dam. 1 Resp. Sens. 1 STOT SE 3 Skin Irrit. 2 H315; H318; H334; H335	Acute Tox. Oral 5 Eye Dam. 1 Resp. Sens. 1 STOT SE 3 Skin Irrit. 2 H303; H315; H318; H334; H335	
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	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	10, 15, 8

10 - 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 150.

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 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. 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.

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.

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Section 5 Fire Fighting Measures

Flammable Properties	Nonflammable aqueous solution.
5.1 Extinguishing Media	In case of fire use carbon dioxide (CO ₂), 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.

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.
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.

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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 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

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)	1.04 @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

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Section 9 Physical and Chemical Properties (Continued)

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.
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	
Subtilisin CAS # 9014-01-1	Oral LD50 Rat 3700 mg/kg
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Section 11 Toxicological Information (Continued)

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	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	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, 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

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.

1,4-Dioxane is listed.

Phosphoric Acid is listed.

California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. 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.

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

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.

WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Ethylene Oxide is listed.

Ethylene Glycol Monobutyl Ether is listed.

1,4-Dioxane is listed.

Phosphoric Acid is listed.

Magnesium Nitrate is listed.

New Jersey Dept. of Health RTK List

Propylene Glycol is listed.

Ethylene Oxide is listed.

Ethylene Glycol Monobutyl Ether is listed.

1,4-Dioxane is listed.

Patent Blue VF is listed.

Phosphoric Acid is listed.

Magnesium Nitrate is listed.

Section 15 Regulatory Information (Continued)

Pennsylvania RTK

Propylene Glycol is listed.
Ethylene Oxide is listed.
Ethylene Glycol Monobutyl Ether is listed.
1,4-Dioxane is listed.
Phosphoric Acid is listed.
Magnesium Nitrate 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

Propylene Glycol
Ethylene Oxide
Ethylene Glycol Monobutyl Ether
1,4-Dioxane
Phosphoric Acid

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: 3 Reactivity with Water: 0 Contact: 3	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision Changes

Updated to GHS.

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

N - Dangerous for the environment
T - Toxic
Xi - Irritant
Xn - Harmful
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.

Section 16 Other Information (Continued)

R43 May cause sensitization by skin contact.
R37/38 Irritating to respiratory system and skin.
R41 Risk of serious damage to eyes.
R42 May cause sensitization by inhalation.
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. 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.

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

Section 16 Other Information (Continued)

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%

For further information, please contact your local Beckman Coulter, Inc. representative.

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