

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

Revision date: 13/2/2018
Version: 7
Language: en-GB,IE
Date of print: 12/3/2021

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

1.1 Product identifier

Trade name: Lp(a) 21 FS Reagent R1

as part of the kits: 1 7139 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

Additional information: Preparation does not contain dangerous substances above limits that need to be

mentioned in this section according to applicable EU-legislation.

Contains Sodium azide (< 0,1%) as preservative.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air.

Following skin contact: After contact with skin, wash immediately with plenty of water.

Change contaminated clothing. 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. 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. Seek medical

attention.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

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: -

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear suitable protective clothing. Avoid contact with skin and eyes.



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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. Thoroughly clean the contaminated area with 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.

After worktime and during work intervals the affected skin areas must be thoroughly

cleaned.

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. Do not freeze. 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. When using do not eat or drink.

Wash hands before breaks and after work.

Have eye wash bottle or eye rinse ready at work place.



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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Form: liquid

Colour: colourless, clear up to opalescent

Odour: odourless

Odour threshold: No data available

at 25 °C: ca. 8.3 No data available Melting point/freezing point: 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: No data available Water solubility: completely miscible Partition coefficient: n-octanol/water: No data available Auto-ignition temperature: No data available Decomposition temperature: No data available No data available Viscosity, kinematic: 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 and alkalis



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10.6 Hazardous decomposition products

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

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. May cause irritations.

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. Information about Sodium azide:

LD50 Rat, oral: 27 mg/kg. Very toxic if swallowed.

After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure,

unconsciousness, collapse.

Symptoms

Other information:

After eye contact: May cause irritations.

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



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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

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

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

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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

15.2 Chemical Safety Assessment

For this substance 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

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
EU: European Union

IATA: International Air Transport Association

IBC Code: International Code for the Construction and Equipment of Ships carrying

Dangerous Chemicals in Bulk

IMDG Code: International Maritime Dangerous Goods Code

LD50: Lethal dose 50%

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

vPvB: Very persistent and very bioaccumulative

CNS: Central Nervous System

Reason of change: Changes in section 2.3, 7, 11: General revision

Date of first version: 16/10/2008

Department issuing data sheet

Contact person: see section 1: Department responsible for information



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