	-	Safety Data Sheet / sdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 1 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

EU Material Safety Data Sheet according to

Safety Data Sheet according to Regulation (EU) 2020/878; Regulation (EU) No. 1272/2008 (+ Subsequent ATPs) and REACH Regulation 1907/2006 EC (+ Subsequent Regulations)

Date: 30.01.2024

Rev. 11.0

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

1.1. Product identifier: : TUBERCULOSIS IgG ELISA (Art.-Nr. LIO-TUB01)

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

Microtiter plate-based Enzyme assay for the detection of human IgG antibodies to *Mycobacterium tuberculosis*. For research use only.

Contains 7 components (Microtiter plate, Wash buffer (concentrate), Sample diluent, Conjugate solution, TMB-Substrate Solution, Standards and STO-Stop Solution, as liquids or solids.

1.3. Details of the supplier of the safety data sheet

Lionex GmbH Salzdahlumer Str. 196, Geb. 1A D-38126 Braunschweig Tel. +49(0)531 / 2601266 Contact Person: Prof. Dr. Singh:

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e-mail: info@lionex.de

1.4. Emergency telephone number

Germany:

Giftinformationszentrum-Nord der Länder Bremen, Hamburg, Niedersachsen und Schleswig-Holstein Robert-Koch-Straße 40 37075 Göttingen **Tel.: .+49**

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Dänemark / Denmark:	+45 (35) 316 060	Russische – Föderation / Russia	+7 (95) 928 16 47
Finnland / Finland:	+358 (9) 471 977	Schweden / Sweden:	+46 (8) 736 03 84
Frankreich / France:	+33 (3) 883 737 37	Schweiz / Switzerland:	+41 (1) 251 51 51
Griechenland / Greece:	+30 (1) 799 37 77	Slowakei / Slovakia:	+00421 (17) 547 741 66
Großbritannien / GB:	+44 (171) 635 91 91	Slowenien / Slovenia:	+386 (61) 302 457
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Kroatien / Croatia:	+385 (1) 222 302	Ungarn / Hungary:	+36 (1) 215 215
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Norwegen / Norway:	+47 (22) 591 300		

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

Classification of components of the whole preparation according to Regulation (EG) No. 1272/2008:

Component 1: Stop solution

Classification: H314 - Causes severe skin burns and eye damage.

	MSDS (Material S Sicherheits	DO 619b	
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 2 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

Component 2: TMB Substrate

Classification: The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008. The mixture contains 2-pyrrolidone at low concentration (**Repr. 1B, H360D** - May damage the unborn child).

Other components: not hazardous for human health or the environment in any way. The concentrations of hazardous substances of all categories in these mixtures are very low and far below the labelling limit.

2.2. Label elements

Labelling and hazard notes according to Regulation (EG) No. 1272/2008:



Signal word: DANGER! Hazardous component for labelling: Stop solution

Hazard statements:

H314 Causes severe skin burns and eye damage

Safety instructions:

- P280 Wear protective gloves/protective clothing/eye protection/face protection/ hearing protection/....
- P302 + P352 IF ON SKIN: Wash with plenty of water/...
- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- **P337 + P313** If eye irritation persists: Get medical advice/attention.



Signalwort: GEFAHR!

Gefahrenbestimmende Komponente zur Etikettierung: TMB-Substrat

Gefahrenhinweise:

- **H319** Causes serious eye irritation
- **H360D** May damage the unborn child.

Sicherheitshinweise:

- **P264** Wash hands thoroughly after handling.
- **P280** Wear protective gloves/protective clothing/eye protection/face protection.
- P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON CENTER or doctor/physician..

LIONEX Disgroutes and Therapeutics	-	Safety Data Sheet / sdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 3 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

Other components: non-hazardous, no labelling required.

Additional information: -

2.3 Other hazards



Use the product by following the standard safety precautions in a lab. Use appropriate protective clothing (gloves, lab coat, work shoes, safety goggles). Behavior in the lab: DO NOT SMOKE! DO NOT DRINK! DO NOT EAT!

The mixture contains in small quantities a substance included in the list established in accordance with Article 59(1) because it has endocrine disrupting properties (component TMB).

PBT: The mixture does not meet the criteria for classification as PBT or vPvB.

Persistence: none.

