

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 1 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

EG Material Safety Data Sheet according to
Safety Data Sheet according to Regulation (EG) 2015/830 Regulation (EU) No. 1272/2008 (+ Subsequent ATPs) and
REACH Regulation 1907/2006 EC (+ Subsequent Regulations)

Date: 02.02.2018

Rev. 10

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

1.1. Product identifier: TUBERCULOSIS IgA ELISA (Art.-No. LIO-TUB02)

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

In-Vitro Diagnostics for the detection of antibodies to active Tuberculosis. For professional use. Not for personal use. Contains 7 components (microtiter plate, wash buffer (concentrate), sample diluent, conjugate, substrate, standards and stop solution) as liquids or solid phase.

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:

www.lionex.de

FAX +49(0)531 / 6180654

Tel. +49(0)175 / 594 2291

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(0)0551 / 19240

International:

Belgien / Belgium:	+32(70) 245 245	Polen / Poland:	+48 (42) 657 99 00
Bulgarien / Bulgaria:	+359 (2) 515 32 34	Portugal / Portugal:	+351 (1) 795 01 43
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
Holland / Dutch:	+31 (30) 274 88 88	Spanien / Spain:	+34 (91) 562 84 69
Israel / Israel:	+972 (4) 852 92 05	Tschechien / Czech Republik:	+42 (02) 249 192 93
Italien / Italia:	+39 (6) 490 663	Türkei / Turkey:	+90 (312) 433 70 01
Kroatien / Croatia:	+385 (1) 222 302	Ungarn / Hungary:	+36 (1) 215 215
Litauen / Lithuania:	+370 (2) 269 583	Österreich / Austria:	+43 (1) 406 43 43
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.

Component 2: TMB substrate

Classification: **Repr. 1B, H360D** - May damage fertility or the unborn child.

Other components (Micro titre plate, wash buffer, sample buffer, conjugate and standards): not hazardous for human health or the environment in any way.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 2 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

The concentrations of hazardous substances in these preparations are low. The concentration of all toxic substances, environmentally harmful substances, harmful substances, irritating substances and corrosive substances is far below the labeling limit. The content of all hazardous substances has no influence on the assessment of the product.

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:

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.



Signal word: DANGER!

Hazardous component for labelling: TMB-Substrate

Hazard statements:

H360D May damage fertility or the unborn child.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection..

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

Other components: non-hazardous, no labelling required.

Additionally Statements: -

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!

PBT: not applicable. / vPvB: not applicable.

SECTION 3. Composition/information on ingredients

3.1. Substances

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

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 3 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

3.2. Mixtures

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

Table of hazardous substances in the mixture:

Kit component	Designation of substance	CAS No.	EC No.	Concentration in the component	H rules	P rules
Stop solution 12 mL	Sulfuric acid, 1 mol/L	7664-93-9	231-639-5	1,96 %	H290 H314	P280 P302+P352 P305+P351+P338 / P337+P313

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

Table of hazardous substances in the mixture:

Kit component	Designation of substance	REACH-Registration number	CAS Nr.	EC Nr.	Concentration in the component	H rules	P rules
TMB Substrat (12 mL)	N-Methyl-2-Pyrrolidon	01-2119472430-46-XXXX	872-50-4	212-828-1	< 5,0 %	H315 H319 H360D, H335	P280 P308+P313
	Wasserstoff-peroxid H ₂ O ₂	05-2115513322-63-00000	7722-84-1	231-765-0	< 0,01 %	H302 H318	P260
	3,3',5,5'-Tetramethyl benzidine	--	54827-17-7	259-364-6	< 0,04 %	H301 H311 H330, H341	P270 P260 P280

Component 3 – 6 (not hazardous): 10 x wash buffer sample diluent, conjugate, standards, micro titre plate

Table of hazardous substances in the mixture:

Kit component	Designation of substance	CAS No.	EC No.	Concentration in the component	H rules	P rules
Wash buffer, 10 x concentrate (60 mL), sample diluent (100 mL), conjugate (12 mL), standards (4 x 2 mL), microtiter plate (12 x 8 wells)	5-Bromo-5-Nitro-1,3-Dioxane C ₄ H ₆ BrNO ₄	30007-47-7	250-001-7	≤ 0,05 %	H302 H315	P280
	Potassium dihydrogen phosphate - KH ₂ PO ₄	7778-77-0	231-913-4	≤ 0,2 %	-	P260
	Sodium chloride - NaCl	7647-14-5	231-598-5	≤ 8 %	H319	P280

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 not intended to be part of this product. Therefore it is not expected that the concentration of such substances is > 0,1 % in the product.

