

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.)

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)

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

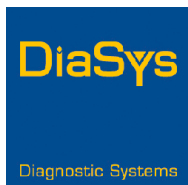
Labelling (CLP)



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.



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

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Special labelling

Text for labelling: Contains Diethylene glycol

2.3 Other hazards

No risks worthy of mention.

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:

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

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.

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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:

Hazchem-Code: -

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:

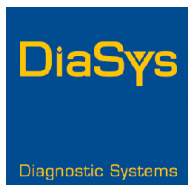
Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

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.



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Hints on joint storage: Do not store with strong oxidizing agents.
Keep away from food, drink and animal feedingstuffs.

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	Great Britain: WEL-TWA Ireland: 8 hours	101 mg/m ³ ; 23 ppm 100 mg/m ³ ; 23 ppm

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded.
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

Appearance: Physical state at 20 °C and 101.3 kPa: liquid
Colour: clear, colourless to yellowish

Odour: like alcohol

Odour threshold: No data available

pH: at 20 °C, 200 g/L: 7

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Melting point/freezing point:	approx. -6.5 °C (Diethylene glycol)
Initial boiling point and boiling range:	approx. 245 °C (Diethylene glycol)
Flash point/flash point range:	approx. 138 °C (Diethylene glycol)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): approx. 0.70 Vol-% (Diethylene glycol) UEL (Upper Explosive Limit): approx. 22.00 Vol-% (Diethylene glycol)
Vapour pressure:	at 25 °C: 0.008 hPa (Diethylene glycol)
Vapour density:	No data available
Density:	at 20 °C: 1.12 g/mL
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.
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	Product is not explosive. Vapours can form explosive mixtures with air.
Oxidizing characteristics:	No data available

9.2 Other information

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 toxicological effects

Toxicological effects:	<p>The statements are derived from the properties of the single components. No toxicological data is available for the product as such.</p> <p>Acute toxicity (oral): Acute Tox. 4; H302 = Harmful if swallowed.</p> <p>Acute toxicity (dermal): Lack of data.</p> <p>Acute toxicity (inhalative): Lack of data.</p> <p>Skin corrosion/irritation: Lack of data.</p> <p>Serious eye damage/irritation: Lack of data.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Lack of data.</p> <p>Germ cell mutagenicity/Genotoxicity: Lack of data.</p> <p>Carcinogenicity: Lack of data.</p> <p>Reproductive toxicity: Lack of data.</p> <p>Effects on or via lactation: Lack of data.</p> <p>Specific target organ toxicity (single exposure): Lack of data.</p> <p>Specific target organ toxicity (repeated exposure): STOT RE 2; H373 = May cause damage to organs through prolonged or repeated exposure.</p> <p>Aspiration hazard: Lack of data.</p>
Other information:	<p>Information about Diethylene glycol:</p> <p>LD50 human, oral: 1,120 mg/kg bw</p> <p>LD50 Rat, oral: 16,500 mg/kg bw</p> <p>LD50 Rabbit, dermal: 13,300 mg/kg bw/24h</p> <p>LC50 Rat, inhalative: > 4.6 mg/L/4h</p>

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:	<p>Information about Diethylene glycol:</p> <p>Daphnia toxicity:</p> <p>EC50 Daphnia magna (Big water flea): >10,000 mg/L/48h</p> <p>Fish toxicity:</p> <p>LC50 Pimephales promelas (fathead minnow): 75,200 mg/L/96h</p>
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12.2 Persistence and degradability

Further details:	<p>Information about Diethylene glycol:</p> <p>Biodegradability: 91.8 %/28 d. Readily biodegradable.</p>
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12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:	<p>at 25 °C: -1.98 log P(o/w) (Diethylene glycol)</p> <p>Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.</p>
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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

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:
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

Further 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.

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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
OEL: Occupational Exposure Limit Value
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
EC50: Effective Concentration 50%
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
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
TLV: Threshold Limit Value
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Reason of change: Changes in section 2: classification, labelling
Changes in section 3: Composition / information on ingredients
Changes in section 15: Regulatory information
General revision
Date of first version: 16/11/2011

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.

