

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

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 users.

Uses advised against

None known.

1.3. Details of the supplier of the safety data sheet

Company and address

Medicago AB

Danmark Berga 13

74176 Uppsala

Sweden

+46 18 56 11 80

www.medicago.se

E-mail

info@medicago.se

Revision

03/10/2023

SDS Version

1.0

Date of previous version

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

1.4. Emergency telephone number

Contact The National Poisons Information Service (dial 111, 24 h service).

See section 4 "First aid measures".

SECTION 2: Hazards identification

Classified according to Regulation (EC) No. 1272/2008 (CLP) as retained and amended in UK law.

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

-

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

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)

If skin irritation occurs: Get medical advice/attention. (P332+P313)

Storage

-

Disposal

Dispose of contents/container to an approved waste facility. (P501)

Hazardous substances

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

Additional labelling

Restricted to professional users.

2.3. Other hazards

Additional warnings

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

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) 2018/605.

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 EC No.: 212-828-1 UK-REACH: Index No.: 606-021-00-7	1-3%	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 (SCL: 10.00 %) Repr. 1B, H360D	[1], [3], [5]
sulphuric acid	CAS No.: 7664-93-9 EC No.: 231-639-5 UK-REACH: Index No.: 016-020-00-8	<1%	Skin Corr. 1A, H314	[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 UK 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.

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

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 medic

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_x)

Carbon oxides (CO / CO₂)

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 111, 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.

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

See section 8 "Exposure controls/personal protection" for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Recommended storage material

Keep only in original packaging.

Storage temperature

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

Long term exposure limit (8 hours) (ppm): 10

Long term exposure limit (8 hours) (mg/m³): 40

Short term exposure limit (15 minutes) (ppm): 20

Short term exposure limit (15 minutes) (mg/m³): 80

Annotations:

Sk = Can be absorbed through the skin and lead to systemic toxicity.

sulphuric acid

Long term exposure limit (8 hours) (mg/m³): 0,05 (Mist) (Thoraic fraction)

The Control of Substances Hazardous to Health Regulations 2002. SI 2002/2677 The Stationery Office 2002.
EH40/2005 Workplace exposure limits (Fourth Edition 2020).

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 ³
Long term – Systemic effects - Workers	Inhalation	14.4 mg/m ³

sulphuric acid

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

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

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

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. Always wash 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 UKCA marked protective equipment.


Respiratory Equipment

No specific requirements


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, EN374-3, EN388	

Eye protection

Type	Standards	
Safety glasses with side shields.	EN166	

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Liquid

Colour

Testing not relevant or not possible due to the nature of the product.

Odour / Odour threshold

Testing not relevant or not possible due to the nature of the product.

pH

Testing not relevant or not possible due to the nature of the product.

Density (g/cm³)

Testing not relevant or not possible due to the nature of the product.

Kinematic viscosity

Testing not relevant or not possible due to the nature of the product.

Particle characteristics

Does not apply to liquids.

Phase changes

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

Melting point/Freezing point (°C)

Testing not relevant or not possible due to the nature of the product.

Softening point/range (waxes and pastes) (°C)

Does not apply to liquids.

Boiling point (°C)

Testing not relevant or not possible due to the nature of the product.

Vapour pressure

Testing not relevant or not possible due to the nature of the product.

Relative vapour density

Testing not relevant or not possible due to the nature of the product.

Decomposition temperature (°C)

Testing not relevant or not possible due to the nature of the product.

Data on fire and explosion hazards

Flash point (°C)

Testing not relevant or not possible due to the nature of the product.

Flammability (°C)

Testing not relevant or not possible due to the nature of the product.

Auto-ignition temperature (°C)

Testing not relevant or not possible due to the nature of the product.

Lower and upper explosion limit (% v/v)

Testing not relevant or not possible due to the nature of the product.

Solubility

Solubility in water

Testing not relevant or not possible due to the nature of the product.

n-octanol/water coefficient

Testing not relevant or not possible due to the nature of the product.

Solubility in fat (g/L)

Testing not relevant or not possible due to the nature of the product.

9.2. Other information

Oxidizing properties

Testing not relevant or not possible due to the nature of the product.

Other physical and chemical parameters

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

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 as retained and amended in UK law

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 sensitisation

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

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.

11.2. Information on other hazards

Long term effects

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.

Endocrine disrupting properties

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

Other information

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

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

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

Waste treatment methods

Product is not covered by regulations on dangerous waste.

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

Regulation (EU) No 1357/2014 of 18 December 2014 on waste as retained and amended in UK law.

EWG code

Not applicable.

Specific labelling

Contaminated packing

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

SECTION 14: Transport information

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

	14.1 UN / ID	14.2 UN proper shipping name	14.3 Hazard class(es)	14.4 PG*	14.5 Env**	Other information:
ADR	-	-	-	-	-	-
IMDG	-	-	-	-	-	-
IATA	-	-	-	-	-	-

* Packing group

** Environmental hazards

Additional information

Not dangerous goods according to ADR, 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 be exposed to this product.

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)

UK-REACH, Annex XVII

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

Additional information

Not applicable.

Sources

The Management of Health and Safety at Work Regulations 1999.

The Health and Safety at Work etc. Act 1974 Regulations 2013.

Regulation (EU) No 1357/2014 of 18 December 2014 on waste as retained and amended in UK law.

The Controlled Drugs (Drug Precursors) Regulations 2008.

Council Regulation (EC) No 2019/1148 on explosives precursors as retained and amended in UK law.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) as retained and amended in UK law.

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as retained and amended in UK law.

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

According to REACH Regulation (EC) No 1907/2006, as retained and amended SI 2019/758 and SI 2020/1577

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
EINECS = European Inventory of Existing Commercial chemical Substances
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
IARC = International Agency for Research on Cancer (IARC)
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
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 substance/mixture in regard of health hazards are in accordance with the calculation methods given by Regulation (EC) No. 1272/2008 (CLP) as retained and amended in UK law.

The safety data sheet is validated by

Jonas Nielsen

Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue 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: GB-en