Bioaccumulation: none.

Toxicity: Toxic to reproduction (component TMB)

vPvB: The mixture does not meet the criteria for classification as PBT or vPvB.

Persistence: none.

Bioaccumulation: none.

Toxicity: Toxic to reproduction (component TMB)

SECTION 3. Composition/information on ingredients

3.1. Substances

Not applicable. Mixtures from substances listed below contain non-hazardous components like water or proteins.

3.2. Mixtures

Composition/Information on ingredients

Component 1 (Causes severe skin burns and eye damage): Stop solution

List of hazardous substances in the mixture:

Kit Component	Substance	CAS No.	EC No.	Concentration in	H Sätze	P Sätze
				the mixture		
Stop solution	Sulfuric acid, 1	7664-93-9	231-639-5	1.96 %	H314	P280, P302+P352
	mol/L				H319	P303+P361+P353
						P305+P351+P338
						P337+P313

Component 2 (May damage fertility or the unborn child): TMB Substrate

List of hazardous substances in the mixture:

Kit Component	Substance	CAS No.	EC No.	Concentration in the mixture	H Sätze	P Sätze
Substrat solution	2-Pyrrolidon	616-45-5	210-483-1	1 - < 3 %	H360D	P264
						P280
						P305+P351+P338
						P310

Substances with statutory EU-limits:

For full description of H- and P-rules refer to section 16.

Substances, which are listed in the "Candidate List of Substances of Very High Concern (SVHC) for authorisation" of European Chemicals Agency (ECHA) are present in small quantities in the mixture.

LIONEX Degnostes and Therapeutics	-	l Safety Data Sheet / eitsdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 4 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

SECTION 4. First-aid measures

4.1 Beschreibung der Erste-Hilfe-Maßnahmen:

4.1. Description of first-aid measures



General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out the dangerous area. Hand out the medical doctor this MSDS.

If inhaled: Inhaling is not possible. If there should occur any troubles (e.g. shortness of breath): land the person on fresh air. In case of breathing difficulties transmit oxygen. Consult a doctor. Remove person to fresh air and keep comfortable for breathing.

Skin contact (and hair): Take off immediately all contaminated clothing. Instantly wash with water and rinse thoroughly. Remove any clothing contaminated by the product. Seek medical advice if irritations arise. Wash contaminated clothes before reuse. Call the doctor.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical advice.

If swallowed: If swallowed rinse mouth for several minutes under running water. Do not swallow! If swallowed the Stop solution rinse mouth by water. Do not induce vomiting. Seek medical or contact emergency call.

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

Skin contact: The stop solution causes severe skin burns and eye damage. May damage fertility or the unborn child.

Eye contact: The stop solution causes severe skin burns and eye damage. May damage fertility or the unborn child.

If swallowed: The stop solution causes severe skin burns and eye damage. May damage fertility or the unborn child.

If inhaled: Under normal circumstances, it is not possible to inhale the components. If the stop solution is nevertheless inhaled, this will cause severe burns of the respiratory tract.

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

Not available.

SECTION 5. Fire fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Every extinguishing agent, which is suitable for the controlling fire.

Extinguishing media unsuitable for safety reasons: none.

5.2. Special hazards arising from the substance or mixture

Adapt extinguishing measures to the surrounding fire. No special risks known. Hazardous vapours/gases may be produced in case of fire: Carbon monoxide, carbon dioxide (see 10.1).

5.3. Advice for firefighters

Wear self-contained breathing apparatus and suitable protective clothing for fighting against a fire, whereby chemicals are involved.

Move container from fire area if it can be done without risk. Use water spray to keep fire exposed containers cool.

Evacuate area. Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire.

Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

LIONEX Dagnostics and Therapeutics	-	l Safety Data Sheet / eitsdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 5 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use suitable personal protective equipment (safety glasses, white coat, gloves). Avoid breathing dust or aerosols. Do not breathe fumes. Ensure adequate ventilation and clean well the affected area after complete elimination of the material.

6.2. Environmental precautions

Prevent product and large quantities of contaminated wash water from entering waterways and soil. Cover sewage systems to prevent the product from entering the sewage system.

Absorb liquids after spillage with an absorbent material (paper towel).

