

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.)

UFI: G820-A0QE-A00G-107Q

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

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.

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

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:	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.

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:

Wear self-contained breathing apparatus.

Additional information:

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

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. Keep away from food, drink and animal feedingstuffs.

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:

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.

Environmental exposure controls

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

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: clear, colourless up to slightly pink

Odour: no characteristic odour

Odour threshold: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

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: approx. 6,90

Viscosity, kinematic: No data available

Water solubility: at 20 °C: completely miscible

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

Vapour pressure: No data available

Density: at 20 °C: 1,0057 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, ADN, IMDG, IATA-DGR:
not applicable**14.2 UN proper shipping name**ADR/RID, ADN, IMDG, IATA-DGR:
Not restricted**14.3 Transport hazard class(es)**ADR/RID, ADN, IMDG, IATA-DGR:
not applicable**14.4 Packing group**ADR/RID, ADN, 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 - IMDG: 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: 8.8.2019

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

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



SAFETY DATA SHEET

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

HDL-c direct FS Reagent R1

Material number 1 3561 R1

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Replaces version: 3.0

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