

SAFETY DATA SHEET

## Protein L ligand leakage ELISA kit

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

#### 1.1. Product identifier

Trade name

Protein L ligand leakage ELISA kit

Product no.

10-0027, 10-0028

Document number

34-0009

Unique formula identifier (UFI)

GE70-J90G-U00E-XJDU

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

Relevant identified uses of the substance or mixture

Laboratory use

Restricted to professional and industrial use.

Uses advised against

None known.

#### 1.3. Details of the supplier of the safety data sheet

Company and address

**Medicago AB**

Danmarks-Berga 13

74176 Uppsala

Sweden

+46 18 56 11 80

www.medicagogroup.com

E-mail

qa@medicagogroup.com

▼ Revision

01/07/2026

▼ SDS Version

4.0

Date of previous version

2019-06-18 (Doc. 24-0017u04, old template, V4), 2023-05-25 (34-0009V01)

#### 1.4. Emergency telephone number

In urgent situations: Call 112 and request the poison information centre. (24h service)

In less severe situations: Call 010-456 6700 (24h service)

See also section 4 "First aid measures".

### SECTION 2: Hazards identification

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

#### 2.1. Classification of the substance or mixture

Repr. 1B; H360D, May damage the unborn child.

#### 2.2. ▼ Label elements

Hazard pictogram(s)



**Signal word**

Danger

**Hazard statement(s)**

May damage the unborn child. (H360D)

**Precautionary statement(s)**

**General**

Not applicable.

**Prevention**

Obtain special instructions before use. (P201)

Wear eye protection/protective gloves/protective clothing. (P280)

**Response**

IF exposed or concerned: Get medical advice/attention. (P308+P313)

**Storage**

Not applicable.

**Disposal**

Dispose of contents/container in accordance with local regulation.  
(P501)

**Hazardous substances**

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone  
sulphuric acid

**▼ Additional labelling**

Restricted to professional users.

UFI: GE70-J90G-U00E-XJDU

**2.3. Other hazards**

**Additional warnings**

This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.  
This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2023/707.

**SECTION 3: Composition/information on ingredients**

**3.1. Substances**

Not applicable. This product is a mixture.

**3.2. ▼ Mixtures**

| Product/substance                              | Identifiers                                                                                       | % w/w | Classification                                                                                              | Note     |
|------------------------------------------------|---------------------------------------------------------------------------------------------------|-------|-------------------------------------------------------------------------------------------------------------|----------|
| N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone | CAS No.: 872-50-4<br>EC No.: 212-828-1<br>REACH: 01-2119472430-46-XXXX<br>Index No.: 606-021-00-7 | 1-3%  | Skin Irrit. 2, H315<br>Eye Irrit. 2, H319<br>STOT SE 3, H335 (SCL: 10.00 %)<br>Repr. 1B, H360D              | [1], [5] |
| sulphuric acid                                 | CAS No.: 7664-93-9<br>EC No.: 231-639-5<br>REACH:<br>Index No.: 016-020-00-8                      | <1%   | Skin Corr. 1A, H314 (SCL: 15.00 %)<br>Skin Irrit. 2, H315 (SCL: 5.00 %)<br>Eye Irrit. 2, H319 (SCL: 5.00 %) | [1]      |

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

**Other information**

[1] European occupational exposure limit.

[3] According to REACH, Annex XVII, the substance is subject to restrictions.

[5] Substance is included in the Candidate List of substances of very high concern (SVHC).

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet.  
Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

#### Inhalation

Upon breathing difficulties or irritation of the respiratory tract: Bring the person into fresh air and stay with him/her.

#### Skin contact

Remove contaminated clothing and shoes immediately. Ensure to wash exposed skin thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.  
If skin irritation occurs: Get medical advice/attention.

#### Eye contact

If in eyes: Flush eyes with water or saline water (20-30 °C) for at least 5 minutes. Remove contact lenses. Seek medical assistance and continue flushing during transport.

#### Ingestion

If the person is conscious, rinse the mouth with water and stay with the person. Never give the person anything to drink.  
In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the person lean forward with head down to avoid inhalation of or choking on vomited material.

#### Burns

Not applicable.

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

None known.

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

IF exposed or concerned:

Get immediate medical advice/attention.

#### Information to medics

Bring this safety data sheet or the label from this product.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media: Alcohol-resistant foam, carbon dioxide, powder, water mist.

Unsuitable extinguishing media: Waterjets should not be used, since they can spread the fire.