6.3. Methods and material for containment and cleaning up

For larger quantities: not relevant. The volume of all liquid components is \leq 100 mL.

For residues: Absorb spilled material with absorbent material (paper towel) and collect for disposal in the designated containers according to local regulations.

6.4. Reference to other sections

Applicable limits for occupational exposition are listed in section 7 and 8. For disposal refer to section 13.

SECTION 7. Handling and storage

7.1. Protective measures for safe handling

Notes on safe handling

Close containers with liquids immediately after use to avoid spillage. Store container under lock and key. Wear protective gloves / protective clothing / eye protection. Wash contaminated clothing before reuse.

General hygiene measures: do not eat, drink, smoke in the laboratory. Remove contaminated clothing and protective equipment before entering areas where food is consumed. Clean hands after use. Wash exposed skin thoroughly after use.

Advice on fire and explosion protection

Specific fire and explosion protection measures are not required. The stop solution may be corrosive to metals.

All solutions are non-flammable

7.2. Conditions for safe storage, including any incompatibilities Requirements for storage rooms and containers:

Specific devices for fire and explosion protection or to prevent corrosion are not required. Keep container tightly closed. Store separately from food. Secure from unauthorised access.

Interactions of the ingredients with incompatible substances: Separate storage of explosive hazardous substances (Class 1, Class 4.1A), separate storage of hazardous substances that form flammable gases on contact with water (Class 4.3), separate storage of infectious substances (Class 6.2) and radioactive substances (Class 7). Conditions for evaporation: no dangerous effects known Potential sources of ignition: not present in the product Effects of weather conditions: none known Effects of ambient conditions: none known

	-	afety Data Sheet / sdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 6 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

Effects of the temperature: store at 2-8 °C, can be stored up to the expiration date

Effects of sunlight: avoid exposure of sunlight on TMB-Substrate

Effects of moisture: protect the enclosed microtiterplate from moisture

Effects of vibrations: non known

Special requirements for storage rooms or containers (including containment facilities and **Ventilation**): No special requirements

Suitable packaging: Store in the original packaging

7.3. Specific end use(s)

No specific end uses. For additional information, please refer to our Technical Data Sheet.

SECTION 8. Limitation and monitoring of the exposition/ personal protective equipments

8.1. 8.1. Control parameters

Biological limits according to TRGS 900 and 903:

Substance	CAS-No.	EC-No.	MAK (TRGS 900)	Concentration (%)*
Sulfuric acid	8014-95-7	231-639-5	0.1 E mg/m ³	1.9 %

* The highest concentration of the substances contained in the individual buffers of the preparation is indicated in each case .

Currently recommended monitoring procedures:

If the product is used in accordance with the regulations, no air pollution is to be expected. Therefore no current monitoring procedures necessary.

8.2. Exposure controls



Personal protective equipment: select personal protective equipment according to the concentration of hazardous substances on the specific workstation.

Eye and face protection: wear safety goggles according to EN 166 (EU), NIOSH (US)



Skin protection: protective gloves according to EN 374 (nitrile rubber > 0,28 mm or natural latex \ge 0,22 mm and AQL 1,5). Respect allergies!

Further protective measures: wear a lab coat, closed footwear, follow the hygiene instructions in the laboratory.



Breathing protection: Respiratory protection mask not required. In case of deviating risk assessment, use full-face mask with multi-purpose combination filter type ABEK (EN 14387).

Thermal hazards: Not expected.

Limitation and monitoring of environmental exposure See sections 6 and 7.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties and appearance

Information on basic physical and chemical properties

Microtiter plate	
Physical state:	solid pha
	foil in co
Color:	Transpar
Odor:	no typica
Melting point/freezing point:	not dete
Initial boiling point and boiling range:	not appl

solid phase, common used 96 well microtiterplate with individual breakable wells, sealed in aluminum
foil in combination with desiccant bag
Transparent plastic, in silver aluminium bag
no typical odor
not determined
not applicable

LIONEX Dugrostics and Therapeutics	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 7 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01
Flammability: Lower and upper explosion limit: Flash point: Ignition temperature: Decomposition temperature: pH-value: Kinematic viscosity: Solubility: Vapor pressure: Relative density: Relative vapor density: Particle Properties:	flammable in open fire not applicable not applicable not determined not determined, not a self-o not applicable not applicable not applicable not determined not applicable not applicable	decomposing mixture	

