

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

Revision date:	27/6/2018
Version:	14
Language:	en-GB,IE
Date of print:	6/9/2022

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

1.1 Product identifier

Trade name:

Lipase DC FS Reagent R1

As part of the kits: 1 4321 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

No risks worthy of mention.

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. Contains surfactants.

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable EU-legislation. Contains Sodium azide (0.95 g/L) as preservative.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

- Following skin contact: Change contaminated clothing. Remove residues with water. In case of skin irritation, 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 opthalmologist.
- After swallowing: Rinse mouth thoroughly with water. Induce vomiting. Have victim drink large quantities of water, with active charcoal if possible. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact: Mild irritant

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. In case of fire may be liberated: Nitrogen oxides (NOx), sulphur oxides, 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 fire water to penetrate into surface or ground water.



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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes, and clothing. Wear suitable protective clothing. In enclosed areas: Provide fresh air.

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, 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. Wear appropriate protective equipment. 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. Do not freeze. Keep sterile.

Hints on joint storage: Do not store together with: acids, 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.



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Eye protection: Body protection: Tightly sealed goggles according to EN 166. Wear suitable protective clothing.

General protection and hygiene measures:

Avoid contact with skin, eyes, and clothing. Change contaminated clothing. Do not breathe vapours. Wear appropriate protective equipment. 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: colourless, clear
Odour:	no characteristic odour
Odour threshold:	No data available
pH:	at 25 °C: 8.0
Melting point/freezing point:	approx. 0 °C
Initial boiling point and boiling range:	approx. 100 °C
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: 1.007 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	

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.



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10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Acids, 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:	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:	Contains Sodium azide (0.95 g/L): After resorption: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.
0	

Symptoms

After eye contact: Mild irritant

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

12.2 Persistence and degradability

Further details: No data available



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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.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Troduct		
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

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

no

Marine pollutant:



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14.6 Special precautions for user

DiaS

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

National regulations - EC member states

Further regulations, limitations and legal requirements: No data available

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.



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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 **CNS: Central Nervous System** 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:
 6/8/2007

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.