

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

1.1 Product identifier

Trade name: Cholinesterase FS Reagent R1

As part of the kits: 1 1401 XX XX XXX
(The positions X code different packages.)

UFI: D110-801V-100J-S72T

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)

Eye Dam. 1; H318 Causes serious eye damage.

2.2 Label elements

Labelling (CLP)



Signal word: **Danger**

Hazard statements: H318 Causes serious eye damage.

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.

P310 Immediately call a POISON CENTER/doctor.

Special labelling

EUH208 Contains 2-Chloracetamide. May produce an allergic reaction.

Text for labelling: Contains Tetrasodium pyrophosphate-10-hydrate.

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

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: Aqueous solution of inorganic salts and organic compounds.

Hazardous ingredients:

Identifiers	Designation Classification	Content
REACH 01-2119489794-17-xxxx EC No. 231-767-1 CAS 13472-36-1	Tetrasodium pyrophosphate-10-hydrate Acute Tox. 4; H302. Eye Dam. 1; H318.	1 - 5 %
EC No. 201-174-2 CAS 79-07-2	2-Chloracetamide Acute Tox. 3; H301. Skin Sens. 1; H317. Repr. 2; H361f. Specific concentration limits (SCL): Skin Sens. 1; H317: C ≥ 0,1 %	0,01 - 0,1 %

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: Move victim to fresh air. If you feel unwell, seek medical advice.

Following skin contact: Immediately clean with water and soap followed by thorough rinsing. Take off contaminated clothing and wash it before reuse. 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. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye damage.

May cause allergic reactions in already sensitized persons.

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: Phosphorus oxides, sodium compounds, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information:

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

Avoid contact with skin and eyes. Wear appropriate protective equipment. Do not breathe vapours. If possible, eliminate leakage. Provide adequate ventilation. Take off contaminated clothing and wash it before reuse. Keep unprotected people away.

6.2 Environmental precautions

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

In case of release, notify competent authorities.

6.3 Methods and material for containment and cleaning up

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. Wash spill area with plenty of water.

Additional information:

Special danger of slipping by leaking/spilling product.

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. 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.

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 light.

Hints on joint storage:

Do not store together with strong acids or alkalis.

Keep away from food, drink and animal feedingstuffs.

Storage class:

12 = Non-combustible liquids

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 filter type ABEK 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:	Wear suitable protective clothing.
General protection and hygiene measures:	Avoid contact with skin and eyes. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

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

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:	yellow, clear
Odour:	no characteristic odour
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	not combustible
Decomposition temperature:	No data available
pH:	at 37 °C: approx. 7,6
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 1,024 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
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

refer to 10.3

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 from frost, heat and sunlight.

10.5 Incompatible materials

Strong acids and alkalis

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): Based on available data, the classification criteria are not met.

ATEmix (calculated): $2000 < ATE \leq 5000$ mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

ATEmix (calculated): $2000 < ATE \leq 5000$ mg/kg

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Eye Dam. 1; H318 = Causes serious eye damage.

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.

Aspiration hazard: Lack of data.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Other information: Information about Tetrasodium pyrophosphate-10-hydrate:

LD50 Rat, oral: approx. 1.624 mg/kg (OECD 401)

LD50 Rat, dermal: > 2.000 mg/kg (OECD 402)

Information about 2-Chloracetamide:

LD50 Rat, oral: 138 mg/kg (OECD 401)

LD50 Rat, dermal: > 2.000 mg/kg (OECD 402)

SECTION 12: Ecological information

12.1 Toxicity

Water Hazard Class: 1 = slightly hazardous to water

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 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information:

Contains phosphates: May contribute to the eutrophication of water supplies.
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: 12 = Non-combustible liquids

Water Hazard Class: 1 = slightly hazardous to water

Technical guidance air: 5.2.5

Information on working limitations:

Observe employment restrictions for young people.

Further regulations, limitations and legal requirements:

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

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

H301 = Toxic if swallowed.

H302 = Harmful if swallowed.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H361f = Suspected of damaging fertility.

EUH208 = Contains 2-Chloracetamide. May produce an allergic reaction.

Reason of change: General revision

Date of first version: 25.2.2008

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

Cholinesterase FS Reagent R1

Material number 1 1401 R1

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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
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- Eye Dam.: Eye damage
- 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
- LD50: Lethal dose 50%
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- OECD: Organisation for Economic Co-operation and Development
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- Repr.: Reproductive toxicity
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- Skin Sens.: Skin sensitisation
- 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.