

SAFETY DATA SHEET

Document ID: 628022-75 Version AR
Revision Date (year/month/day) 2024/11/01
Last Revision Date (year/month/day) 2024/09/27

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

1.1 Product identifier

Product name COULTER DxH Cleaner
Part number 628022, 628023

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
7075 Financial Drive
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
DELFI Building, Sliema Road, Gzira,
GZR 1637

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

	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 Blue; Liquid; Odorless
Classification according to EC 1272/2008 (CLP/GHS)	Eye Irritation Category 2, H319
Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS	Respiratory Sensitization Category 1 Eye Irritation Category 2
2.2 Label elements	According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS
	Hazardous ingredients 2-Phenoxyethanol Subtilisin Ethoxylated lauryl alcohol
	Pictogram 
	Signal word DANGER

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Section 2 Hazards identification (Continued)

Hazard statements

H319 Causes serious eye irritation.

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

Precautionary statements

Prevention

P261 Avoid breathing vapours.

P280 Wear protective gloves, protective clothing and eye/face protection.

P284 In case of inadequate ventilation, wear respiratory protection.

Response

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

Storage

None

Disposal

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
2-Phenoxyethanol CAS # 122-99-6 EINECS # 204-589-7 Index # 603-098-00-9	< 1	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 STOT SE 3, H335 Acute Toxicity Estimates (ATE) ATE Oral = 1394 mg/kg	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 STOT SE 3, H335	REST
Ethoxylated lauryl alcohol CAS # 9002-92-0 EINECS # Not available Index # Not available	< 1	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315 Acute Toxicity Estimates (ATE) ATE Oral = 1000 mg/kg	Acute Tox. Oral 4, H302 Eye Dam. 1, H318 Skin Irrit. 2, H315	

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Section 3 Composition and information on ingredients (Continued)

<p>Subtilisin CAS # 9014-01-1 EINECS # 232-752-2 Index # 647-012-00-8</p>	<p>0.1 - < 0.3</p>	<p>Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Skin Irrit. 2, H315</p>	<p>Acute Tox. Oral 5, H303 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Skin Irrit. 2, H315</p>	<p>REST</p>
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REST - Subject to Restriction as per Annex XVII of REACH Regulation (EC) No 1907/2006

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 for 15 minutes or longer, making sure that the eyelid is held open. If pain or irritation occurs, obtain medical advice/attention.

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

Causes serious eye irritation.
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 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 (an aqueous solution).

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Section 5 Firefighting measures (Continued)

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	Observe general safety guidelines for protection; avoid eye and skin contact. Wear protective gloves, protective clothing and eye/face protection.
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6.2 Environmental precautions	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
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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.
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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	Use good laboratory procedures; avoid eye and skin contact.
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7.2 Conditions for safe storage, including any incompatibilities

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
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ACGIH

Subtilisin CAS # 9014-01-1	0.00006 mg/m ³ Ceiling (as crystalline active enzyme) (listed under Subtilisins)
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ACGIH Biological Exposure Indices (BEI)

None established

DFG MAK

2-Phenoxyethanol CAS # 122-99-6	1 ppm Peak (can occur as vapor and aerosol at the same time); 5.7 mg/m ³ Peak (can occur as vapor and aerosol at the same time); 1 ppm TWA MAK (can occur as vapor and aerosol at the same time); 5.7 mg/m ³ TWA MAK (can occur as vapor and aerosol at the same time)
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Section 8 Exposure controls and personal protection (Continued)

Ireland

Subtilisin
CAS # 9014-01-1 0.00006 mg/m3 TWA (proteolytic enzymes); 0.00006 mg/m3 STEL

IOELVs

None established

NIOSH

Subtilisin
CAS # 9014-01-1 0.00006 mg/m3 STEL (60 min) (listed under Subtilisins)

China

Subtilisin
CAS # 9014-01-1 15 ng/m3 TWA

Croatia

Subtilisin
CAS # 9014-01-1 Skin Notation; 0.00004 mg/m3 TWA [GVI]

Japan

None established

Sweden (AFS 2015:7 and amendments)

Subtilisin
CAS # 9014-01-1 1 glycine unit/m3 TLV NGV; 3 glycine unit/m3 Binding STEL Bindande KGV

Turkey

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 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	Density and/or relative density	≈ 1
Color	Blue	Solubility	
Odor	Odorless	Water	Miscible
pH	8.5	Organic	Not determined

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Section 9 Physical and chemical properties (Continued)

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	Not applicable		
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	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 hazard classes

Toxicity data for hazardous ingredients

2-Phenoxyethanol CAS # 122-99-6	Dermal LD50 Rabbit 5 mL/kg (NLM_CIP); Inhalation LC50 Rat >0.057 mg/L 8 h (no deaths occurred)(vapor)(EU_CLH); Oral LD50 Rat 1850 mg/kg (EU_CLH)
Subtilisin CAS # 9014-01-1	Oral LD50 Rat 3700 mg/kg (NZ_CCID)
Ethoxylated lauryl alcohol CAS # 9002-92-0	Dermal LD50 Rat >2000 mg/kg (ECHA_API); Oral LD50 Rat 1 g/kg (NLM_CIP)

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/irritation Causes serious eye irritation.

Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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.

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 No further relevant information available.

Section 12 Ecological information

12.1 Toxicity

Fresh water species

2-Phenoxyethanol
CAS # 122-99-6 LC50 96 h Pimephales promelas: 337 - 352 mg/L [flow-through] (EPA); LC50 96 h Pimephales promelas: 366 mg/L [static] (IUCLID)

Microtox/organisms No information available.

Section 12 Ecological information (Continued)

Water flea

2-Phenoxyethanol
CAS # 122-99-6

EC50 48 h Daphnia magna: >500 mg/L (IUCLID)

Fresh water algae

2-Phenoxyethanol
CAS # 122-99-6

EC50 72 h Desmodesmus subspicatus: >500 mg/L (IUCLID)

- 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** 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.

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 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)

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

CAS # 129-17-9 Patent Blue VF

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

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.

Section 15 Regulatory information (Continued)

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

CAS # 122-99-6	2-Phenoxyethanol	Entry No.: 75
CAS # 9014-01-1	Subtilisin	Entry No.: 75

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

No ingredients listed.

UK Regulations

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

No ingredients listed.

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: 3 Reactivity with water: 0 Physical contact: 3	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision changes

Added the registry number in Croatian language.

Document version and issue/revision date

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Section 16 Other information (Continued)

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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

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4

Acute Tox. Oral 5 - Acute Toxicity Oral, Category 5

Eye Dam. 1 - Eye Damage Category 1

Resp. Sens. 1 - Respiratory Sensitization Category 1

Skin Irrit. 2 - Skin Irritation Category 2

STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3

H302 - Harmful if swallowed.

H303 - May be harmful if swallowed.

H315 - Causes skin irritation.

H318 - Causes serious eye damage.

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

H335 - May cause respiratory irritation.

Abbreviations and acronyms

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

Section 16 Other information (Continued)

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
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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