### 5.2. Special hazards arising from the substance or mixture

Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

If the product is exposed to high temperatures, e.g. in the event of fire, dangerous decomposition compounds are produced. These are:

Halogenated compounds

Nitrogen oxides (NO<sub>x</sub>)

Carbon oxides (CO / CO<sub>2</sub>)

Some metal oxides

### 5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Upon direct exposure contact

The National Poisons Information Service (dial 112, 24 h service) in order to obtain further advice.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid direct contact with spilled substances.  
Ensure adequate ventilation, especially in confined areas.  
Contaminated areas may be slippery.

### 6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. In the event of leakage to the surroundings, contact local environmental authorities.

### 6.3. Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.  
Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

### 6.4. Reference to other sections

See section 13 "Disposal considerations" on handling of waste.  
See section 8 "Exposure controls/personal protection" for protective measures.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Avoid direct contact with the product.  
Avoid contact during pregnancy and while nursing.  
Smoking, drinking and consumption of food is not allowed in the work area.  
See section 8 "Exposure controls/personal protection" for information on personal protection.

### 7.2. Conditions for safe storage, including any incompatibilities

Store locked up. A sign warning of toxic materials shall be affixed the room and cupboard containing the product(s).  
Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

#### Recommended storage material

Keep only in original packaging.

#### Storage conditions

Protein L reference is stored at either -20°C (2 years) or -80°C (5 years). The rest of the kit/components is stored at +4°C.

#### Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

### 7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone  
Short term exposure limit (15 minutes) (ppm): 20  
Short term exposure limit (15 minutes) (mg/m<sup>3</sup>): 80  
Long term exposure limit (8 hours) (ppm): 3,6  
Long term exposure limit (8 hours) (mg/m<sup>3</sup>): 14,4

Annotations:

H = The substance is easily absorbed through the skin.

R = The substance affects reproduction.

sulphuric acid

Short term exposure limit (15 minutes) (mg/m<sup>3</sup>): 0,2 (inhalerbar fraktion)

Long term exposure limit (8 hours) (mg/m<sup>3</sup>): 0,1 (inhalerbar fraktion)

Annotations:

C = The substance is carcinogenic.

V = Indicative short term limit.

22 = Studies show aerosols of sulfuric acid to be carcinogenic.

The Swedish Work Environment Authority's regulations and general guideline (AFS 2023:14) on limit values for respiratory exposure in the work environment.

#### DNEL

N-methyl-2-pyrrolidone;1-methyl-2-pyrrolidone

| Duration:                              | Route of exposure: | DNEL:                  |
|----------------------------------------|--------------------|------------------------|
| Long term – Systemic effects - Workers | Dermal             | 4.8 mg/kg bw/day       |
| Long term – Local effects - Workers    | Inhalation         | 40 mg/m <sup>3</sup>   |
| Long term – Systemic effects - Workers | Inhalation         | 14.4 mg/m <sup>3</sup> |

sulphuric acid

| Duration:                            | Route of exposure: | DNEL:                 |
|--------------------------------------|--------------------|-----------------------|
| Long term – Local effects - Workers  | Inhalation         | 50 µg/m <sup>3</sup>  |
| Short term – Local effects - Workers | Inhalation         | 100 µg/m <sup>3</sup> |

#### PNEC

N-methyl-2-pyrrolidone;1-methyl-2-pyrrolidone

| Route of exposure:                | Duration of Exposure: | PNEC:      |
|-----------------------------------|-----------------------|------------|
| Freshwater                        |                       | 250 µg/L   |
| Freshwater sediment               |                       | 1.09 mg/kg |
| Intermittent release (freshwater) |                       | 5 mg/L     |
| Marine water                      |                       | 25 µg/L    |
| Marine water sediment             |                       | 109 µg/kg  |
| Sewage treatment plant            |                       | 10 mg/L    |
| Soil                              |                       | 70.1 µg/kg |

#### 8.2. Exposure controls

Compliance with the given occupational exposure limits values should be controlled on a regular basis.

##### General recommendations

Smoking, drinking and consumption of food is not allowed in the work area.

##### Exposure scenarios

There are no exposure scenarios implemented for this product.

##### Exposure limits

Professional users are subjected to the legally set maximum concentrations for occupational exposure. See occupational hygiene limit values above.

##### Appropriate technical measures

Do not recirculate outlet air that contain the substances.

The formation of vapours must be kept at a minimum and below current limit values (see above). Installation of a local exhaust system if normal air flow in the work room is not sufficient is recommended. Ensure eyewash and emergency showers are clearly marked.

Apply standard precautions during use of the product. Avoid inhalation of vapours.

##### Hygiene measures

In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Pay special attention to hands, forearms and face.

