

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

### 1.1 Product identifier

Trade name: HDL-C Immuno FS Reagent R1  
As part of the kits: 1 3521 XX XX XXX  
(The positions X code different packages.)

UFI: VH30-X02C-W00W-X3YP

### 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.  
Aquatic Chronic 3; H412 Harmful to aquatic life with long lasting effects.

### 2.2 Label elements

#### Labelling (CLP)



Signal word:

**Warning**

Hazard statements:

H317 May cause an allergic skin reaction.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection.  
P302+P352 IF ON SKIN: Wash with plenty of water/soap.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

#### 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

No risks worthy of mention.

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 - 0,025 %

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:	Move victim to fresh air. In case of respiratory difficulties seek medical attention. If victim is at risk of losing consciousness, position and transport on their side.
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. In case of troubles or persistent symptoms, 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.

### 5.2 Special hazards arising from the substance or mixture

In the event of a fire, the following may be produced when the water evaporates: in traces hydrogen chloride, sulphur oxides, nitrogen oxides (NO<sub>x</sub>), 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:

Contaminated fire-fighting water must be collected separately. 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

Avoid contact with skin and eyes. Wear suitable protective clothing.  
Do not breathe vapour/aerosol. Provide adequate ventilation. Keep unprotected people away.  
Take off contaminated clothing and wash it before reuse.

### 6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.  
In case of release, notify competent authorities.

### 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. Thoroughly clean surrounding area.

### 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.  
Avoid the formation of aerosol.  
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 against heat /sun rays. Protect from frost. 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:	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: Butyl caoutchouc (butyl 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. Do not eat, drink or smoke when using this product. 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 to yellowish
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 20 °C: 7,0
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: 1,0018 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 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 against heat /sun rays.

### 10.5 Incompatible materials

Strong acids

### 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

### Symptoms

After eye contact: weak irritant

## SECTION 12: Ecological information

### 12.1 Toxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.

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.



# SAFETY DATA SHEET

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

## HDL-C Immuno FS Reagent R1

Material number 1 3521 R1

Revision date: 20.12.2022

Version: 16.0

Replaces version: 15.0

Language: en-DE

Date of print: 11.1.2023

Page: 6 of 8

Water Hazard Class: 2 = obviously 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

ADN: ID 9006

### 14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR: Not restricted

ADN: ID 9006, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

### 14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR: not applicable

ADN: Class 9, Code: M12

### 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

#### Inland waterway craft (ADN)

Hazard label: -  
Transport permitted: T  
Equipment necessary: PP

### 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: 2 = obviously hazardous to water

Technical guidance air: 5.2.5

Information on working limitations:  
Observe employment restrictions for young people.

Further regulations, limitations and legal requirements:  
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

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.  
H412 = Harmful to aquatic life with long lasting effects.  
EUH071 = Corrosive to the respiratory tract.

Reason of change: Changes in section 1: Product Identification  
General revision

Date of first version: 25.7.2008

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

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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.