Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)
Product Name: Protein Total Mono, Biuret
Version: 04
Date: March 19, 2024

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Protein Total Mono, Biuret

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

Relevant identified use
Reagent for in-vitro diagnostics in human samples.
For professional use only.

Uses advised against
None

1.3. Details of the supplier of the safety data sheet

Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
Hondastrasse, Objekt M55, IZ-NOE Sued, 2351 Wr. Neudorf, Austria

Phone / e-mail: +43 2236 660 910 0 / office@dialab.at

Responsible person:
safety@dialab.at

1.4. Emergency telephone number

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24 h)

Section 2. Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) 1272/2008 (CLP):
Met. Corr. 1; H290 May be corrosive to metals.
Skin Irrit. 2; H315 Causes skin irritation.
Eye Irrit. 2; H319 Causes serious eye irritation.
STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.
Aquatic Chronic 3; H412 Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) 1272/2008 (CLP):

Pictogram(s) and signal words:

Signal word: **Warning**

Hazard-determining components of labelling:

Hazard statements:

H290	May be corrosive to metals.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements:

P234	Keep only in original packaging.
P273	Avoid release to the environment.
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.
P314	Get medical advice/attention if you feel unwell.
P390	Absorb spillage to prevent material damage

Special labelling:
Contains Potassium iodide.

2.3. Other hazards

A corrosive effect cannot be ruled out because of the pH value.

Endocrine disrupting properties, Results of PBT and vPvB assessment:
No data available.

Section 3. Composition / information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Chemical characterisation: Aqueous solution.

Hazardous ingredients:

Sodium hydroxide, EC-No.: 215-185-5, CAS No.: 1310-73-2.
Concentration (%): < 1%
Classification according to Regulation (EC) 1272/2008: Met. Corr. 1; H290. Skin Corr. 1A; H314.
Specific concentration limits (SCL): Skin Corr. 1A; H314: C ≥ 5 % / Skin Corr. 1B; H314: 2 % ≤ C < 5 % / Skin Irrit. 2; H315: 0.5 % ≤ C < 2 % / Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %.

Potassium iodide, EC-No.: 231-659-4, REACH No.: 01-2119966161-40-xxxx, CAS No.: 7681-11-0
Concentration (%): < 0.5%
Classification according to Regulation (EC) 1272/2008: STOT RE 1; H372.

Copper sulphate-5-hydrate, EC-No.: 231-847-6, CAS No.: 7758-99-8.
Concentration (%): < 0.25%
Classification according to Regulation (EC) 1272/2008: Acute Tox. 4; H302. Eye Dam. 1; H318. Aquatic Acute 1; H400. Aquatic Chronic 1; H410.
Acute toxicity estimate (ATE): Oral: 481 mg/kg bw.
M-factors: Aquatic Acute 1: M = 10. Aquatic Chronic 1: M = 1.

Components with occupational exposure limits:
Sodium hydroxide, EC-No.: 215-185-5, CAS No.: 1310-73-2.

Copper sulphate-5-hydrate, EC-No.: 231-847-6, CAS No.: 7758-99-8.

The wording of the listed hazard warnings can be found in Section 16.

Substances that are on the "Candidate List of Substances of Very High Concern (SVHC) for authorization by the European Chemicals Agency (ECHA) are not intended to be part of this product. It is therefore not to be expected that these substances are contained in the product in quantities of > 0.1 %.

Section 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.

Following inhalation:
Move victim to fresh air, put at rest and loosen restrictive clothing. Seek medical aid in case of troubles.

Following skin contact:
Take off immediately all contaminated clothing and wash it before reuse. After contact with skin, wash immediately with plenty of water. Cover with sterile dressing material to protect against infection. Seek medical attention.

Following 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 seek the immediate attention of an ophthalmologist.

Following ingestion:
Never give anything by mouth to an unconscious person. Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Risk of perforation! Do not try to neutralize. Seek medical attention.

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

May cause damage to organs through prolonged or repeated exposure. Causes skin irritation.
Causes serious eye irritation.
A corrosive effect cannot be ruled out because of the pH value. May cause respiratory irritation.
In case of ingestion: Irritant up to corrosive.

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.

Unsuitable extinguishing media:
No data available.

5.2. Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.
In the event of a fire, the following may be produced when the water evaporates: Sodium compounds, copper oxide, hydrogen iodide, sulphur oxides, carbon monoxide and carbon dioxide.

5.3. Advice for firefighters

Special protective equipment for firefighters:
In case of surrounding fires: Wear a self-contained breathing apparatus and chemical protective clothing.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:
Avoid contact with skin and eyes. Take off immediately all contaminated clothing and wash it before reuse.
Wear appropriate protective equipment. Provide adequate ventilation. Do not breathe vapours.
Keep unprotected people away.

For emergency responders:
No data available.