SECTION 4. First-aid measures



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.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 4 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

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

Skin contact: The stop solution causes severe skin burns and eye damage.

Eye contact: The stop solution causes severe skin burns and eye damage.

If swallowed: The stop solution causes severe skin burns within the mouth, pharynx and digestive tract.

If inhaled: The stop solution can cause severe skin burns of mucosa 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

Every extinguishing agent, which is suitable for the controlling fire. Gear extinguishing agent to the surrounding.

5.2. Special hazards arising from the substance or mixture

There are not known special risks, which can be caused by the substance or the mixture. Generally: toxic vapours can be released in case of fire (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.

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

Avoid entering major volumes of TMB- and stop solution in sewerage. Wipe up the liquid with an absorbent material (paper).

6.3. Methods and material for containment and cleaning up

Dam liquid and absorb with suitable material (paper) and dispose it carefully in closed containers. Rinse with high volumes of water.

6.4. Reference to other sections

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

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 5 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Advice for safe handling: Store stop solution locked.

Close containers immediately after use to avoid spillage. Wear protective clothing (gloves / safety clothes / goggles).

Hygiene measures: Do not smoke, drink or eat in the laboratory. Wash hands after use, put off contaminated clothes and protective equipment before entering a break room.

7.2. Conditions for safe storage, including any incompatibilities

No specific measures for prevention of explosive atmospheres necessary.

No risk of corrosion known

The solutions are not flammable.

Interactions of the ingredients with incompatible substances: store separate from explosive substances (hazard class 1, hazard class 4.1A), store separate from substances which develop flammable gases in contact with water (hazard class 4.3), store separate from infectious substances (hazard class 6.2) and radioactive substances (hazard class e 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

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 solution

Effects of moisture: protect the enclosed microtiterplate from moisture

Effects of vibrations: non known

7.3. Specific end use(s)

None.

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

8.1. Control parameters

Substance	CAS-No.	EC-No.	MAK (by TRGS 900)	content (%)
Hydrogen peroxide	7722-84-1	231-765-0	1,4 mg/m ³	< 0,01%
N-Methyl-2-pyrrolidon	872-50-4	212-821-1	82 mg/m ³	< 5,0 %
5-Bromo-5-Nitro-1,3-Dioxan	30007-47-7	250-001-7	not listed	≤ 0,05%
Sodium chloride	7647-14-5	231-598-3	not listed	≤ 8 %
3,3',5,5'-Tetramethylbenzidine	54827-17-7	259-364-6	not listed	< 0,04 %
Sulphuric acid	8014-95-7	231-639-5	0,1 E mg/m ³	1,9 %
Potassium dihydrogen phosphate	7778-77-0	231-913-4	not listed	≤ 0,2 %
Sodiumum chloride	7647-14-5	231-211-8	not listed	≤ 8 %

***For National exposition limits in other Countries than Germany refere to the corresponding rules!**

BGW by TRGS 903: 150 mg/l urine after work finish (Parameter: N-Methyl-2-pyrrolidon)

Current recommended monitoring procedures:

In case of proper use of the product no air pollution load will be expected. Therefore no current monitoring procedures are necessary.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 6 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

8.2. Exposure controls



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

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 ≥ 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: respirator mask is not necessary.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Microtiter plate

Appearance:	solid phase, common used 96 well microtiterplate with individual breakable wells, sealed in aluminum foil in combination with desiccant bag.
Odor:	no typical odor
pH-value:	not specified, solid
melting point/freezing point:	not specified, unknown
boiling point and boiling range:	not specified, solid
flashpoint:	not specified, solid
rate of vaporization:	not specified, solid
inflammability (solid, gaseous):	flammable in open fire
upper/ lower inflammability or explosion limit:	not specified
Vapor pressure:	not specified, solid
Vapor density:	not specified, solid
specific gravity:	not specified, solid
solubility:	not specified, solid
distribution coefficient:	not specified, solid
self-ignition point:	no self-ignition possible
decomposition temperature:	not specified, solid
viscosity:	not specified, solid
explosive properties:	none, no explosive substances are used for production.
oxidizing properties:	none, no oxidizing substances are used for production.

