

Section 1. Identification of the substance / mixture and of the company**1.1. Product identifier**GLDH Test Kit, VT 0200 and VT 0201

Reagent R1 - cuvette

Reagent R2 - capping

Substance name	Sodium acid
EC No.	not applicable
REACH Registration No.	not applicable ¹
CAS No.	26628-22-8

Substance name	Ammonium Acetate
EC No.	211-162-9
REACH Registration No.	not applicable ¹
CAS No.	631-61-8

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

In-vitro diagnostics; please refer to the product insert.

1.3. Supplier's details

Company name	Eurolyser Diagnostica GmbH
Address, P.O. Box	Bayernstraße 11a
Postcode / Place	5020 Salzburg
Country	Österreich
Telephone	+43 662 432100
Facsimile	+43 662 432100 50
E-Mail	sds@eurolyser.com

¹ No registration number is given for this substance since it is exempted from the registration requirements according to REACH Title II and also exempted from titles V and VI.

1.4. Emergency telephone number

Toxicological information-emergency centre +43 1 406 43 43
MO – SU, 0 – 24 h German and English

Section 2. Hazards Identification

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No. 1272/2008 (CLP)

Reagent 1 not classified as hazardous
Reagent 2 not classified as hazardous

2.1.2. Other hazards

Sodium acid

Classification	category	note
Acute toxicity (dermal)	Acute Tox. 4	H 312
Hazardous to aquatic environment (chronic aquatic toxicity)	Aquatic Chronic 3	H 412

For the full text of the H-statements mentioned in this Section, see Section 16.

2.2. Label elements

Reagent 1 has not to be labelled
Reagent 2 has not to be labelled
Hazard pictograms not applicable
Signal words not applicable
Hazard statement(s) in full not applicable
Precautionary statement(s) in full not applicable
Any additional hazardous information (EU) not applicable
Any additional applicable label elements not applicable

2.3. Other hazards

Product (Reagent 1) contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

No data available. This substance / mixture does not contain any components with a concentration of 0,1% or higher, which are not classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

Section 3. Composition / information on ingredients

3.1. Substance

Not applicable.

3.2. Mixture

Reagent 1 und Reagent 2

Aqueous solution of inorganic and organic substances with surfactants. One ingredient is classified as dangerous (Sodium acid).

Substance	Identifier	w. %	Classification in acc. with 1272/2008/EC
Sodium acid	CAS-Nr. 26628-22-8	< 0,1	Acute Tox. 2 H 300 Acute Tox. 1 H 310 STOT RE2 H 373 Aquatic Chronic 1 H 410

For the full text of the H-statements mentioned in this Section, see Section 16.

Section 4. First aid measures

4.1. Description of first aid measures

General notes

Dilutable with water. Remove contaminated clothing.

Following inhalation

Supply fresh air. If you feel unwell, consult a doctor. In case of unconscious place in recovery position.

Following skin contact

Rinse skin with soap and water. If symptoms persist, consult a doctor.

Following eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Following ingestion

Give water to drink. Seek medical advice immediately. Induce vomiting.

Self-protection of the first aider

No data available.

4.2. Most important symptoms and effects, both acute and delayed

Eye contact: causes serious eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

Section 5. Firefighting measures

5.1. extinguishing media

Suitable extinguishing media

Product is non-combustible. Extinguishing materials should therefore be selected according to surrounding.

Unsuitable extinguishing media

Not applicable.

5.2. special hazards arising from the substance or mixture

hazardous combustion products

Reagent 1: In the event of fire, the following may be produced when the water evaporates: Nitrogen oxides (NO_x).

Reagent 2: Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3. advice for firefighters

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

Preventive skin protection recommended. Use disposable gloves. Do not swallow.

6.1.1. For non-emergency personnel

No data available.

6.1.2. For emergency responders

No data available.

6.2. Environmental precautions

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations.

6.3. Methods and materials for containment and cleaning up

6.3.1. Appropriate containment

Cover drains. Collect, bind and pump off spills. Collect the material for disposal in tightly closed containers.

6.3.2. Clean-up procedures

Spillages should be washed with soap and water.