6.2. Environmental precautions

Do not allow to enter into ground-water, surface water or drains. If necessary notify appropriate authorities.

6.3. Methods and material for containment and cleaning up

Absorb spillage to prevent material damage. Dilute with plenty of water.
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. Final cleaning.
Never return spills in original containers for re-use.

6.4. Reference to other sections

Refer additionally to section 8 and 13.

Section 7. Handling and storage

7.1. Precautions for safe handling

Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Avoid contact with skin and eyes. Take off immediately all contaminated clothing and wash it before reuse. Wear appropriate protective equipment. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.
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 25 °C. Protect from light. Keep away from heat. Store containers in upright position. Unsuitable materials: Metals, light metals.

Hints on joint storage: Do not store together with ammonium compounds or acids. Keep away from food, drink and animal feedingstuffs.

Storage class: 8B = Non-combustible corrosive substances.

7.3. Specific end use(s):

No information available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values:

Sodium hydroxide, REACH: 01-2119457892-27-xxxx, EC-No.: 215-185-5, CAS No.: 1310-73-2.

Type	Limit value
Austria: MAK, TMW	2 mg/m3
Austria: MAK, KZW	4 mg/m3
France: VME	2 mg/m³

Copper sulphate-5-hydrate, EC-No.: 231-847-6, CAS No.: 7758-99-8

Type	Limit value
France: VLE	2 mg/m³ (Dust)
France: VME	0.2 mg/m³ (Fume)
France: VME	1 mg/m³ (Dust)
Germany: DFG short-term	0.02 mg/m³ (respirable fraction)
Germany: DFG long-term	0.01 mg/m³ (respirable fraction)

8.2. Exposure controls

When aerosols and vapours form: Withdraw by suction.

Appropriate engineering controls
No data available.

Individual protection measures, such as personal protective equipment

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. Use filter type (P2/P3) according to EN 14387.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber-Layer thickness: 0.11 mm.
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: Do not breathe vapours. Do not get in eyes, on skin, or on clothing. Take off immediately all contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Have eye wash bottle or eye rinse ready at work place. Wash hands before breaks and after work.

Environmental exposure controls
Do not allow to enter into ground-water, surface water or drains.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Parameter	Value / test method / remarks
Physical State	At 20 °C and 101.3 kPa: liquid
Colour	Light blue, clear
Odour	No characteristic odour
Melting point / freezing point	Approx. 0 °C
Boiling point or initial boiling point and boiling range	Approx. 100 °C
Flammability	No data available
Lower and upper explosion limit	No data available
Flash point	Not combustible
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	At 25 °C: 12.80
Kinematic viscosity	No data available
Solubility in water / in other solvents	Water: completely miscible (at 20 °C)
Partition coefficient n-octanol/water (log value)	No data available
Vapour pressure	No data available
Density and/or relative density	at 20 °C: 1.009 g/mL
Relative vapour density	No data available
Particle characteristics	Not applicable
Explosive properties	No data available
Oxidizing characteristics	No data available
Evaporation rate	No data available

9.2. Other information

Information with regard to physical hazard classes:
No data available.

Other safety characteristics:
No data available.

Section 10. Stability and reactivity

10.1. Reactivity

May be corrosive to metals.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Reacts with ammonium compounds: Formation of ammonia.
Reacts violently with metals and light metals. Formation of hydrogen!

10.4. Conditions to avoid

Protect from frost, heat and sunlight.

10.5. Incompatible materials

Acids.

10.6. Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

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): ATE > 5000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.
ATEmix (calculated): ATE > 5000 mg/kg

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Skin Irrit. 2; H315 = Causes skin irritation.

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

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

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): STOT RE 2; H373 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

11.2. Information on other hazards

Endocrine disrupting properties: No data available.

Symptoms: A corrosive effect cannot be ruled out because of the pH value. Can cause skin, eye and respiratory tract irritation.

In case of ingestion: Irritant up to corrosive.

Section 12. Ecological information

12.1. Toxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.

Harmful effects on water organisms by modification of pH-value.

Information about Copper sulphate anhydrous:
Daphnia toxicity:
EC50 *Daphnia magna* (Big water flea): 0.02 mg/L/48h
Fish toxicity:
LC50 *Oncorhynchus mykiss*: 0.11 mg/L/96h

Water Hazard Class: 2 = obviously hazardous to water.

12.2. Persistence and degradability

Further details: Methods for the determination of biodegradability are not applicable to inorganic substances.

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: Do not allow to enter into ground-water, surface water or drains.

Section 13. Disposal considerations

13.1. Waste treatment methods

Product

Waste key:
06 03 13* = Solid salts and solutions containing heavy metals.
* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

Package

Waste key:
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: UN 1824.

14.2. UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR: UN 1824, SODIUM HYDROXIDE SOLUTION.

14.3. Transport hazard class(es)

ADR/RID, AND: Class 8, Code: C5
IMDG: Class 8, Subrisk -
IATA-DGR: Class 8.

