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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: 15.03.2023

Rev. 4.0

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

1.1. Product identifier: LIOFeron®TB/LTBI; HUMAN IFN- γ ELISA (Art.-Nr. LIO-Feron 02_22 / LIO-Feron 02_44)

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 8 components: Microtiter plate, Standard (lyophilized), Detection Antibody Solution, Conjugate Solution, Substrate Solution, Stop Solution, Wash Buffer (concentrate) and Incubation Buffer as liquids or solid phase.

1.3. Details of the supplier of the safety data sheet

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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: The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008. The mixture contains 2-pyrrolidone at low concentration (**Repr. 1B, H360** - May damage fertility or the unborn child).

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Other components (Microtiter plate, Standard, Detection antibody, Conjugate, Wash buffer (concentrate) and Incubation buffer): not hazardous for human health or the environment in any way.

2.2. Label elements

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



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



Signalwort: **GEFAHR!**
Gefahrenbestimmende Komponente zur Etikettierung: **TMB-Substrat**

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.

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)

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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 the mixture	H Sätze	P Sätze
Stop solution	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

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 %	H319 H360	P264 P280 P305+P351+P338 P310

Other components: Detection antibody

List of hazardous substances in the mixture:

Kit Component	Substance	CAS No.	EC No.	Concentration in the mixture	H Sätze	P Sätze
Detection antibody solution	Mixture of 5-Chlor-2-methyl-2H-isothiazol-3-on (CMIT) and 2-Methyl-2H-isothiazol-3-on (MIT) in a ratio of 3:1	55965-84-9	247-500-7/ 220-239-6	≤ 0.00112 % M-factor = 100	H301 H310 H314 H317 H330 H410	P261 P264 P273 P280 P302 + P352 P305 + P351 + P338

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.

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.

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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.


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.

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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: No dangerous effects known

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 the original packaging

7.3. Specific end use(s)

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

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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 %
CMIT/MIT	55965-84-9	247-500-7/ 220-239-6	0.2 mg/m ³	≤ 0.0014 %

* 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 ≥ 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 phase, common used 96 well microtiterplate with individual breakable wells, sealed in aluminum foil in combination with desiccant bag
Color:	Transparent plastic, in silver aluminium bag
Odor:	no typical 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
Flash point:	not applicable
Ignition temperature:	not determined
Decomposition temperature:	not determined, not a self-decomposing mixture
pH-value:	not applicable
Kinematic viscosity:	not applicable
Solubility:	not applicable
Vapor pressure:	not applicable
Relative density:	not determined
Relative vapor density:	not applicable
Particle Properties:	not applicable

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Standard (dried)


Physical state:	solid phase, Dried protein in screw cap container
Color:	plastic tube
Odor:	no typical 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
Flash point:	not applicable
Ignition temperature:	not determined
Decomposition temperature:	not determined, not a self-decomposing mixture
pH-value:	not applicable
Kinematic viscosity:	not applicable
Solubility:	not applicable
Vapor pressure:	not applicable
Relative density:	not determined
Relative vapor density:	not applicable
Particle Properties:	not applicable

Incubation buffer, conjugate solution, detection antibody solution and wash buffer (concentrate), 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/cm ³ , experimental data
Relative vapor density:	not determined
Particle Properties:	not applicable

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Stop solution, aqueous solutions

Physical state:	liquid
Color:	colourless
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:	< pH 0.1 (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

9.2. Other information

Information on physical hazard classes

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

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 (NO _x), Carbon monoxide (CO), Carbon dioxide (CO ₂)
Sulfuric acid	strong Oxidans	Thermal decomposition can result in the formation of sulphur oxides.
CMIT / MIT	Oxidans, Amine, Mercaptane	Thermal decomposition can result in the formation of Reducing agents, Nitrogen oxides (NO _x), sulphur Oxides and Hydrogen chloride

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.

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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.

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 Toxicity:	Not expected
Aspiration hazard:	No Information available

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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

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 (≤ 100 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 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 and cyanobacteria:	EC50 (72 h) 500 mg/L 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 (<i>Lepomis macrochirus</i>):	LC50 (mg/L) = 16 - 29 (96 h)
Invertebrata (<i>Daphnia magna</i>):	EC50 (mg/L) = 20 (24 h)

CMIT/MIT

Fish:	LC ₅₀ (mg/L) = 0,019 – 2,13 (96 h)
Invertebrata (<i>Crustacea</i>):	EC ₅₀ (mg/L) = 0,056 - 18 (48 h)
Algae:	EC ₅₀ (mg/L) = 0,06 - 0,13 (72 / 96 h)

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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 (≤ 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.
CMIT/MIT	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Concentration is less than 0.002 % in the preparation.

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

For CMIT (methylchloroisothiazolinones): log POW = $0.401 (24^{\circ}\text{C}) \leq 4$, no accumulation in organisms expected.

For MIT (methylisothiazolinones): log POW = $-0.83 \leq 4$, no accumulation in organisms to be expected.

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 exposure	For workers	General population
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 $\mu\text{g}/\text{kg}$ bw/day
Oral	Not available	Long Term: (DNEL) 670 $\mu\text{g}/\text{kg}$ 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

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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 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

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- "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 – no modifications, 1st release (23.03.2018)

Rev. 2.0 –1.1: catalogue no. completed / Section 3.2, Section 8.1, Section 10.1, Section 11.1, Section 12.1 – 12.3:

Information about new ingredients completed (modification of buffer composition of the detection antibody: new ingredients CMIT/MIT and NaOH)

Section 9.1 – corrected, volumes adapted to kit format

Section 16.1 – source of information completed

Section 16.3 – declarations of H- and P-rules completed

Rev. 3.0 –1.2: detection of HUMAN IFN- γ instead of human antibodies.

Rev. 4.0 - 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 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>

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

<http://www.reach-clp-biozid-helppdesk.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: 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](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:


List H-phrases	Meaning
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H360	May damage fertility or the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

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
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face 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.
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)

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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 navigation intérieures)
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

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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.