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

1.1 Product identifier

Trade name: LDL-c direct FS Reagent R1
As part of the kits: 1 4131 XX XX XXX
(The positions X code different packages.)

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

General use: Reagent for in-vitro diagnostics in human samples
For professional use only

1.3 Details of the supplier of the safety data sheet

Company name: DiaSys Diagnostic Systems GmbH
Street/POB-No.: Alte Strasse 9
Postal Code, city: 65558 Holzheim
WWW: http://www.diasys.de
E-mail: mail@diasys.de
Telephone: +49 (0) 6432-9146-0
Telefax: +49 (0) 6432-9146-32

Department responsible for information:
Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: mail@diasys.de

1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Skin Sens. 1; H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling (CLP)

Signal word: **Warning**

Hazard statements:
H317 May cause an allergic skin reaction.

Precautionary statements:
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water/soap.

Special labelling

Text for labelling: Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1)

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution of inorganic salts and organic compounds.

Hazardous ingredients:

Ingredient	Designation	Content	Classification
list no. 611-341-5 CAS 55965-84-9	Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1)	0.0015 - 0.0025 %	Acute Tox. 3; H301. Acute Tox. 2; H310. Acute Tox. 2; H330. Skin Corr. 1C; H314. Eye Dam. 1; H318. Skin Sens. 1A; H317. Aquatic Acute 1; H400 (M-factor = 100). Aquatic Chronic 1; H410 (M-factor = 100). (EUH071).

Full text of H- and EUH-statements: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: If medical advice is needed, have product container or label at hand.

In case of inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if problems persist.

Following skin contact: After contact with skin, wash immediately with plenty of water. Take off contaminated clothing and wash it before reuse. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible.
Never give anything by mouth to an unconscious person. Immediately get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

Extinguishing media which must not be used for safety reasons:

Full water jet

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.
In the event of a fire, the following may be produced when the water evaporates: sulphur oxides, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information: Hazchem-Code: -

Move container away or cool with water from a protected position. Do not allow fire water to penetrate into surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe vapours. If possible, eliminate leakage. Keep unprotected people away. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Wear appropriate protective equipment.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Small quantities: Collect spilled material using cloth and/or paper towels. Place in suitable container for disposal.
Larger quantities: Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance.
Thoroughly clean surrounding area.

Additional information: Special danger of slipping by leaking/spilling product.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Wear appropriate protective equipment. Do not breathe vapours.
Take off contaminated clothing and wash it before reuse. Wash hands thoroughly after handling. When using do not eat or drink.
Keep all containers, equipment and working place clean. Have eye wash bottle or eye rinse ready at work place.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Do not freeze. Protect from sunlight. Keep sterile.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.
Do not store together with strong acids and alkalis.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: When aerosols and vapours form: Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber-Breakthrough time: > 480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid contact with skin and eyes.
Take off contaminated clothing and wash it before reuse.
Wash hands thoroughly after handling. When using do not eat or drink.
Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Physical state at 20 °C and 101.3 kPa: liquid
Colour: yellow, clear up to pink

Odour: no characteristic odour

Odour threshold: No data available

pH: at 25 °C: 6.65

Melting point/freezing point:	approx. 0 °C
Initial boiling point and boiling range:	approx. 100 °C
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 °C: 1.0061 g/mL
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available

9.2 Other information

Additional information: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Refer to subsection "Possilbility of hazardous reactions".

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Strong acids and alkalis

10.6 Hazardous decomposition products

No decomposition when used properly.

Thermal decomposition: No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.
Acute toxicity (oral): Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Skin Sens. 1; H317 = May cause an allergic skin reaction.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Information about Mixture of 5-chloro-2-methyl-2H-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1):
Very toxic to aquatic life with long lasting effects.
Daphnia toxicity: EC50 Daphnia: 0.16 mg/L/48 h.
Fish toxicity: LC50 trout: 0.19 - 0.28 mg/L/96 h.

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 05 06* = Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.
* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

Package

Waste key number: 15 01 02 = Plastic packaging.

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR:

not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:

not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

14.5 Environmental hazards

Marine pollutant: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

SECTION 15: Regulatory information

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

National regulations - Great Britain

Hazchem-Code: -

No data available

National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Further information

Wording of the H-phrases under paragraph 2 and 3:

H301 = Toxic if swallowed.
H310 = Fatal in contact with skin.
H314 = Causes severe skin burns and eye damage.
H317 = May cause an allergic skin reaction.
H318 = Causes serious eye damage.
H330 = Fatal if inhaled.
H400 = Very toxic to aquatic life.
H410 = Very toxic to aquatic life with long lasting effects.
EUH071 = Corrosive to the respiratory tract.

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
AS/NZS: Australian Standards/New Zealand Standards
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC50: Effective Concentration 50%
EC: European Community
EN: European Standard
EU: European Union
IATA: International Air Transport Association
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
LC50: Median lethal concentration
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
M-factor: Multiplication factor
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 2: Classification, labelling
Changes in section 3: Composition / information on ingredients (CAS No. 55965-84-9)
Changes in section 15: Regulatory information
General revision

Date of first version: 6/3/2020

Department issuing data sheet

Contact person: see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.