14.4. Packing group

ADR/RID: III.

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

Land transport (ADR/RID)	
Warning board:	ADR/RID: Kemmler-number 80, UN number UN 1824
Hazard label:	8
Limited quantities:	5 L
EQ:	E1
Package - Instructions:	P001 IBC03 LP01 R001
Special provisions for packing together:	MP19
Portable tanks - Instructions:	T4
Portable tanks - Special Provisions:	TP1
Tank coding:	L4BN
Tunnel restriction code:	E
Inland waterway craft (ADN)	
Hazard label:	8
Limited quantities:	5 L
EQ:	E1
Transport permitted:	T
Equipment necessary:	PP - EP
See transport (IMDG)	
EmS:	F-A, S-B
Special Provisions:	223
Limited quantities:	5 L
Excepted quantities:	E1
Package - Instructions:	P001, LP01
Package - Provisions:	-
IBC - Instructions:	IBC03
IBC - Provisions:	-
Tank instructions - IMO:	-
Tank instructions - UN:	T4
Tank instructions - Provisions:	TP1
Stowage and handling:	Category A.
Segregation:	SG35
Properties and observations:	Colourless liquid. Corrosive to aluminium, zinc and tin. Reacts with ammonium salts, evolving ammonia gas. Causes burns to skin, eyes and mucous membranes. Reacts violently with acids.
Segregation group:	18
Air transport (IATA)	
Hazard label:	Corrosive
Excepted Quantity Code:	E1
Passenger and Cargo Aircraft:	Ltd.Qty.: Pack.Instr. Y841 - Max. Net Qty/Pkg. 1 L
Passenger and Cargo Aircraft:	Pack.Instr. 852 - Max. Net Qty/Pkg. 5 L
Cargo Aircraft only:	Pack.Instr. 856 - Max. Net Qty/Pkg. 60 L
Special Provisions:	A3 A803
Emergency Response Guide-Code (ERG):	8L

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 – EC members states:
Further regulations, limitations and legal requirements: Use restriction according to REACH annex XVII, no.: 3.

National regulations – Austria:
Storage class: 8B = Non-combustible corrosive substances.

National regulations – France:
No data available.

National regulations – Germany:
Storage class: 8B = Non-combustible corrosive substances.

Water hazard class: 2 = obviously hazardous to water.

Information on working limitations: Observe employment restrictions for young people.
Observe employment restrictions for expectant or nursing mothers.

Further regulations, limitations and legal requirements: The product is not subject to the Chemicals Prohibition Ordinance (ChemVerbotsV).

National regulations – Switzerland:
No data available.

15.2. Chemical safety assessment

For this mixture a chemical safety assessment is not required.

Section 16. Other information

SDS according to COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Reason of Change:
Correction of section 2.2.

Hazard statements mentioned in Sections 2 and 3:
Directive (EC) 127/2008:
H290 = May be corrosive to metals.
H302 = Harmful if swallowed.
H314 = Causes severe skin burns and eye damage.
H315 = Causes skin irritation.
H318 = Causes serious eye damage.
H319 = Causes serious eye irritation.
H372 = Causes damage to organs through prolonged or repeated exposure.
H373 = May cause damage to organs through prolonged or repeated exposure.
H400 = Very toxic to aquatic life.
H410 = Very toxic to aquatic life with long lasting effects.
H412 = Harmful to aquatic life with long lasting effects.

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
Aquatic Acute: Hazardous to the aquatic environment - acute
Aquatic Chronic: Hazardous to the aquatic environment – chronic
ATE: Acute toxicity estimate
Bw: Body weight
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging
EC: European Community

EC50: Effective Concentration 50%
EN: European Standard
EQ: Excepted quantities
EU: European Union
Eye Dam.: Eye damage
Eye Irrit.: Eye irritation
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: International Maritime Dangerous Goods
IMO: International Maritime Organization
KZW: Kurzzeitwert
LC50: Median lethal concentration
MAK: Maximale Arbeitsplatz-Konzentration
Met. Corr.: Corrosive to metals
M-factor: Multiplication factor
PBT: Persistent, bioaccumulative and toxic
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Skin Corr.: Skin corrosion
Skin Irrit.: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
TMW: Tagesmittelwert
UN: United Nations
VME: Valeur Moyenne d'Exposition
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Literature:
BG RCI:
- Merkblatt M004 'Reizende Stoffe/Ätzende Stoffe'
- Merkblatt M050 'Umgang mit Gefahrstoffen'
- Merkblatt M053 'Arbeitsschutzmaßnahmen für den Umgang mit Gefahrstoffen'

RIS:
- Bundesgesetzblatt Nr. BGBl. II Nr. 156/2021, Anhang I/2021

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