##### Measures to avoid environmental exposure

Keep damming materials near the workplace. If possible, collect spillage during work.

#### Individual protection measures, such as personal protective equipment

##### Generally

Use only CE marked protective equipment.

### Respiratory Equipment

| Type            | Class | Colour | Standards |
|-----------------|-------|--------|-----------|
| Use in fumehood |       |        |           |

### Skin protection

| Recommended                                                                                                      | Type/Category | Standards |
|------------------------------------------------------------------------------------------------------------------|---------------|-----------|
| Wear appropriate protection clothing, e.g. coveralls in polypropylene or working clothes in cotton or polyester. | -             | -         |



### Hand protection

| Material | Glove thickness (mm) | Breakthrough time (min.) | Standards                 |
|----------|----------------------|--------------------------|---------------------------|
| Nitrile  | 0,2                  | > 240                    | EN374-2, EN16523-1, EN388 |



### ▼ Eye protection

| Type                              | Standards               |
|-----------------------------------|-------------------------|
| Safety glasses with side shields. | EN 166 / EN ISO 16321-1 |



## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Physical state

Liquid

#### Colour

No data available.

#### Odour / Odour threshold

No data available.

#### pH

No data available.

#### Density (g/cm<sup>3</sup>)

No data available.

#### Kinematic viscosity

No data available.

#### Particle characteristics

Does not apply to liquids.

#### Phase changes

##### Melting point/Freezing point (°C)

No data available.

##### Softening point/range (°C)

Does not apply to liquids.

##### Boiling point (°C)

No data available.

##### Vapour pressure

No data available.

##### Relative vapour density

No data available.

Decomposition temperature (°C)

No data available.

Data on fire and explosion hazards

Flash point (°C)

No data available.

Flammability (°C)

No data available.

Auto-ignition temperature (°C)

No data available.

Lower and upper explosion limit (% v/v)

No data available.

Solubility

Solubility in water

No data available.

n-octanol/water coefficient (LogKow)

No data available.

Solubility in fat (g/L)

No data available.

9.2. Other information

Other physical and chemical parameters

No data available.

Oxidizing properties

No data available.

## SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

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

Skin corrosion/irritation

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

Serious eye damage/irritation

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

Respiratory sensitization

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

Skin sensitisation

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

Germ cell mutagenicity

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

#### Carcinogenicity

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

#### Reproductive toxicity

May damage the unborn child.

#### STOT-single exposure

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

#### STOT-repeated exposure

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

#### Aspiration hazard

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

#### Symptoms related to the physical, chemical and toxicological characteristics

Reproductive toxicity: This product contains teratogenic substances, which may produce anomalies and/or developmental defects to the human offspring. Adverse effects include: death, growth retardation, congenital disorders, delayed mental development, and functional disorders.

#### 11.2. Information on other hazards

##### Endocrine disrupting properties

This mixture/product does not contain any substances known to have hormone-disrupting properties in relation to health.

##### Other information

sulphuric acid has been classified by IARC as a group 1.

### SECTION 12: Ecological information

#### 12.1. Toxicity

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

#### 12.2. Persistence and degradability

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

#### 12.3. Bioaccumulative potential

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

#### 12.4. Mobility in soil

No data available.

#### 12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances known to fulfil the criteria for PBT and vPvB classification.

#### 12.6. Endocrine disrupting properties

This mixture/product does not contain any substances considered to have endocrine-disrupting properties in relation to the environment.

#### 12.7. Other adverse effects

None known.

### SECTION 13: Disposal considerations

#### 13.1. ▼ Waste treatment methods

Product is not covered by regulations on dangerous waste.

HP 10 – Toxic for reproduction

Dispose of contents/container to an approved waste disposal plant.

Waste regulation (SFS 2020:614).

##### EWC code

Not applicable.

##### Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

### SECTION 14: Transport information



|                 | 14.1<br>UN / ID | 14.2<br>UN proper shipping name | 14.3<br>Hazard class(es) | 14.4<br>PG* | 14.5<br>Env** | Other information: |
|-----------------|-----------------|---------------------------------|--------------------------|-------------|---------------|--------------------|
| ADR/A<br>DN/RID | -               | -                               | -                        | -           | -             | -                  |
| IMDG            | -               | -                               | -                        | -           | -             | -                  |
| IATA            | -               | -                               | -                        | -           | -             | -                  |

\* Packing group

\*\* Environmental hazards

#### Additional information

Not dangerous goods according to ADR/ADN/RID, IATA and IMDG.

#### 14.6. Special precautions for user

Not applicable.