6.3.3. Other information

No further information.

6.4. Reference to other sections

Hazardous combustion products: Section 5

Personal protective equipment: Section 8

Incompatible materials: Section 10

Disposal considerations: Section 13

Section 7. Handling and storage

7.1. Precautions for safe handling

Ensure adequate ventilation. Avoid skin and eye contact. Use appropriate disposal gloves. Do not swallow. Wash hands before breaks and immediately after product handling. Keep away from food, beverages and animal feedstuff. In case of contamination remove contaminated clothing.

Additional information to reagent 1: product contains bovine material. Even though tests on infectious diseases ended negative, this product should be handled as potentially infectious biomaterial.

7.2. Conditions for safe storage, including any incompatibilities

Store according to temperature stated on the product label or according to the package insert provided. Avoid direct sunlight and temperature outside the recommended storage conditions.

7.3. Specific end use(s)

No data available.

Section 8. Exposure controls / personal protection

8.1. Control parameters

Country	Substance	CAS No.	OEL [mg/m ³]	reference
EU	Sodium acid	26628-22-8	0,29	ACGIH Report, 2008

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

8.2.2. Personal protective equipment

Avoid skin and eye contact. Wash hands before breaks and immediately after product handling. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the workplace.



8.2.2.1. Eye / face protection

Avoid skin and eye contact. No further measures need to be taken into account.

8.2.2.2. Skin protection

Use appropriate disposal gloves according to EN 374. It is recommended to check the chemical resistance of the protective gloves. Also pay attention to a proper method to strip off the gloves.

8.2.2.3. Respiratory protection

Not relevant.

8.2.2.4. Thermal hazards

Not relevant.

8.2.3. Environmental exposure controls

Avoid emissions into soil or water.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

	<u>Reagent 1</u>	<u>Reagent 2</u>
Appearance	colourless solution	yellowish solution
Physical state	Liquid	liquid
Odour	No specific odour	No specific odour
Odour threshold	No data available	No data available

Other physical and chemical parameters

pH-value	8,0 at 25 °C	9,6 at 25 °C
Melting point / freezing point	No data available	No data available
Initial boiling point / boiling range	No data available	No data available
Flash point	No data available	No data available
Evaporation rate	No data available	No data available
Flammability (solid, gas)	No data available	No data available

Flammability or explosive limits

Upper limit	No data available	No data available
Lower limit	No data available	No data available
Vapour pressure	No data available	No data available
Vapour density	No data available	No data available
Relative density	1,006 g/mL at 20 °C	1,001 g/mL at 20 °C

Solubility(ies)

Water solubility	soluble	soluble
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Partition coefficient

n-Octanol/water	No data available	No data available
Auto-ignition temperature	No data available	No data available
Decomposition temperature	No data available	No data available
Viscosity	No data available	No data available
Explosive properties	No data available	No data available
Oxidising properties	No data available	No data available

9.2. Other information

No data available.

Section 10. Stability and Reactivity

10.1. Reactivity

No hazardous reactions for the mixture and the contained substances in dissolved state were observed.

10.2. Chemical stability

Both reagents are stable under normal ambient conditions and at normal storage and handling conditions.

10.3. Possibility of hazardous reactions

Stable under normal temperature and pressure conditions.

10.4. Conditions to avoid**Reagent 1 and Reagent 2**

Avoid direct sunlight, vibration or high temperature.

10.5. Incompatible materials

Acids, alkalis.

10.6. Hazardous decomposition products

Reagent 1: In the event of fire, the following may be produced when the water evaporates: Nitrogen oxides (NO_x).

Reagent 2: Fires in the immediate vicinity may cause the development of dangerous vapours.

Section 11. Toxicological information

The mixture does not meet the criteria for classification according to Regulation (EC) No. 1272/2008.

11.1. Information on toxicological effects²

Reagent 1 (Sodium acid) and Reagent 2 (Sodium acid)

Sodium acid

Acute toxicity

- Method	LD50	LD50	LC50
- Species	Rat	Rapid	Rat
- Route of exposure	Oral	Dermal	Inhalation
- Effective Dose	45 mg/kg	20 mg/kg	37 mg/m ³
- Exposure time	n.a	n.a	n.a
- Results	n.a	n.a	n.a

Skin corrosion / irritation

May cause skin irritation.