Sample diluent, conjugate and standards 1 - 4, aqueous solution

Appearance:	liquid, 12 mL in a PE-bottle, transparent white to light yellowish
Odor:	no typical odor
Odor threshold:	not specified
pH-value:	7,4
melting point/freezing point:	0°C
boiling point and boiling range:	100°C
flashpoint:	not specified, aqueous solution without flammable ingredients
rate of vaporization:	not specified, like water
inflammability (solid, gaseous):	not flammable
upper/ lower inflammability or explosion limit:	not explosive
vapor pressure:	not specified, aqueous solution
vapor density:	not specified, aqueous solution
specific gravity:	not specified, like water
solubility:	not specified, aqueous solution
distribution coefficient:	not specified
self-ignition point:	no self-ignition possible
decomposition temperature:	not specified
viscosity:	not specified, aqueous solution

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 7 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

explosive properties: none, contains no explosive substances
oxidizing properties: none, contains no oxidizing substances

Wash buffer, 10 x concentrate, aqueous solution

Appearance: liquid, 60 mL in a PE-bottle, transparent
Odor: no typical odor
Odor threshold: not specified
pH-value: 6,8
melting point/freezing point: 0°C
boiling point and boiling range: 100°C
flashpoint: not specified, aqueous solution without flammable ingredients
rate of vaporization: not specified, like water
inflammability (solid, gaseous): not flammable
upper/ lower inflammability or explosion limit: not explosive
vapor pressure: not specified, aqueous solution
vapour density: not specified, aqueous solution
specific gravity: not specified, like water
solubility: not specified, aqueous solution
distribution coefficient: not specified
self-ignition point: no self-ignition possible
decomposition temperature: not specified
viscosity: not specified, aqueous solution
explosive properties: none, contains no explosive substances
oxidizing properties: none, contains no oxidizing substances

TMB Substrate, aqueous solution

Appearance: liquid, 12 mL in a PE-bottle, colourless to slight bluish
Odor: no characteristic odour
Odor threshold: not specified
pH-value: 3,6 – 3,8
Melting point/freezing point: 0°C
Boiling point and boiling range: 100°C
Flashpoint: not specified, aqueous solution, contains flammable ingredients just in a small amount
Rate of vaporization: not specified, like water
Inflammability (solid, gaseous): not flammable
Upper/lower inflammability or explosive limit: not explosive
Vapour pressure: not specified, aqueous solution
Vapour density: not specified, aqueous solution
Specific gravity: 1,003 g/ml
Solubility: not specified, aqueous solution
Distribution coefficient: not specified
Self-ignition point: no self-ignition possible
Decomposition temperature: not specified
Viscosity: not specified, aqueous solution
Explosive properties: None. Contains explosive substances just in small amount.
Oxidizing properties: None. Contains oxidizing substances just in small amount.

Stop Solution, aqueous solution

Appearance: liquid, 12 mL in a PE-bottle, transparent
Odour: no characteristic odour
Odour threshold: not specified
pH-value: < pH 3.0
Melting point/freezing point: 0°C
Boiling point and boiling range: 100°C
Flashpoint: not specified, aqueous solution without flammable ingredients
Rate of vaporization: not specified, link water
Inflammability (solid, gaseous): not flammable
Upper/lower inflammability or explosive limit: not explosive
Vapour pressure: not specified, aqueous solution
Vapour density: not specified, aqueous solution
Specific gravity: not specified, like water
Solubility: not specified, aqueous solution
Distribution coefficient: not specified

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 8 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

Self-ignition point:	self-ignition not possible
Decomposition temperature:	not specified
Viscosity:	not specified, aqueous solution
Explosive properties:	None. Concentration undervalued.
Oxidizing properties:	None. Concentration undervalued.

9.2. Further information

All liquid components of the preparation are infinite water-soluble. No potential for the formation of radicals. No 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 current lab conditions. Down below data of the mixture are denoted.

Ingredients	Incompatible material	Hazardous decomposition product
Hydrogen peroxide N-Methyl-2-pyrrolidon	metals, catalysts, light, heat strong oxidant, strong acids	none In case of thermic decomposition carbon oxides (CO and CO ₂) and nitrogen oxides (NO _x) can occur.
5-Bromo-5-Nitro-1,3-Dioxane	strong oxidant	In case of thermic decomposition carbon oxides, nitrogen oxides and bromide can occur.
3,3',5,5'-Tetramethylbenzidin	metals, strong oxidant, strong acid	In case of thermal decomposition carbon oxides and nitrogen oxides can occur.
Sulphuric acid	strong oxidants	In case of thermic decomposition sulphuric oxides can occur.

