

EU SAFETY DATA SHEET

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

Lipase R2 - Material number: 01 00032

1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Name of product: Lipase Reagent R2
as part of the kits: 01 00032 XX XX XXXX
(The positions X code different packages.)

1.2 Relevant identified uses of the substance or mixture and uses advised against

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: DiaSystem Scandinavia AB
Street/POB-No.: Datorgatan 3
State/city/postal code: 561 33 Jönköping
Sweden
World Wide Web: <http://www.diasystem.se>
Email: info@diasystem.se
Telephone: +46 (0) 36 12 62 20
Telefax: +46 (0) 36 18 77 30
Dept. responsible for information:
DiaSystem, Telephone: +46 (0)36 126220

1.4 Emergency telephone number

Giftinformationscentralen, Telephone +46 112

2. Hazards identification**2.1 Classification of the substance or mixture****Classification according to EC regulation 1272/2008 (CLP)**

Skin Irrit. 2; H315 Causes skin irritation.
Eye Dam. 1; H318 Causes serious eye damage. 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: H319 Causes serious eye irritation.
Precautionary statements: P280 Wear protective gloves/protective clothing/eye protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.
Special labelling: EUH208 Contains 2-Chloracetamide. May produce an allergic reaction.

2.3 Other hazards

Product can cause skin irritation because of the pH-value.
Results of PBT and vPvB assessment: No data available

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3. Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterization: Aqueous preparation with surfactants

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 200-746-9 CAS 71-23-8	Propan-1-ol	< 3 %	Flam. Liq. 2; H225. Eye Dam. 1; H318. STOT SE 3; H336.
EC No. 201-174-2 CAS 79-07-2	2-Chloracetamide 0.01	< 0.1<%	Acute Tox. 3; H301. Skin Sens. 1; H317. Repr. 2; H361f

Full text of H- and EUH-statements: see section 16:

Additional information: Contains polyethylene glycol. The maximum workplace exposure limits are, where necessary, listed in section 8.

4. First aid measures**4.1 Description of first aid measures**

General information: First aider: Pay attention to self-protection! If medical advice is needed, have product container or label at hand. Take off immediately all contaminated clothing and wash it before reuse.

In case of inhalation: Provide fresh air. If you feel unwell, seek medical advice.

Following skin contact: Immediately clean with water and soap followed by thorough rinsing. 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. 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. Never give anything by mouth to an unconscious person. Do not induce vomiting. Seek medical attention..

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation. May cause allergic reactions in already sensitized persons.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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: 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.

6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Avoid contact with skin and eyes. Do not breathe vapours. Wear appropriate protective equipment. In enclosed areas: Provide fresh air. If possible, eliminate leakage. Keep unprotected people away..

6.2 Environmental precautions

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

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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.

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 vapours. Wear appropriate protective equipment. Keep all containers, equipment and working place clean. Take off immediately all contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. When handling large quantities, supply emergency spray.

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 Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

No information available.

8. Exposure controls / Personal protection equipment**8.1 Control parameters**

Occupational exposure limit values:

Ingredient	Designation	Type	Limit value
71-23-8	Propan-1-ol	Great Britain: WEL-STEL	625 mg/m ³ ; 250 ppm (may be absorbed through the skin)
		Great Britain: WEL-TWA	500 mg/m ³ ; 200 ppm (may be absorbed through the skin)
		Ireland: 8 hours	100 ppm (may be absorbed through the skin)

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. Use a breathing protection against vapours/aerosol. 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.

Eye protection:

Tightly sealed goggles according to EN 166.

Body protection:

Lab coat

General protection and hygiene measures:

Do not breathe vapours. Avoid contact with skin and eyes. Take off immediately all contaminated clothing and wash it before reuse. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. When handling large quantities, supply emergency spray.

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:

Colour: slightly turbid, orange-red

Odour:

characteristic odour

Odour threshold:

No data available

pH value:

at 25 °C: 4.0

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

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Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 °C: 1.0238 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

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.

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

11. Toxicological information**11.1 Information on toxicological effects**

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): B Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Based on available data, the classification criteria are not met

Serious eye damage/irritation: Eye Irrit. 2; H319 = Causes serious eye irritation.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Based on available data, the classification criteria are not met. Contains 2-Chloracetamide.

May produce an allergic reaction

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. prolonged or repeated exposure.

Aspiration hazard: Lack of data.

Symptoms

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

12. Ecological information**12.1 Toxicity**

Further details: No data available

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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 into ground-water, surface water or drains

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. Waste disposal according to official state regulations.

Contaminated packaging

Waste key number 15 01 02 = Plastic packaging.

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.**14.1 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

15. Other 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.

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16. Other information

Further information

Wording of the H-phrases under paragraph 2 and 3:

- H225 = Highly flammable liquid and vapour.
- H301 = Toxic if swallowed.
- H317 = May cause an allergic skin reaction.
- H318 = Causes serious eye damage.
- H319 = Causes serious eye irritation.
- H336 = May cause drowsiness or dizziness.
- H361f = Suspected of damaging fertility.
- EUH208 = Contains 2-Chloracetamide. May produce an allergic reaction.

Reason of change:

General revision (Regulation (EU) No 2015/830)

Date of first version:

2011-07-01

Department issuing data sheet

Contact person:

see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations). 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.