Wash buffer (concentrate), Sample diluent, Standards, Conjugate Solution, aqueous solutions

Physical state:	liquid
Color:	colourless or orange (conjugate solution)
Odor:	no typical odor
Melting point/freezing point:	not determined
Initial boiling point and boiling range:	not determined
Flammability:	Non flammable
Lower and upper explosion limit:	not determined (non-explosive)
Flash point:	not determined, aqueous solution
Ignition temperature:	not determined, aqueous solution
Decomposition temperature:	not determined, not a self-decomposing mixture
pH-value:	6.8 – 7.4 (20°C)
Kinematic viscosity:	not determined
Solubility:	not determined
Vapor pressure:	not determined, aqueous solution
Relative density:	not determined, aqueous solution
Relative vapor density:	not determined, aqueous solution
Particle Properties:	not applicable, aqueous solution

Substrate solution, aqueous solutions

Physical state:	liquid
Color:	colourless-weak yellow
Odor:	characteristic
Melting point/freezing point:	not determined
Initial boiling point and boiling range:	approx. 100°C (like water) not specified, irrelevant
Flammability:	not determined
Lower and upper explosion limit:	not determined (non-explosive)
Flash point:	120 °C (calculated flash point)
Ignition temperature:	not determined
Decomposition temperature:	not determined
pH-value:	3.5 – 4.0 (20°C, experimental data)
Kinematic viscosity:	not determined
Solubility:	not determined (100 % in water)
Vapor pressure:	not determined, aqueous solution
Relative density:	1.0109 g/cm³, experimental data
Relative vapor density:	not determined
Particle Properties:	not applicable

Stop solution, aqueous solutions

Physical state:
Color:
Odor:
Melting point/freezing point:
Initial boiling point and boiling range:
Flammability:
Lower and upper explosion limit:
Flash point:

liquid colourless no typical odor not determined not determined Non flammable not determined (non-explosive) not determined, aqueous solution

LIONEX Begrostes and Therapeutics	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 8 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01
Ignition temperature: Decomposition temperature: pH-value:	not determined, aqueous solution not determined, not a self-decomposing mixture < pH 0.1 (20°C)		
Kinematic viscosity: Solubility: Vapor pressure: Relative density:	not determined not determined not determined, aqueous solution not determined, aqueous solution		
Relative vapor density:	not determined, aqueous solution		

9.2. Other information

Particle Properties:

Information on physical hazard classes

The mixture is not explosive, hardly flammable, is not self-reactive or pyrophoric, oxidising or corrosive.

not applicable, aqueous solution

Other safety characteristics:

None known (no mechanical sensitivity; self-accelerating polymerisation; formation of explosive dust-air mixtures; buffer capacity; evaporation rate; miscibility; conductivity; corrosivity; gas group; redox potential; radical formation potential; photocatalytic properties).

SECTION 10. Stability and reactivity

10.1. Reactivity

The application of all these components during preparation is not attendant on especial hazards. The mixture is stable under the conditions that usually prevail in the laboratory. Since no data are available for the preparation, data for the individual substances contained in the mixture are given below.

Component	Incompatible materials	Hazardous decomposition products
2-Pyrrolidon	strong Oxidans strong Acid	Thermal decomposition can result in the formation of Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO2)
Sulfuric acid	strong Oxidans	Thermal decomposition can result in the formation of sulphur oxides.

10.2. Chemical stability

Under normal conditions of the environment, temperature and pressure all products are stable while they are stored or in use. The storage conditions of the whole preparation are remarked on the label. The preparation is stable within the expiration date which is denoted at the label.

10.3. Potential hazardous reactions

No dangerous reactions are to be expected when used as intended.

10.4. Conditions to avoid

There is no dangerous reaction, but unsuitable conditions will render the product unusable. Strong heating above 30°C should be avoided, and in the case of the TMB substrate, exposure to direct sunlight should also be avoided. Under normal ambient conditions and under the temperature and pressure conditions to be expected during storage and handling, the components are stable until the expiry date.