Serious eye damage / irritation

May cause eye irritation.

Respiratory or skin sensitisation

May cause respiratory problems.

Germ cell mutagenicity

No data available.

Carcinogenicity

No data available.

² Acute toxicity is related to ingredient sodium acid and not to mixture.

Reproductive toxicity

No data available.

STOT – single exposure

No data available.

STOT – repeated exposure

No data available.

Aspiration hazard

Fatal if swallowed.

Section 12. Ecological information

12.1. Toxicity³

Reagent 1 (Sodium acid) und Reagent 2 (Sodium acid)

Sodium acid

Acute (short-term) toxicity

- Fish No data available
- Crustacea No data available
- Algae / aquatic plants ErC50 | 348 µg/L – 96h (Algae)
- Other organisms No data available

Chronic (long-term) toxicity

- Fish No data available
- Crustacea No data available
- Algae / aquatic plants Very toxic to aquatic organisms
- Other organisms No data available

³ Acute toxicity is related to ingredient sodium acid and not to mixture.

12.2. Persistence and degradability

Reagent 1 und Reagent 2

Abiotic degradation

No data available.

Physical- and photo-chemical elimination

No data available.

Biodegradation

No data available.

12.3. Bioaccumulative potential

Reagent 1 und Reagent 2

Partition coefficient n-Octanol / water (log K_{ow})

No data available.

Bioconcentration factor (BCF)

No data available.

12.4. Mobility in soil

Reagent 1 und Reagent 2

Known or predicted distribution to environmental compartments

No data available.

Surface tension

No data available.

Adsorption / Desorption

No data available.

12.5. Results of PBT- and vPvB assessment

No data available. This substance / mixture does not contain any components with a concentration of 0,1% or higher, which are not classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

12.6. Other adverse effects

Avoid emissions into soil or water.

12.7. Other information

No data available.

Section 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product and packaging disposal

Waste disposal must be in accordance with appropriate Federal and local regulations.

13.1.2. Waste treatment-relevant information

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations. Cover drains. Collect, bind and pump off spills.

13.1.3. Sewage disposal-relevant information

Avoid emissions into soil or water.

13.1.4. Other disposal recommendations

No data available.

Section 14. Transport information**14.1. UN number**

Transportation of the product is not regulated by ADR.

14.2. UN proper shipping name

Not relevant.

14.3. Transport hazard class(es)

Not relevant.

14.4. Packaging group

Not relevant.

14.5. Environmental hazards

No. (Not dangerous for the environment according to dangerous goods regulation).

14.6. Special precautions for user

No further information's available.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Cargo is not transported in bulk.

Section 15. Regulatory information

15.1. safety, health and environmental regulations / legislation specific for the substance or mixture

Reagent 1 und Reagent 2

Classification, labelling and packaging of substances and mixtures (CLP)

VO (EG) Nr. 1272/2008

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

VO (EG) Nr. 2015/830

Regulations of the insurance funds

Federal law on occupational health and safety

BGBI.Nr. 60/2015

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out for this substance / mixture by the supplier.

Section 16. Other information

Abbreviation

ADR	Accord européen relative au transport international des marchandises Dangereuses par Route
CLP	Classification, Labelling and Packaging
OEL	Occupational Exposure Limit
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
STOT RE	specific target organ toxicity – repeated exposure

Sodium acid

H 300	Fatal if swallowed
H 310	Fatal in contact with skin
H 312	Harmful in contact with skin
H 373	May cause damage to organs through prolonged or repeated exposure
H 400	Very toxic to aquatic life
H 410	Very toxic to aquatic life with long-lasting effects
H 412	Harmful to aquatic life with long-lasting effects

The information provided in this Safety Data Sheet is provided in the interest of promoting safe handling of the material. While this information is believed to be correct Eurolyser Diagnostica GmbH makes no warranty in respect to any of the information disclosed. Observe all federal, provincial, state and local laws concerning health and pollution.