

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

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

### **1.1 Product identifier**

Trade name:

HDL-C Immuno FS Reagent R2

As part of the kits: 1 3521 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)

This mixture is classified as not hazardous.

#### 2.2 Label elements

#### Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

#### 2.3 Other hazards

Hazardous properties cannot be excluded. No dangers expected for the user if used according to directions.

Results of PBT and vPvB assessment:

No data available



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## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances: not applicable

#### 3.2 Mixtures

Chemical characterisation: Aqueous solution, enzymes

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Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable EU-legislation.

## **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

In case of inhalation:	Provide fresh air.
Following skin contact:	Change contaminated clothing. Remove residues with water.
After eye contact:	With eyelids open, wash out eyes for several minutes under flowing water.
After swallowing:	Rinse mouth and drink large quantities of water. Induce vomiting. Seek medical attention.

#### 4.2 Most important symptoms and effects, both acute and delayed

No data available

#### 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

Fires in the immediate vicinity may cause the development of dangerous vapours.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters:

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

Additional information: Hazchem-Code: -

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.

#### 6.2 Environmental precautions

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



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6.3 Methods and material for containment and cleaning up

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. Wash spill area with plenty of water.

### 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.

## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between + 2  $^{\circ}$ C and + 8  $^{\circ}$ C. Protect from light. Protect from frost. Keep sterile.

## 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 adequate ventilation, and local exhaust as needed.

## Personal protection equipment

### **Occupational exposure controls**

Respiratory protection:	Provide adequate ventilation.	
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:	Lab coat	
General protection and hygiene measures:		
	Change contaminated clothing. Wash hands before breaks and after work.	

## **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: yellowish, clear



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Odour: Odour threshold:	no characteristic odour No data available
pH:	at 25 °C: 7.0
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: 1.0024 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**

No data available

#### 10.2 Chemical stability

Stable under recommended storage conditions.

#### **10.3 Possibility of hazardous reactions**

No hazardous reaction when handled and stored according to provisions.

#### **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



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## **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

Toxicological effects:	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: Lack of data.
	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.
Other information:	Hazardous properties cannot be excluded. No dangers expected for the user if used according to directions.

## **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 undiluted resp. in large quantities into surface water or into drains.



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## **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.
Dookogo	

#### Package

Waste key number:	15 01 02 = Plastic packaging	
	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



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### National regulations - EC member states

Further regulations, limitations and legal requirements:

DiaS

No data available

## 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

## **SECTION 16: Other information**

### **Further information**

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

EC: European Community

EN: European Standard

EQ: Excepted quantities

EU: European Union

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

MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships

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 TRGS: Technical Rules for Hazardous Substances vPvB: Very persistent and very bioaccumulative

Reason of change: General revision Date of first version: 28/7/2008

#### 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.