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

All the components of the preparation do not cause hazardous reactions at all, such as polymerisation.

10.4. Conditions to avoid

Avoid heating over a temperature of 30 °C. Additionally prevent the TMB substrate from direct solar radiation. Accordingly it does not provoke a hazardous reaction, however the product becomes defective.

Under normal conditions of the environment, temperature and pressure all components are stable till the expiration date has passed.

10.5. Incompatible materials

None of the components of the preparation reacts with other materials in that way, that a hazardous situation could arise. Avoid a contact of the TMB substrate solution with heavy metal salts, peroxidases or catalases. It does not provoke a hazardous reaction, however the product becomes defective.

10.6. Hazardous decomposition products

Under normal temperature and storage conditions the components of preparation do not form hazardous decomposition products. The end product of decomposition of the TMB substrate is the yellow diammonium ion of the tetramethyl benzidine. It is a slightly water-soluble and bio-degradable substance, which is not categorised as a hazardous material.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 9 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

SECTION 11. Toxicologic information

11.1. Information about toxicologic effects

The information about the toxicological effects applies to the ingredients of the preparation. The components 3 – 7 of the preparation as a whole is categorised as non-hazardous, because the concentration of the ingredients are very low. The whole preparation, unless otherwise specified, is classified as non-toxic, non-corrosive, non-irritant, non-sensitizing, not carcinogen and not mutagenic.

Acute toxicity

Substance	Acute toxicity / species	concentration
Hydrogen peroxide	LD ₅₀ oral (rat):	1232 mg/kg
	LD ₅₀ dermal (rabbit):	3000 mg/kg
N-Methyl-2-pyrrolidon	LD ₅₀ oral (rat):	3398 mg/kg
	LC ₅₀ inhalative (rat):	> 5,1 mg/l
5-Bromo-5-Nitro-1,3-Dioxane	LD ₅₀ oral (rat):	455 mg/kg
	LD ₅₀ oral (mouse):	590 mg/mg
Sodium chloride	LD ₅₀ oral (rat):	3000 mg/kg
	LD ₅₀ dermal (rabbit):	> 10000 mg/kg
3,3',5,5'-Tetramethylbenzidine	not available	-
Sulfuric acid	LD ₅₀ oral (rat):	2140 mg/kg
Potassium dihydrogene-phosphate	LD ₅₀ skin (rabbit):	> 4640 mg/kg
	LD ₅₀ oral (rat):	> 2000 mg/kg
Sodium chloride	LD ₅₀ oral (rat):	3000 mg/kg
	LD ₅₀ dermal (rabbit):	> 10000 mg/kg

Skin corrosion/irritation:

Component 1 (Stop solution) causes severe skin burns.

Eye irritation:

Component 1 (Stop solution) causes severe eye burns.

Respiratory or skin sensitization:

not expected.

Genetic toxicity:

not expected.

Toxicity to reproduction:

May damage fertility or the unborn child: component 2 (TMB-Substrate), Repr. 1B.

Teratogenicity:

May damage fertility or the unborn child: component 2 (TMB-Substrate), Repr. 1B.

Carcinogenicity (relevant component: 5-Bromo-5-Nitro-1,3-Dioxane):

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.2

Danger of aspiration:

No information available.

If swallowed, contact to skin or eye:

Component 1 (Stop-solution) Causes serious eye- and skin damage.

Component 2 (TMB-substrate) may damage fertility or the unborn child.

SECTION 12. Ecological information

12.1. Toxicity

The TMB substrate solution contains substances that are hazardous to the environment (N-Methyl-2-pyrrolidon). Because of the low concentration an **aquatic toxicity is not to be expected**. Hazardous effects for long term are not to be expected. The other components contain substances with low toxicity only or the concentration of hazardous substances very low and the volumes are low (≤ 100 mL). Environmental toxicity is not expected. The Details of environmental toxicity shown below are valid for the substances in the mixture. Due to the low concentrations of hazardous substances the final mixture is generally recognised as safe.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 10 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

Acute toxicity of the row substances to aquatic organisms:

N-Methyl-2-pyrrolidon

Bluegill	LC ₅₀ (mg/L/96 h) = 832
<i>Leuciscus idus</i>	LC ₅₀ (mg/L/96 h) = > 500
Green algae	IC ₅₀ (mg/L/72 h) = > 500
Invertebrata (<i>Daphnia magna</i>)	EC ₅₀ (mg/L/48 h) = 4897

Potassium dihydrogen phosphate

Fish (<i>Leuciscus idus</i>):	LC ₅₀ (mg/L) = 900
Fish (rainbow trout, <i>Oncorhynchus mykiss</i>)	LC ₅₀ (mg/L) > 100 (96 h)
Mollusca (Zebra mussels)	LC ₅₀ (mg/L) = 92 (72 h)
Mollusca (Corbicula Fluminea)	LC ₅₀ (mg/L) = 2000 (72 h)
Invertebrata (<i>Daphnia magna</i>)	EC ₅₀ (mg/L) > 100 (48 h)

Sodium chloride

Fish (<i>Pimephales promelas</i>):	LC ₅₀ (mg/L) = 7650 (96 h)
Fish (<i>Morone saxatilis</i> - Larven):	LC ₅₀ (mg/L) = 1000
Invertebrata (<i>Daphnia magna</i>)	EC ₅₀ (mg/L) = 1000 (48 h)
Algae (<i>Cypris subglobosa</i>)	EC ₅₀ (mg/L) = 2430
Krustazeeen (<i>Navicula seminulum</i>)	IC ₅₀ (mg/L) = 6870

Sulphuric acid

Fish (<i>Lepomis macrochirus</i>):	LC ₅₀ (mg/L) = 16 - 29 (96 h)
Invertebrata (<i>Daphnia magna</i>)	EC ₅₀ (mg/L) = 20 (24 h)

Chronic toxicity of the row substances to aquatic organisms:

Sodium chloride

Plantae (<i>Lemna minor</i>)	NOEC (mg/L) = 6000
Invertebrata (<i>Daphnia pulex</i>)	NOEC (mg/L) = 3140
Fish (<i>Gambusia holbrooki</i>):	NOEC (mg/L) = 100

Terrestrial environment: nontoxic for plants, animals and earth organisms are expected. No long-lasting hazardous effects on the environment.

12.2. Persistence and degradability

Available information about persistence and degradability of the mixture.

Substance	Ecological details:
Hydrogen peroxide	An enrichment of this chemical in the biosystem is not supposable. Biological degradable.
N-Methyl-2-pyrrolidon	> 90 % / 20 d. Biological degradable.
5-Bromo-5-Nitro-1,3-Dioxan	Not available. Concentration very low ($\leq 0,05$ %).
Sodium chloride	Biological degradable.
3,3',5,5'-Tetramethylbenzidine	Toxic for aquatic organism, May cause long-term adverse effects in the environment. Concentration in the mixture is below 0,25 %.
Sulfuric acid	Concentration in the mixture is below 2 %. Long-term adverse effects in the environment not expected.
Potassium dihydrogenephosphate	Concentration in the mixture is below 0,5 %. Long-term adverse effects in the environment not expected.

12.3. Potential of bioaccumulation

Agents that are hazardous to the environment occur just in a small concentration over the entire preparation. In case of a correct application and disposal there is no reason for potential bioaccumulation. For N-Methyl-2-pyrrolidon: log POW ≤ 4 , no accumulation expected in organism.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 11 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

12.4. Mobility in the ground

There are no data available about the mobility in the ground.

12.5. Result of PBT- and vPvB-assessment

All substances used during the preparation are not listed in the PBT- data base. No data are available concerning the mobility in the ground.

12.6. Other adverse effects

Unknown.

SECTION 13. Disposal considerations

13.1. Waste treatment methods

The disposal has to be done according to current regional, national and local laws and standards.

Relevant legal basic principles for disposal: see 16.2!

Waste production should be avoided or minimised as far as possible.

Excessive and not recyclable products are not allowed to be disposed by an accepted waste disposal company. The disposal of these products as well as solutions and coproducts has to be done at any time according to the environmental requirements, disposal laws and demand of the local administration.

The disposal must not take place in wastewater.

Especial measures of precaution related to the recommended solutions of waste management:

The disposal has to be done according to current regional, national and local laws and standards.

Disposal of the outer packaging: dispose according to current regional, national and local laws and standards.