LIONEX Disposites and Theopenics	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 9 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

10.5. Incompatible materials

None of the components reacts with materials in such a way that a hazardous situation could arise. Contact of the TMB substrate solution with heavy metal salts, peroxidases and catalases should be avoided. No dangerous reaction occurs, but the product becomes unusable.

10.6. Hazardous decomposition products

No hazardous decomposition products are formed from the components of the preparation under normal conditions of temperature and storage.

SECTION 11. Toxicologic information

11.1. Information about toxicologic effects according to Directive (EG) Nr. 1272/2008

The information on toxicological effects refers to the ingredients contained in the preparation. The preparation as a whole is classified as non-hazardous, since the concentrations of the ingredients are very low (see 3.1 and 11.2).

Substance	Acute toxicity / species	Concentration	
2-Pyrrolidon	LD ₅₀ oral (Rat):	4150 mg/kg	
	LC ₅₀ inhalativ (Rat):	> 5.1 mg/l	
	LD50 dermal (Rat)	>5000 mg/kg	
Sulfuric acid	LD ₅₀ oral (Rat):	2140 mg/kg	

Acute toxicity:	Not expected
Skin corrosion/irritation:	Component 1 (stop solution) causes severe burns
Serious eye damage/irritation:	Component 1 (stop solution) causes severe burns Component 2 (TMB) causes severe eye irritation
Respiratory/skin sensitization:	Not expected
Germ Cell Mutagenicity:	No Information available
Carcinogenicity:	No Information available
Reproductive toxicity:	May impair fertility or harm the unborn child: Component 2 (TMB substrate), Repr. 1B.
Specific target organ toxicity (single exposure):	Not expected
Specific Target Organ Repeated Exposure	Not expected
Toxicity:	
Aspiration hazard:	No Information available

Information on likely routes of exposure:

By ingestion, eye contact or skin contact:	Component 1 (stop solution) causes severe burns to the eyes, skin and mucous membranes. Component 2 (TMB substrate) may impair fertility or harm the unborn child.
Delayed and immediate effects and chronic effects after short or prolonged exposure:	Not expected
Symptoms related to the physical, chemical and toxicological properties:	Not expected
Interactions:	Not expected

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 10 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

11.2. Information on other hazards

Endocrine disrupting properties: The mixture contains a substance in small quantities which has endocrine disrupting properties (component TMB).

Other information: not available

SECTION 12. Ecological information

12.1. Toxicity

The TMB substrate contains environmentally hazardous substances (2-pyrrolidone). Due to their low concentration, **aquatic toxicity is not expected**. Longer-term adverse effects are not expected.

The other components exclusively contain substances of low toxicity in very low concentrations and are offered in small volumes ($\leq 100 \text{ mL}$). Environmental toxicity is therefore not to be expected.

The information on environmental toxicity refers to the ingredients contained in the preparation. The preparation as a whole is classified as non-hazardous because the concentrations of the ingredients are very low.

Acute Toxicity of the raw materials for o	environmental organisms:
2-Pyrrolidon	
Short-term toxicity to fish:	LC50 (4 days) 4.6 - 10 g/L
	NOEC (4 days) 4.64 g/L
Short-term toxicity to invertebrates:	EC50 (48 h) 500 mg/L
	EC0 (48 h) 500 mg/L
	EC100 (48 h) 500 mg/L
Toxicity to aquatic algae	EC50 (72 h) 500 mg/L
and cyanobacteria:	EC50 (72 h) 500 mg/L
	EC10 (72 h) 22.2 mg/L
Toxicity for microorganisms:	EC50 (30 min) 1 g/L
Sulfuric acid	
Fish (Lepomis macrochirus):	LC50 (mg/L) = 16 - 29 (96 h)
Invertebrata (<i>Daphnia magna</i>):	EC50 (mg/L) = 20 (24 h)
intercestata (Bapinia inagila).	2000 (116/2) - 20 (2+11)

Acute Toxicity of the raw materials for environmental organisms:

Chronic toxicity of raw materials for aquatic organisms:

Not available.

Terrestrial Environment: the preparation is expected to be non-toxic to plants, animals and terrestrial organisms. No long-term effects on the environment known. Environmentally harmful substances are present in extremely low concentrations in the mixture, and the total volume of the mixture is very small (\leq 24 mL) so that no environmental hazard is expected.

