

HDL-c direct FS Reagent R1

Material number 1 3561 R1

Page: 1 of 8

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

1.1 Product identifier

Trade name: HDL-c direct FS Reagent R1
As part of the kits: 1 3561 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-chloro-2-methyl-2H-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

HDL-c direct FS Reagent R1

Material number 1 3561 R1

Page: 2 of 8

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

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 611-341-5 CAS 55965-84-9	Mixture of 5-chloro-2-methyl-2H- isothiazolin-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	< 0.0025 %	Acute Tox. 3; H301. Acute Tox. 3; H311. Acute Tox. 3; H331. Skin Corr. 1B; H314. Skin Sens. 1; H317. Aquatic Acute 1; H400. Aquatic Chronic 1; H410.

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: Take off contaminated clothing and wash it before reuse. After contact with skin, wash immediately with plenty of water. 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: Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Seek 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.

HDL-c direct FS Reagent R1

Material number 1 3561 R1

Page: 3 of 8

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 (NO_x), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information: Hazchem-Code: -

Do not allow water used to extinguish fire to enter drains, ground or waterways.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide fresh air. Do not breathe vapours. Avoid contact with skin and eyes. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

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. Final cleaning.

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. Have eye wash bottle or eye rinse ready at work place. Take off contaminated clothing and wash it before reuse. When using do not eat or drink. Wash hands before breaks and after work. Keep all containers, equipment and working place clean.

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. Protect from direct sunlight. Keep sterile.

Hints on joint storage: 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: If vapours form, use respiratory protection.
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:
Do not breathe vapours. Take off contaminated clothing and wash it before reuse. Avoid contact with skin and eyes. Wash hands before breaks and after work. When using do not eat or drink.
Have eye wash bottle or eye rinse ready at work place.

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: clear, colourless up to slightly rose
- Odour: no characteristic odour
- Odour threshold: No data available
- pH value: at 25 °C: approx. 6.85
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- 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: 1.0057 g/mL
- Water solubility: at 20 °C: 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



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830

Revision date: 8/8/2019
Version: 1
Language: en-GB,IE
Date of print: 11/9/2019

HDL-c direct FS Reagent R1

Material number 1 3561 R1

Page: 5 of 8

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 10.3

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

Further details: No data available

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.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830

Revision date: 8/8/2019
Version: 1
Language: en-GB,IE
Date of print: 11/9/2019

HDL-c direct FS Reagent R1

Material number 1 3561 R1

Page: 7 of 8

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.

Contaminated packaging

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



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830

Revision date: 8/8/2019
Version: 1
Language: en-GB,IE
Date of print: 11/9/2019

HDL-c direct FS Reagent R1

Material number 1 3561 R1

Page: 8 of 8

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.

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.

Date of first version: 8/8/2019

Department issuing data sheet

Contact person: see section 1: Department responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

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.