SECTION 14. Transport remarks

14.1. UN-Number

ADR/RIS: -

IMGD: -

IATA: -

14.2. UN proper shipping name

ADR/RIS: no dangerous goods

IMGD: no dangerous goods

IATA: no dangerous goods

14.3. Transport hazard class

ADR/RIS: -

IMGD: -

IATA: -

14.4. Packing group

ADR/RIS: -

IMGD: -

IATA: -

14.5. Environmental hazards

ADR/RIS: nein

IMGD: Marine pollutant no

IATA: no

14.6. Special precautions for user

None.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not relevant.

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 12 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

SECTION 15. Regulatory information

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

Safety, health and environmental regulations/legislation refer to national rules.

This material data sheet is prepared according to Regulation (EG) 2015/830 Regulation (EU) No. 1272/2008 (+ Subsequent ATPs) and REACH Regulation 1907/2006 EC (+ Subsequent Regulations).

Acute toxicity (ATE) of the mixtures are calculated according to Regulation (EG) 1272/2008, Annex I.

According to EG 1272/2008, Annex I the mixtures are not classified as water polluting substances.

15.2. Chemical safety assessment

For the product which was mentioned in chapter 1 no safety estimation was prepared.

SECTION 16. Other information

16.1 History of modifications

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).

16.2 References and data source:

REACH-Regulation (EG) No. 1907/2006

CLP-Regulation (EG) 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>

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 13 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

<http://echa.europa.eu/de/information-on-chemicals/registered-substances>

<http://www.chemicalbook.com/>

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

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

Arbeitsmaterialien zur ökologischen Entsorgung für Arztpraxen und Weg zur richtigen Entsorgung. Editor:

Ärztchammer Niedersachsen, Authors: Dr. H.-Bernhard Behrends, H. Cremer, Dr. Claus Rink. Web page:

[http://www.aekn.de/web_aekn/home.nsf/ContentView/1E8914148D4E37BFC1256FB70036DAF7/\\$File/arbeitsmaterialien.pdf](http://www.aekn.de/web_aekn/home.nsf/ContentView/1E8914148D4E37BFC1256FB70036DAF7/$File/arbeitsmaterialien.pdf)

16.3 Hazard- and Precautionary rules

The list explains the meaning of the H rules that are given in chapter 3.1. The H rules are valid for the ingredients as a pure substance not for the preparation.

List H rules	Meaning
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H360D	May damage fertility or the unborn child.

The list explains the meaning of the P rules that are given in chapter 3.1. The P rules are valid for the ingredients as a pure substance not for the preparation.

List P rules	Meaning
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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)

	MSDS (Material Safety Data Sheet / Sicherheitsdatenblatt)		DO 619
DO 619 Revision /Fassung Nr.: 2.0	Gültig ab: 03.07.2017	QMH – Abschnitt: 5.5	Seiten: 14 von 14
Ausgefülltes Dokument: Revision /Fassung Nr.: 10.0	Gültig ab: 02.02.2018	Produktname: TUBERKULOSE IgA ELISA	Katalog –Nr.: LIO-TUB02

16.4 Abbreviations

Abbreviations	Meaning
IARC	International Agency for Research on Cancer
ACGIH	American Conference of Governmental Industrial Hygienists
OSHA	Occupational Safety & Health Administration
PBT	persistent, bio accumulative and toxic substances
vPvB	very persistent and very bio accumulative substances
CAS	Chemical Abstracts Service registration number
EC/EG/EWG	European Community
g	Gramme
h	Hour
kg	Kilogramme
LD ₅₀ , LC ₅₀	middle lethal dosis of the agent for 50 % of the observed population
EC ₅₀	half maximal effective concentration (dosis/concentration which induces a response halfway between the baseline and maximum after a specified exposure time)
IC ₅₀	half maximal inhibitory concentration
NOEC	no observed effect level
m ³	cubic metre
MAK	Maximale Arbeitsplatzkonzentration
mg	Milligramme
mL	Milliliter
TMB	Tetramethylbenzidine
%	Percent (part of 100)

16.3 Method which was used to evaluate hazard information for the mixtures

Hazard information's are evaluated according to Regulation (EG) 2015/830 Regulation (EU) No. 1272/2008 (+ Subsequent ATPs) and REACH Regulation 1907/2006 EC (+ Subsequent Regulations).

Method used according to Article 9 of Regulation (EG) No. 1272/2008 for Assessment of Information for Classification of the mixtures: Calculation methods

16.4 Further informations

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The information does not represent any guarantee of the properties of the product.