12.2. Persistence and degradability

Available information on persistence and degradability:

Substance	Ecological information:	
2-Pyrrolidon	Fully biologically degradable.	
Sulfuric acid	Concentration in the preparation is less than 2 %. Harmful effects on the environment are not expected.	

LIONEX Disposites and Theopeutes	•	l Safety Data Sheet / eitsdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 11 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

12.3. Bioaccumulative potential

Environmentally hazardous substances are contained in the total preparation only in low concentrations. No bioaccumulation potential is expected if used and disposed of properly.

For 2-Pyrrolidone:

Partition coefficient n-octanol/water; log POW = -0.71 Bioaccumulation Factor (BCF) - L/kg ww: 3.16 L/kg ww

12.4 Mobility in the ground

For 2-Pyrrolidon:

Koc at 20°C: 7.377

12.5. Result of PBT- and vPvB-assessment

None of the substances used is listed as PBT or vPvB relevant.

12.6. Endocrine disrupting properties

Für 2-Pyrrolidon:

Systemic effects Developmental toxicity / teratogenicity:

Route of	For workers	General population
exposure		
Inhalation	Long Term: (DNEL) 29.62 mg/m ³	Long Term: (DNEL) 1.985 mg/m ³
Dermal	Long Term: (DNEL) 4.2 mg/kg bw/day	Long Term: (DNEL) 670 µg/kg bw/day
Oral	Not available	Long Term: (DNEL) 670 µg/kg bw/day
Eye	Low risk (no threshold value derived)	Low risk (no threshold value derived)

Derived no- or minimum effect level = (DN(M)EL)

Short-term systemic effects: no risk identified

12.6. other adverse effects

Unknown.

SECTION 13: Disposal instructions

13.1 Waste treatment procedures

Disposal must be carried out in accordance with applicable regional, national and local laws and regulations.

Relevant legal basis for disposal: see 16.2!

Waste generation should be avoided or minimised wherever possible.

Excess products and products not suitable for recycling must be disposed of via a recognised waste disposal company. Disposal of this product and its solutions and by-products must be carried out at all times in compliance with environmental protection requirements and waste disposal legislation as well as local authority requirements. Disposal must not be via waste water.

Disposal of outer packaging: in accordance with applicable regional, national and local laws and regulations.

	-	al Safety Data Sheet / eitsdatenblatt)	DO 619b
DO 619b	Gültig ab:	QMH – Abschnitt:	Seiten:
Revision /Fassung Nr.:	08.03.2023	5.5	12 von 15
3.0			
Ausgefülltes Dokument:	Gültig ab:	Produktname:	Katolog –Nr.:
Revision /Fassung Nr.: 11.0	30.01.3024	TUBERCULOSIS IgG ELISA	LIO-TUB01
SECTION 14: Transpor	t information		

14.1. UN-Number		
ADR/RIS: -	IMGD: -	IATA: -
14.2. Proper UN shipping	g name	
ADR/RIS: -	IMGD: -	IATA: -
14.3. Transport hazard c	lasses	
ADR/RIS: -	IMGD: -	IATA: -
14.4. Packing group		
ADR/RIS: -	IMGD: -	IATA: -
14.5. Environmental haz	ards	
ADR/RIS: -	IMGD: -	IATA: -
14.6. Special precautions	s for the user	

See sections 6 - 8.

14.7. Carriage in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery only in packagings approved and suitable for transport.

Pollution category (X, Y or Z): not determined

Ship type (1, 2 or 3): not determined

SECTION 15: Legislation

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

National regulations

- Closed Substance Cycle and Waste Management Act (KrW-/AbfG)
- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008
- "Directive on the proper disposal of waste from health care establishments

Health Services" (LAGA Directive)".

- European Waste List (EWL)
- Ordinance on the European List of Wastes (List of Wastes Ordinance [AVV])
- Protection against Infection Act (IfSG)
- Waste Water Ordinance (AbwV)

General Administrative Regulation on the Water Resources Act on the Classification of Substances Hazardous to Water (Administrative Regulation on Substances Hazardous to Water - VwVwS)

Technical Rules for Hazardous Substances (TRGS)

EU regulations

Regulation (EC) No 1005/2009 (substances that deplete the ozone layer): Not applicable

Regulation (EC) No 850/2004 (Persistent Organic Pollutants): Not applicable

Regulation (EC) No 649/2012 (export and import of dangerous chemicals): Not applicable

Authorisations under Title VII of Regulation (EC) No 1907/2006: No restrictions under Title VIII, observe restriction under Annex XVII entry 3.

