EG 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: 15.03.2023 Rev. 3.0

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 HUMAN IFN-γ. 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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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:
not hazardous for human health or the environment in any way.
As far as known, no hazardous substances are contained in these mixtures.

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!

The mixture does not contain a substance included in the list established in accordance with Article 59(1) because it has endocrine disrupting properties.
PBT: The mixture does not meet the criteria for classification as PBT or vPvB.
Persistence: None.
Bioaccumulation: None.
Toxicity: None.
vPvB: The mixture does not meet the criteria for classification as PBT or vPvB.
Persistence: None.
Bioaccumulation: None.
Toxicity: None.

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
None.

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.

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.

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

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. Solids offered in small quantity / volume.

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. Schutzmaßnahmen unter Abschnitt 7, 8 und 13 beachten.

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.

All components are flammable.

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 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
Special requirements for storage rooms or containers (including containment facilities and Ventilation): No special requirements
Suitable packaging: store in original packaging

7.3. Specific end use(s)

None.

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

8.1. Control parameters

Biological limits according to TRGS 900 and 903: none

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 ≥ 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.

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

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

Physical state:	Solid, commercial test tubes containing Li-Heparin and proteins.
Color*:*	Transparent plastic, with colorful lids (white, black, blue, green).
Odor:	no specific odor
Melting point/freezing point:	not determined
Initial boiling point and boiling range:	Not applicable
Flammability:	flammable in open fire
Lower and upper explosion limit:	Not applicable (Solid material)
Flash point:	Not applicable, Solid material
Ignition temperature:	not determined
Decomposition temperature:	not determined, no self-decomposing mixture
pH-value:	Not applicable
Kinematic viscosity:	Not applicable
Solubility:	Not applicable
Vapor pressure:	Not applicable, Solid material
Relative density:	not determined
Relative vapor density:	Not applicable, Solid material
Particle Properties:	Not applicable, Solid material

9.2. Other information

Information on physical hazard classes
The mixture is not explosive, hardly flammable, is not self-reactive or pyrophoric, oxidizing or corrosive.

Other safety characteristics:
None known (no mechanical sensitivity; self-accelerating polymerization; 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 current lab conditions. In case of thermic decomposition carbon oxides (CO and CO_2) 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.

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 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 no toxic ingredients are contained (see 3.1 and 11.2).

Acute toxicity:	Not expected.
Skin corrosion/irritation:	Not expected.
Serious eye damage/irritation:	Not expected.
Respiratory/skin sensitization:	Not expected.
Germ Cell Mutagenicity:	Not expected.
Carcinogenicity:	Not expected.
Reproductive toxicity:	Not expected.
Specific target organ toxicity (single exposure):	Not expected.
Specific Target Organ Repeated Exposure Toxicity:	Not expected.
Aspiration hazard:	Not expected.

Information on likely routes of exposure:

By ingestion, eye contact or skin contact:	Not expected.
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.

11.2. Information on other hazards
Endocrine disrupting properties: Not expected.
Other information: No data available.

SECTION 12. Ecological information

12.1.
The mixture contains no hazardous substances. **Environmental toxicity is not expected**.
Longer-term adverse effects are not expected. Environmental toxicity is not expected.
The preparation as a whole is classified as non-hazardous.

Acute toxicity of raw materials to environmental organisms:
None - no hazardous ingredients
Chronic toxicity of raw materials to aquatic organisms:
None - no hazardous ingredients

Terrestrial environment: preparation is expected to be non-toxic to plants, animals and terrestrial organisms.

No known long-term effects on the environment. Environmentally harmful substances are not present in the mixture.
No environmental hazard is expected.

12.2. Persistence and degradability
Available information on persistence and degradability: none. No hazardous substances contained.

12.3. Potential of bioaccumulation
Environmentally hazardous substances are not contained in the total preparation. No bioaccumulation potential is expected if used and disposed of properly.

12.4 Mobility in the ground

Not applicable.

12.5. Result of PBT- and vPvB-assessment

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

12.6. Endocrine disrupting properties

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.

SECTION 14: Transport information

14.1. UN-Number

ADR/RIS: - IMGD: - IATA: -

14.2. Proper UN shipping name

ADR/RIS: - IMGD: - IATA: -

14.3. Transport hazard classes

ADR/RIS: - IMGD: - IATA: -

14.4. Packing group

ADR/RIS: - IMGD: - IATA: -

14.5. Environmental hazards

ADR/RIS: - IMGD: - IATA: -

14.6. Special precautions 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 specified Ship type (1, 2 or 3): not specified.

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.

SECTION 16: Other information

16.1 Changes since the last version:

Rev. 1.0 – none, first revision (23.03.2018)

Rev. 2.0 – Section 1.1: Catalogue number completed and terminology of product name corrected (tubes instead of vials).

Rev. 3.0 – 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 sub-chapters updated, Endocrine disrupting properties added, Section 12: Endocrine disrupting properties added, the list of hazardous ingredients updated (no hazardous ingredients, 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/

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: http://www.aekn.de/web_aekn/home.nsf/ContentView/1E8914148D4E37BFC1256FB70036DAF7/$File/arbeitsmaterialien.pdf

16.3 Hazard warnings and safety precautions

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

None. Contains no hazardous substances.

16.4 Legend

Abbreviation	Meaning
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
EC_{50}	half maximal effective concentration (dosis/concentration which induces a response halfway between the baseline and maximum after a specified exposure time)
EmS	Emergency Schedules
ErC50	Effective Concentration 50%, growth rate
GHS	Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
g	gram
h	hour
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
ICAO	International Civil Aviation Organization
IMDG	International Maritime Code for Dangerous Goods
IC_{50}	half maximal inhibitory concentration
kg	kilogram
LC_{50}	Lethal concentration, 50%
LD_{50}	Lethal dose, 50%
LL_{50}	Lethal loading, 50%
MFAG	Medical First Aid Guide
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
NOEC	no observed effect level
PBT	persistent, bioaccumulative and toxic substances
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation and Authorization of Chemicals
SVHC	Substance of Very High Concern
UN	United Nations
OSHA	Occupational Safety & Health Administration
PBT	persistent, bioaccumulative, toxic
RID	Regulations concerning the international carriage of dangerous goods by rail
vPvB	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: not applicable.

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.