

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

CHOL2

Version
1.6

Revision Date:
20.02.2015

Date of last issue: 31.07.2014
Date of first issue: 11.10.2012

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Commercial Product Name : CHOL2
Mat.-No./ Genisys-No. : 03039773190

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
- Sandhoferstrasse 116
68305 Mannheim
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH
Centre for detoxification: : Mainz +49(0)6131-19240
Munich +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with wa-

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P337 + P313

ter for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1 (A / B / C)

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2

H319: Causes serious eye irritation.

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
Dodecyl alcohol, ethoxylated	9002-92-0 500-002-6	Xn; Xn; R22 Xi; Xi; R41	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318	$\geq 1 - < 3$
phenol	108-95-2 203-632-7	Mut.Cat.3; R68 T; R23/24/25 C; R34 Xn; R48/20/21/22	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Corr. 1B; H314 Muta. 2; H341 STOT RE 2; H373	$\geq 0,1 - < 1$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.
If on skin, rinse well with water.

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If on clothes, remove clothes.

In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not breathe vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : When using do not eat or drink. When using do not smoke.
Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Storage class (TRGS 510) : 12, Non Combustible Liquids

Other data : No decomposition if stored and applied as directed.

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7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

R1 (A / B / C)

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
phenol	108-95-2	TWA	2 ppm 7,8 mg/m ³	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		TWA	2 ppm 8 mg/m ³	2009/161/EU
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	4 ppm 16 mg/m ³	2009/161/EU
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		AGW (Vapour and aerosols)	2 ppm 8 mg/m ³	DE TRGS 900
Peak-limit: excursion factor (category)	2;(II)			
Further information	European Union (The EU has established a limit value: deviations in value and peak limit are possible), Sum of vapor and aerosols., Skin absorption			

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Phenol	108-95-2	phenol: 120 mg/g Creatinine (Urine)	Immediately after exposition or after working hours	TRGS 903

8.2 Exposure controls

Personal protective equipment

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time

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which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1 (A / B / C)

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: 6,8
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: The product is not flammable., Does not sustain combustion.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: No data available
Ignition temperature	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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9.2 Other information

R1 (A / B / C)

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1 (A / B / C)

Acute toxicity

Not classified based on available information.

Components:

Dodecyl alcohol, ethoxylated:

Acute oral toxicity : LD50 Oral (Rat): 2.000 mg/kg

phenol:

Acute oral toxicity : LD50 Oral (Rat): 317 mg/kg

LD50 Oral (Mouse): 270 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0,9 mg/l
Exposure time: 8 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 Dermal (Rat): 669 mg/kg

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LD50 Dermal (Rabbit): 630 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Dodecyl alcohol, ethoxylated:

Result: Irritating to skin.

phenol:

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Dodecyl alcohol, ethoxylated:

Result: Risk of serious damage to eyes.

phenol:

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

phenol:

Genotoxicity in vitro : Remarks: In vitro tests showed mutagenic effects

Germ cell mutagenicity- Assessment : In vitro tests showed mutagenic effects

Carcinogenicity

Not classified based on available information.

Components:

phenol:

Remarks: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:

phenol:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

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STOT - repeated exposure

Not classified based on available information.

Components:

phenol:

Assessment: May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:

phenol:

No aspiration toxicity classification

Further information

Components:

phenol:

Remarks: Symptoms of overexposure are dizziness, headache, tiredness, nausea, unconsciousness, cessation of breathing.

SECTION 12: Ecological information

12.1 Toxicity

R1 (A / B / C)

Components:

Dodecyl alcohol, ethoxylated:

M-Factor (Acute aquatic toxicity) : 1

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

phenol:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 1,75 mg/l
Exposure time: 96 h

LC50 (Carassius auratus (goldfish)): 46 mg/l
Exposure time: 24 h

LC50 (Oncorhynchus mykiss (rainbow trout)): 5 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 12 mg/l
Exposure time: 24 h

EC50 (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 48 h

EC50 (Daphnia magna (Water flea)): 4,2 mg/l

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	Exposure time: 48 h
Toxicity to algae	: IC50 (Pseudokirchneriella subcapitata (green algae)): 150 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
	EC50 (Chlorella vulgaris (Fresh water algae)): 370 mg/l Exposure time: 96 h
Toxicity to bacteria	: (Pseudomonas putida): 64 mg/l
Ecotoxicology Assessment	
Acute aquatic toxicity	: This product has no known ecotoxicological effects.
Chronic aquatic toxicity	: This product has no known ecotoxicological effects.
Toxicity Data on Soil	: Not expected to adsorb on soil.
Other organisms relevant to the environment	: No data available

12.2 Persistence and degradability

R1 (A / B / C)

Components:

Dodecyl alcohol, ethoxylated:

Biodegradability	: Biodegradation: > 99 % Exposure time: 672 h Method: OECD Test Guideline 302
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phenol:

Biodegradability	: Biodegradation: 96 % Exposure time: 28 d Method: OECD Test Guideline 302 Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.
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Biochemical Oxygen Demand (BOD)	: 1.680 mg/g Incubation time: 5 d
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Chemical Oxygen Demand (COD)	: 2.300 mg/g
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Impact on Sewage Treatment	: Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).
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12.3 Bioaccumulative potential

R1 (A / B / C)

Components:

phenol:

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Partition coefficient: n-
octanol/water : log Pow: 1,46

12.4 Mobility in soil

R1 (A / B / C)

No data available

12.5 Results of PBT and vPvB assessment

R1 (A / B / C)

Not relevant

12.6 Other adverse effects

R1 (A / B / C)

Components:

Dodecyl alcohol, ethoxylated:

Additional ecological infor-
mation

: Remarks: Very toxic to aquatic life.
An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

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14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remarks : Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water contaminating class (Germany) : WGK 1 slightly water endangering

R1 (A / B / C)

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
Response:
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.

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The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

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15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of R-Phrases

- R22 : Harmful if swallowed.
- R23/24/25 : Toxic by inhalation, in contact with skin and if swallowed.
- R34 : Causes burns.
- R41 : Risk of serious damage to eyes.
- R48/20/21/22 : Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
- R68 : Possible risk of irreversible effects.

Full text of H-Statements

- H301 : Toxic if swallowed.
- H302 : Harmful if swallowed.
- H311 : Toxic in contact with skin.
- H314 : Causes severe skin burns and eye damage.
- H315 : Causes skin irritation.
- H318 : Causes serious eye damage.
- H331 : Toxic if inhaled.
- H341 : Suspected of causing genetic defects.
- H373 : May cause damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

- Acute Tox. : Acute toxicity
- Eye Dam. : Serious eye damage
- Muta. : Germ cell mutagenicity
- Skin Corr. : Skin corrosion
- Skin Irrit. : Skin irritation
- STOT RE : Specific target organ toxicity - repeated exposure

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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