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: 25.10.2018 Rev. 2

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

1.1. Product identifier: LIOFeron®TB/LTBI; HUMAN BLOOD STIMULATION TUBES (Art.-Nr. LIO-Feron 01_1 / LIO-Feron 01_22)

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 4 components: Positive control tubes, Negative control tubes, TB antigen tubes (Test tube A and Test tube B) as solid components.

1.3. Details of the supplier of the safety data sheet

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1.4. Emergency telephone number

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Hamburg, Niedersachsen und Schleswig-Holstein
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37075 Göttingen **Tel.: .+49(0)0551 / 19240**

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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
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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:
not hazardous for human health or the environment in any way.
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 assesment of the product.

2.2. Label elements

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

3.2. Mixtures

Component 1 – 4 (Positive control tubes, negative control tubes, Test tube A and Test tubes B)
Summary of hazardous substances in the mixture:

Kit component	Designation of substance	CAS No.	EC No.	Concentration in the mixture	H rules	P rules
Positive control tubes, Negative control tubes, TB antigen tubes (Test tube A and Test tube B)	Kaliumdihydrogen phosphate - KH_2PO_4	7778-77-0	231-913-4	≤ 0,2 %	-	P260
	Natriumchlorid - 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 conatminated 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 mouthe by water. Do not induce vomitting. 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.

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 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 (safty 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.

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

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-Substrate
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 (%)
Sodiumum chloride	7647-14-5	231-211-8	not listed	≤ 8 %
Potassium dihydrogen phosphate	7778-77-0	231-913-4	not listed	≤ 0,2 %

***For National exposition limits in other Countries than Germany refere to the corresponding rules!**
BGW by TRGS 903: none.

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.

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

Component 1 – 4 (not hazardous): Positive control tube, negative control tube, tubes with TB antigens (Test tube A and Test tube B)

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.

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. In case of thermic decomposition carbon oxides (CO and CO2) 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 becoms 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.

10.6. Hazardous decomposition products

Under normal temperature and storage conditions the components of preparation do not form hazardous decomposition products.

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
Potassium dihydrogene-phosphate	LD_{50} skin (rabbit): LD_{50} oral (rat):	> 4640 mg/kg > 2000 mg/kg
Sodium chloride	LD_{50} oral (rat): LD_{50} dermal (rabbit):	3000 mg/kg > 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: Not hazardous.

SECTION 12. Ecological information

12.1. Toxicity

The mixture contains hazardous substances only in trace amounts. 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.

Acute toxicity of the row substances to aquatic organisms:
Potassium dihydrogen phosphate

Fish (*Leuciscus idus*):	LC_{50} (mg/L) = 900
Fish (rainbow trout, *Oncorhynchus mykiss*)	LC_{50} (mg/L) > 100 (96 h)
Mullusca (Zebra mussels)	LC_{50} (mg/L) = 92 (72 h)
Mullusca (Corbicula Fluminea)	LC_{50} (mg/L) = 2000 (72 h)
Invertebrata (*Daphnia magna)*	EC_{50} (mg/L) > 100 (48 h)

Sodium chloride

Fish (*Pimephales promelas*):	LC_{50} (mg/L) = 7650 (96 h)

Fish (*Morone saxatilis - Larven*):	LC_{50} (mg/L) = 1000
Invetebrata (*Daphnia magna)*	EC_{50} (mg/L) = 1000 (48 h)
Algae *(Cypris subglobosa)*	EC_{50} (mg/L) = 2430
Krustazeen *(Navicula seminulum)*	IC_{50} (mg/L) = 6870

Chronic toxicity of the row substances to aquatic organisms:
Sodium chloride

Plantae *(Lemna minor)*	NOEC (mg/L) = 6000
Invertebrata (*Daphnia pulex)*	NOEC (mg/L) = 3140
Fish (*Gambusia holbrooki*):	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:
Sodium chloride	Biological degradable.
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.

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.

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 chaper 1 no safty estimation was prepared.

SECTION 16. Other information

16.1 History of modifications
Rev. 1.0 – no modifications, 1st release (23.03.2018)
Rev. 2.0 –1.1: catalogue no. completed and terminology corrected (Tubes instead of vials)
Section 3.1 and 9.1 - terminology corrected (Tubes instead of vials)

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

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

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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
H319	Causes serious eye irritation.

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

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	**5**0 < ATE ≤ 300 (oral in mg/kg body weight)
Categorie 4	**30**0 < ATE ≤ 2000 (oral in mg/kg body weight)

16.4 Abbrevations

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 information

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.