Regulation (EU) 2020/878

Regulation (EU) 1272/2008

15.2. Chemical Safety Assessment

The mixture has not been subjected to a safety assessment.

LIONEX Despostes and Therapeutics	•	l Safety Data Sheet / eitsdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 13 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

SECTION 16: Other information

16.1 Changes since the last version:

Rev.2 review done according to REGULATION (EC) No 1272/2008: The health hazards of a preparation is assessed by the conventional method described in DIRECTIVE 1999/45/EC, Annex II, Part A

No modifications.

Rev. 3. Review done according to REGULATION (EC) No Regulation (EG) 1272/2008 (CLP). MSDS is prepared according to REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT (REACH, last modified 2015/326) No modifications.

Rev. 4. Modification of Regulation (EC) No 1907/2006 by REGULATION (EC) No. 830, 28. May 2015. No modifications.

Rev. 5. Modification of Regulation (EC) No 1907/2006 by REGULATION (EC) No. 1494, 04. September 2015. Modification of Regulation (EC) 1272/2008 by REGULATION (EC) No. 2015/1221, 24.June 2015. No modifications.

Rev. 6. Modification of Regulation (EC) No 1907/2006 by REGULATION (EC) No. 217, 16. February 2016. No modifications.

Rev. 7. Regulation (EG) 1272/2008 (CLP), last modified by Regulation (EU) No. 2016/918 from 14. June 2016 and Regulation (EC) Nr. 1907/2006 (REACH Regulation, last modified by Regulation (EU) 2016/1005 from 22. June 2016 and Regulation (EC) No. 2016/1017 from 23. June 2016.

Stop solution is hazardous: causes severe skin burns and eye damage

Rev. 8. Modification of Regulation (EC) Nr. 1907/2006 (REACH Regulation, last modified by Regulation (EU) 2016/1688 from 20. September 2016.

No modifications.

Rev. 9. Modifications of Regulation (EC) No. 1907/2006 (REACH Regulation, not relevant.

Rev. 10 Modifications of Regulation (EG) No. 1272/2008: Modification of labelling requirement due to lower limits of substances (refer to Regulation (EU) 2016/1179 from 19. July 2016), labelling done of component "TMB substrate" by GHS08 and H360D (May damage fertility or the unborn child).

Rev. 11 Completely revised in accordance with Regulation (EU) 2020/878; amendments: Section 2.3 added; Section 7.2: Conditions for safe storage updated, Section 8.2 added (Thermal hazards), Section 9.: Description of chemical and physical properties updated, Section 11: the subchapters updated, Endocrine disrupting properties added, Section 12: Endocrine disrupting properties added, the list of hazardous ingredients updated (see 3.2), list H and P phrases and all relevant chapters updated accordingly, glossary extended.

16.2 References and data sources REACH Regulation (EC) No 1907/2006 CLP Regulation (EC) No. 1272/2008 Internet:

http://www.baua.de http:// publikationen.dguv.de http://gestis.itrust.de http://logkow.cisti.nrc.ca http://www.gischem.de http://echa.europa.eu/en/candidate-list-table http://echa.europa.eu/de/information-on-chemicals/registered-substances http://www.chemicalbook.com/

http://www.reach-clp-biozid-helpdesk.de/de/REACH/Zulassung-Beschraenkung/Beschraenkung/Anhang-XVII/Anhang17.html

PBT-Datenbank: http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt

LIONEX Degenotics and Therapeutics	-	Safety Data Sheet / tsdatenblatt)	DO 619b
DO 619b Revision /Fassung Nr.: 3.0	Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 14 von 15
Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0	Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA	Katolog –Nr.: LIO-TUB01

Arbeitsmaterialien zur ökologischen Entsorgung für Arztpraxen und Weg zur richtigen Entsorgung. Editor: Ärztekammer Niedersachsen, authors: Dr. H.-Bernhard Behrends, H. Cremer, Dr. Claus Rink. Web page: <u>http://www.aekn.de/web_aekn/home.nsf/ContentView/1E8914148D4E37BFC1256FB70036DAF7/\$File/arbeitsmaterialien.pdf</u>

16.3 Hazard warnings and safety precautions Hazard statements referred to in sections 2 and 3 According to Regulation (EC) No 1272/2008:

List H-phrases	Meaning
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H360D	May damage the unborn child.

