

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

1.1 Product identifier

Trade name: Lp-PLA2 FS Reagent R3

As part of the kits: 1 7181 XX XX XXX
(The positions X code different packages.)

UFI: 3630-W09S-P00W-9RNE

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)

Acute Tox. 4; H302 Harmful if swallowed.

STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (CLP)



Signal word:

Warning

Hazard statements:

H302

Harmful if swallowed.

H373

May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P260

Do not breathe mist/vapours/spray.

P264

Wash hands and face thoroughly after handling.

P314

Get medical advice/attention if you feel unwell.

Special labelling

Text for labelling:

Contains Diethylene glycol

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: Mixture of the substance mentioned below with non-hazardous additions:

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 203-872-2 CAS 111-46-6	Diethylene glycol Acute Tox. 4; H302. STOT RE 2; H373.	< 95 %

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: Provide fresh air. If victim is at risk of losing consciousness, position and transport on their side. Seek medical treatment in case of troubles.

Following skin contact: Take off contaminated clothing and wash it before reuse. Remove residues with water. Seek medical treatment in case of troubles.

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. Provide fresh air. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

May cause damage to organs through prolonged or repeated exposure. Harmful if swallowed.

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: Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide.

Extinguishing media which must not be used for safety reasons:

Full water jet

5.2 Special hazards arising from the substance or mixture

Combustible. Vapours can form explosive mixtures with air.

In case of fire may be liberated: carbon monoxide and carbon dioxide

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information:

Cool endangered containers with water spray and, if possible, remove from danger zone. 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

Provide adequate ventilation. Wear appropriate protective equipment. Keep unprotected people away. Avoid contact with skin and eyes. Do not breathe mist/vapours/spray. Take off contaminated clothing and wash it before reuse.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Plug leak if safely possible. 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.

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. Do not breathe mist/vapours/spray. Wear appropriate protective equipment. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse.

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

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

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 heat and direct sunlight.

Do not freeze. Protect from light. Keep sterile. Protect from moisture contamination.

Hints on joint storage:

Do not store with strong oxidizing agents.

Keep away from food, drink and animal feedingstuffs.

Storage class:

10 = Combustible liquids, unless storage class 3

7.3 Specific end use(s)

Reagent for in-vitro diagnostics in human samples

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
111-46-6	Diethylene glycol	Germany: TRGS 900 Kurzzeit	176 mg/m ³ ; 40 ppm (Aerosol and vapour)
		Germany: TRGS 900 Langzeit	44 mg/m ³ ; 10 ppm (Aerosol and vapour)

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 filter type A (= against vapours of organic substances) according to EN 14387.
Hand protection:	Protective gloves according to EN 374. Glove material: nitrile rubber-Layer thickness: 0,3 mm 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:	Use only non-sparking tools. Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Do not breathe vapour/aerosol. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

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:	like alcohol
Odour threshold:	No data available
Melting point/freezing point:	approx. -6,5 °C (Diethylene glycol)
Initial boiling point and boiling range:	approx. 245 °C (Diethylene glycol)
Flammability:	No data available
Upper/lower flammability or explosive limits:	LEL (Lower Explosion Limit): approx. 0,70 Vol-% (Diethylene glycol) UEL (Upper Explosive Limit): approx. 22,00 Vol-% (Diethylene glycol)
Flash point/flash point range:	approx. 138 °C (Diethylene glycol)
Decomposition temperature:	No data available
pH:	at 20 °C, 200 g/L: 7
Viscosity, kinematic:	No data available
Water solubility:	at 20 °C: completely miscible
Partition coefficient: n-octanol/water:	at 25 °C: -1,98 log P(o/w) (Diethylene glycol) Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.
Vapour pressure:	at 25 °C: 0,008 hPa (Diethylene glycol)
Density:	at 20 °C: 1,12 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	Product is not explosive. Vapours can form explosive mixtures with air.
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

In case of warming: On contact with air, potentially explosive mixtures may develop.

Hygroscopic

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidizing agents.

10.4 Conditions to avoid

Protect from frost, heat and sunlight. Protect from moisture contamination.

10.5 Incompatible materials

Strong oxidizing agents

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): Acute Tox. 4; H302 = Harmful if swallowed.

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): STOT RE 2; H373 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Information about Diethylene glycol:
LD50 human, oral: 1.120 mg/kg bw
LD50 Rat, oral: 16.500 mg/kg bw
LD50 Rabbit, dermal: 13.300 mg/kg bw/24h
LC50 Rat, inhalative: > 4,6 mg/L/4h

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Information about Diethylene glycol:
Daphnia toxicity:
EC50 Daphnia magna (Big water flea): >10.000 mg/L/48h
Fish toxicity:
LC50 Pimephales promelas (fathead minnow): 75.200 mg/L/96h
Water Hazard Class: 3 = highly hazardous to water

12.2 Persistence and degradability

Further details: Information about Diethylene glycol:
Biodegradability: 91,8 %/28 d. Readily biodegradable.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
at 25 °C: -1,98 log P(o/w) (Diethylene glycol)
Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

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: 10 = Combustible liquids, unless storage class 3

Water Hazard Class: 3 = highly hazardous to water

Technical guidance air: 5.2.5

Information on working limitations:

Observe employment restrictions for young people.

Observe employment restrictions for expectant or nursing mothers.

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:

H302 = Harmful if swallowed.

H373 = May cause damage to organs through prolonged or repeated exposure.

Reason of change: General revision

Date of first version: 16.11.2011

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

Lp-PLA2 FS Reagent R3

Material number 1 7181 R3

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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
- 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
- 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
- LD50: Lethal dose 50%
- LEL: Lower Explosion Limit
- log P(o/w): Partition coefficient: octanol/water
- 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
- STOT RE: Specific target organ toxicity - repeated exposure
- 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.