

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

LDL-C Gen.3, 200Tests, cobas c,Int

Version
1.6

Revision Date:
24.02.2015

Date of last issue: 11.08.2014
Date of first issue: 19.04.2013

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

1.1 Product identifier

Commercial Product Name : LDL-C Gen.3, 200Tests, cobas c,Int
Mat.-No./ Genisys-No. : 07005717190

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 : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear protective gloves.
Response:

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P333 + P313

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

P362 + P364

Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1 (B)

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

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

Sensitising

R43: May cause sensitisation by skin contact.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	T; R23/24/25 C; R34 R43 N; R50-R53	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Corr. 1B; H314 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	$\geq 0,0015$ - $< 0,06$

For explanation of abbreviations see section 16.

R2 (C)

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

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SECTION 4: First aid measures

4.1 Description of first aid measures

- | | |
|-------------------------|---|
| General advice | : Move out of dangerous area.
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 on skin, rinse well with water. |
| In case of eye contact | : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist. |
| If swallowed | : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician. |

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 | : No information available. |
|---------------------------------------|-----------------------------|

5.3 Advice for firefighters

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

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Further information : The product itself does not burn.

Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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.
If the product contaminates rivers and lakes or drains inform respective authorities.

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 exposure - obtain special instructions before use.
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.
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

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

Hygiene measures : 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.

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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.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

R1 (B)

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	AGW (inhalable fraction)	0,2 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(I)			
Further information	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

R2 (C)

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

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

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us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time 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.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1 (B)

Appearance : liquid

Colour : No data available

Odour : No information available.

Odour Threshold : No data available

pH : 7,0

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) : No data available

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

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Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : No data available

R2 (C)

Appearance : liquid
Colour : No data available
Odour : No information available.
Odour Threshold : No data available
pH : 7,0
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) : No data available
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 : No data available

9.2 Other information

R1 (B)

No data available

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R2 (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 (B)

Acute toxicity

Not classified based on available information.

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):

Acute oral toxicity : LD50 Oral (Rat): 53 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 3 mg/l
Test atmosphere: vapour
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: 300 mg/kg
Method: Expert judgement

Skin corrosion/irritation

Not classified based on available information.

Components:

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mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):

Result: Causes burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: Not classified based on available information.

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):

Assessment: May cause sensitisation by skin contact.

Assessment:

Toxic if swallowed, in contact with skin or if inhaled
May cause an allergic skin reaction.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

R2 (C)

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

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Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

R1 (B)

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):

Toxicity to fish : LC50 (Fish): 0,36 mg/l
Exposure time: 96 h

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

R2 (C)

No data available

12.2 Persistence and degradability

R1 (B)

No data available

R2 (C)

No data available

12.3 Bioaccumulative potential

R1 (B)

No data available

R2 (C)

No data available

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12.4 Mobility in soil

R1 (B)

No data available

R2 (C)

No data available

12.5 Results of PBT and vPvB assessment

R1 (B)

Not relevant

R2 (C)

Not relevant

12.6 Other adverse effects

R1 (B)

Components:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1):

Additional ecological information

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

R2 (C)

No data available

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.

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

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14.3 Transport hazard class(es)

Not regulated as a dangerous good

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 : WGK 2 water endangering (Germany)

R1 (B)

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
Response:
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it

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Disposal:
P501

before reuse.

Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]
and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

R2 (C)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

R23/24/25 : Toxic by inhalation, in contact with skin and if swallowed.
R34 : Causes burns.
R43 : May cause sensitisation by skin contact.
R50 : Very toxic to aquatic organisms.
R53 : May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H301 : Toxic if swallowed.
H311 : Toxic in contact with skin.
H314 : Causes severe skin burns and eye damage.
H317 : May cause an allergic skin reaction.
H331 : Toxic if inhaled.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Acute aquatic toxicity
Aquatic Chronic : Chronic aquatic toxicity
Skin Corr. : Skin corrosion
Skin Sens. : Skin sensitisation

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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