#### 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

##### ▼ Restrictions for application

Restricted to professional users.

People under the age of 18 shall not work with this product. This does not apply if the working task is:

- performed by young people who have completed upper secondary education or equivalent education for the task or
- included in teaching that is located in a school premises or other place that is specially arranged for teaching, or
- included in supervisor-led internships for young people.

Pregnant women and women breastfeeding must not be exposed to this product. The risk, and possible technical precautions or design of the workplace needed to eliminate exposure, must be considered.

##### Demands for specific education

No specific requirements.

##### SEVESO - Categories / dangerous substances

Not applicable.

##### Regulation on drug precursors

sulphuric acid is included (Category 3)

##### Regulation on explosives precursors

sulphuric acid (Annex I)

##### REACH, Annex XVII

N-methyl-2-pyrrolidone;1-methyl-2-pyrrolidone is subject to REACH restrictions (entry 71).

##### REACH - Candidate List of substances of very high concern

N-methyl-2-pyrrolidone;1-methyl-2-pyrrolidone is included in the Candidate List of substances of very high concern (SVHC).

##### Additional information

Use of the product by private persons requires permission from the County Administration (Länsstyrelsen).

Placing the product on the market requires permission from the County Administration (Länsstyrelsen).

##### ▼ Sources

The Swedish Work Environment Authority's regulations and general guideline (AFS 2023:2) on planning and organizing work environment work - Chapter 8. The working environment of minors - basic obligations for you with employer responsibility

The Swedish Work Environment Authority's regulations and general guideline (AFS 2023:2) on planning and organizing work environment work - Chapter 7. Pregnant, recently given birth and breastfeeding employees - basic obligations for you with employer responsibility

Waste regulation (SFS 2020:614).

Council Regulation (EC) No 273/2004 on drug precursors.

Council Regulation (EC) No 2019/1148 on explosives precursors.

The Swedish Chemical Agency's Chemical Products and Biotechnical Organisms Regulations (KIFS 2017:7)  
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).  
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

#### 15.2. Chemical safety assessment

No

### SECTION 16: Other information

#### Full text of H-phrases as mentioned in section 3

H314, Causes severe skin burns and eye damage.

H315, Causes skin irritation.

H319, Causes serious eye irritation.

H335, May cause respiratory irritation.

H360D, May damage the unborn child.

#### ▼ Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

CAS = Chemical Abstracts Service

CE = Conformité Européenne (European conformity)

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CSA = Chemical Safety Assessment

CSR = Chemical Safety Report

DMEL = Derived Minimal Effect Level

DNEL = Derived No Effect Level

EC = Effective concentration

ED = Effective dose

EINECS = European Inventory of Existing Commercial chemical Substances

EL = Effective Loading

ErC = Concentration associated with x% growth rate response

ES = Exposure Scenario

EUH statement = CLP-specific Hazard statement

EuPCS = European Product Categorisation System

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

GWP = Global warming potential

HP = Hazardous Property code

IARC = International Agency for Research on Cancer (IARC)

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IC = X maximum inhibitory concentration

IMDG = International Maritime Dangerous Goods

LC = Lethal concentration

LCLo = Value is the lowest concentration of a material in air reported to have caused the death of animals or humans

LD = Lethal dose

LOAEC = Lowest Observed Adverse Effect Concentration

LOAEL = Lowest Observed Adverse Effect Level

LOEC = Lowest Observed Effect Concentration

LogKow = logarithm of the n-octanol/water coefficient

LL = Lethal Loading

M = For multiplication factor

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

NOAEC = No Observed Adverse Effect Concentration

NOAEL = No Observed Adverse Effect Level

NOEC = No Observed Effect Concentration

NOELR = No Observable Effect Loading Rate

OECD = Organisation for Economic Co-operation and Development

PBT = Persistent, Bioaccumulative and Toxic

PNEC = Predicted No Effect Concentration

RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail

RRN = REACH Registration Number

SCL = A specific concentration limit

SVHC = Substances of Very High Concern

STOT-RE = Specific Target Organ Toxicity - Repeated Exposure

STOT-SE = Specific Target Organ Toxicity - Single Exposure

TWA = Time weighted average

UN = United Nations

UVBC = Unknown or variable composition, complex reaction products or of biological materials

VOC = Volatile Organic Compound

vPvB = Very Persistent and Very Bioaccumulative

#### Additional information

The classification of the mixture in regard of health hazards is in accordance with the calculation methods given by Regulation (EC) No. 1272/2008 (CLP).

#### The safety data sheet is validated by

Elisabet Vikeved

#### Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a triangle.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

Country-language: SE-en