The list explains the meaning of the P phrases given in 3.1. The P phrases apply to the ingredients as a pure substance and not to the preparation.

List P-phrases	Meaning
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/.
P302 + P352	IF ON SKIN: Wash with plenty of water/
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/
P337 + P313	If eye irritation persists: Get medical advice/attention.

Categories of acute toxicity (ATE) according to EG 1272/2008

Categorie 1	0 < ATE ≤ 5 (oral in mg/kg body weight)
Categorie 2	5 < ATE ≤ 50 (oral in mg/kg body weight)
Categorie 3	50 < ATE ≤ 300 (oral in mg/kg body weight)
Categorie 4	300 < ATE ≤ 2000 (oral in mg/kg body weight)

16.4 Legend

Abbreviation	Meaning
IARC	International Agency for Research on Cancer
ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
	(Accord européen relatif au transport international des marchandises dangereuses par voies de
	navigationintérieures)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning
	the International Carriage of Dangerous Goods by Road)
ATE	Acute toxicity estimate
BCF	Bio-concentration factor
CAS	Chemical Abstracts Service registration number
CLP	Classification, labelling and Packaging
EC/EG/EWG	European Community
DNEL	Derived No Effect Level
DMEL	Derived Minimal Effect Level

DO 619b Revision /Fassung Nr.: 3.0 Ausgefülltes Dokument: Revision /Fassung Nr.: 11.0		MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619b	
		Gültig ab: 08.03.2023	QMH – Abschnitt: 5.5	Seiten: 15 von 15 Katolog –Nr.: LIO-TUB01	
		Gültig ab: 30.01.3024	Produktname: TUBERCULOSIS IgG ELISA		
C ₅₀	half maxima	l effective concentration (dosis	/concentration which induces a respo	onse halfway between the	
	baseline and	maximum after a specified exp	posure time)		
mS	Emergency				
C50		ncentration 50%, growth rate			
HS	Globally Har	monised System of Classification	on, Labelling and Packaging of Chemic	cals	
	gram				
	hour				
ARC	Internationa	nternational Agency for Research on Cancer			
ATA	Internationa	ernational Air Transport Association			
BC	Intermediat	diate Bulk Container			
CAO		nal Civil Aviation Organization			
MDG	Internationa	nal Maritime Code for Dangerous Goods			
50	half maxima	inhibitory concentration			
g	kilogram				
C ₅₀	Lethal conce	thal concentration, 50%			
D ₅₀		Lethal dose, 50%			
-50	Lethal loadir	Lethal loading, 50%			
1FAG	Medical Firs	Medical First Aid Guide			
IARPOL	Internationa	International Convention for the Prevention of Marine Pollution from Ships			
OEC	no observed	no observed effect level			
BT	persistent, b	persistent, bioaccumulative and toxic substances			
NEC	Predicted N	Predicted No Effect Concentration			
EACH	-	gistration, Evaluation and Authorization of Chemicals			
VHC	Substance o	stance of Very High Concern			
N	United Natio	ied Nations			
SHA	Occupationa	Occupational Safety & Health Administration			
BT	persistent, b	ioaccumulative, toxic			
ID	Regulations	concerning the international ca	arriage of dangerous goods by rail		
PvB	very persiste	very persistent, very bioaccumulative			

16.5 Method used to evaluate the information for the purpose of classification of preparations according to Article 9 of Regulation (EC) No 1272/2008:

Classification was done according to Regulation (EU) 2020/878; Regulation (EU) 1272/2008 (CLP) (+constituent ATPs) and (EU) No 1907/2006 (+constituent Regulations).

Methods according to Article 9 of Regulation (EC) No 1272/2008 used to evaluate the information for the purpose of classification: Calculation methods

16.6 Further information:

The information in this safety data sheet is based on our present knowledge. The information is intended to describe our products with regard to safety requirements. The information does not constitute a guarantee of product properties and does not establish any contractual legal relationship.