

## 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.)

UFI: TE20-C036-X00F-CPDU

### 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: DE-65558 Holzheim

WWW: <http://www.diasys.de>

E-mail: [mail@diasys.de](mailto: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](mailto: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.

Endocrine disrupting properties, 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:

Identifiers	Designation Classification	Content
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)  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. Aquatic Chronic 1; H410. (EUH071). Specific concentration limits (SCL): Skin Corr. 1C; H314: $C \geq 0,6 \%$ / Skin Irrit. 2; H315: $0,06 \% \leq C < 0,6 \%$ / Eye Dam. 1; H318: $C \geq 0,6 \%$ / Eye Irrit. 2; H319: $0,06 \leq C < 0,6 \%$ Skin Sens. 1A; H317: $C \geq 0,0015 \%$ M-factors: Aquatic Acute 1: M = 100. Aquatic Chronic 1: M = 100.	0,0015 - 0,0025 %

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:

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, siliceous 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.

Storage class:

12 = Non-combustible liquids

### 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

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
Melting point/freezing point:	approx. 0 °C
Initial boiling point and boiling range:	approx. 100 °C
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	not combustible
Decomposition temperature:	No data available
pH:	at 25 °C: 6,70
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 1,0061 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

### 9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available
Additional information:	No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Refer to subsection "Possibility 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 hazard classes as defined in Regulation (EC) No 1272/2008

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.

## 11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information:

No data available

# 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.

Water Hazard Class:

1 = slightly hazardous to water

**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 Endocrine disrupting properties**

No data available

**12.7 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 or ID 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**Dangerous for the environment: Substance/mixture is not environmentally hazardous  
according to the criteria of the UN model regulations.

Marine pollutant: no

**14.6 Special precautions for user**

No dangerous good in sense of these transport regulations.

### 14.7 Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

#### National regulations - Germany

Storage class: 12 = Non-combustible liquids

Water Hazard Class: 1 = slightly hazardous to water

Information on working limitations:

Observe employment restrictions for young people.

Further regulations, limitations and legal requirements:

The product is not subject to the Chemicals Prohibition Ordinance (ChemVerbotsV).

#### 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

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.

Reason of change: General revision

Date of first version: 6.3.2020

Department issuing data sheet: see section 1: Department responsible for information

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2020/878

## LDL-c direct FS Reagent R1

Material number 1 4131 R1

Revision date: 20.12.2022

Version: 3.1

Replaces version: 3.0

Language: en-DE

Date of print: 11.1.2023

Page: 8 of 8

Abbreviations and acronyms:

- Acute Tox.: Acute toxicity
- 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
- Aquatic Acute: Hazardous to the aquatic environment - acute
- Aquatic Chronic: Hazardous to the aquatic environment - chronic
- 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
- EC: European Community
- EC50: Effective Concentration 50%
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Eye Dam.: Eye damage
- IATA: International Air Transport Association
- IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
- 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
- Skin Corr.: Skin corrosion
- Skin Sens.: Skin sensitisation
- TRGS: Technical Rules for Hazardous Substances
- vPvB: Very persistent and very bioaccumulative

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.