BIOTECHNIK

Safety data sheet

According to COMMISSION REGULATION (EU) 2020/878

1218 - Tris base *omni RTECS: TY2900000

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier: 1218 - Tris base *omni 1.1

RTECS: TY2900000

Trometamol

CAS: 77-86-1 201-064-4 FC: Index: Not relevant

REACH: 01-2119957659-16-XXXX

Other means of identification:

Not relevant

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

Relevant uses (Professional users): For use in laboratory and production. Not for human or animal use.

For Professional users only.

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

> GERBU Biotechnik GmbH 69123 Heidelberg - Germany Phone: +49 6221 7264167 safety@gerbu.de www.gerbu.de

1.4 Emergency telephone number: Eire: 01809 2566

Emergency call (EU): 112

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) No 1272/2008:

The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

None

2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Chemical substance

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification			Chemical name/Classification	Concentration
CAS:	77-86-1	Trometamol	Not classified	
Index:	201-064-4 Not relevant 1: 01-2119957659-16- XXXX	Regulation 1272/2008		75 - <100 %

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

3.2 Mixture:

Not relevant

SECTION 4: FIRST AID MEASURES

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SECTION 4: FIRST AID MEASURES (continued)

Description of first aid measures:

Consult a doctor in case of discomfort showing the SDS for the product.

By inhalation:

In case of symptoms, move the person affected into fresh air.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

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SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Minimum Temp.:

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be assessed in the workplace:

Nuisance dust: Inhalable dust 10 mg/m3 // Respirable dust 4 mg/m3

DNEL (Workers):

		Short exposure		Long exposure	
Identification		Systemic	Local	Systemic	Local
Trometamol	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 77-86-1	Dermal	Not relevant	Not relevant	166,7 mg/kg	Not relevant
EC: 201-064-4	Inhalation	Not relevant	Not relevant	117,5 mg/m³	Not relevant

DNEL (General population):

		Short exposure		Long exposure	
Identification		Systemic	Local	Systemic	Local
Trometamol	Oral	Not relevant	Not relevant	8,3 mg/kg	Not relevant
CAS: 77-86-1	Dermal	Not relevant	Not relevant	83,3 mg/kg	Not relevant
EC: 201-064-4	Inhalation	Not relevant	Not relevant	29 mg/m³	Not relevant

PNEC:

	Identification				
Trometamol		STP	300 mg/L	Fresh water	Not relevant
CAS: 77-86-1		Soil	Not relevant	Marine water	Not relevant
EC: 201-064-4		Intermittent	Not relevant	Sediment (Fresh water)	Not relevant
		Oral	Not relevant	Sediment (Marine water)	Not relevant

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

If the working conditions and/or safety measures adopted do not allow keeping the airborne concentration of the product below the exposure limits (if any) or at acceptable levels (if no exposure limits exist), suitable respiratory protection equipment chosen by a qualified professional should be used.

C.- Specific protection for the hands

Not relevant

D.- Eye and face protection

Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

It is not necessary to take additional emergency measures.

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply): 0 % weight
V.O.C. density at 20 °C: 0 kg/m³ (0 g/L)
Average carbon number: Not relevant
Average molecular weight: Not relevant

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Solid

Appearance: Crystalline

Colour: White

Odour: Not relevant *
Odour threshold: Not relevant *

Volatility:

Boiling point at atmospheric pressure:

Vapour pressure at 20 °C:

Vapour pressure at 50 °C:

Not relevant *

Not relevant *

Not relevant *

Evaporation rate at 20 °C:

Not relevant *

Product description:

Density at 20 °C: 1320 kg/m³
Relative density at 20 °C: 1,32

Dynamic viscosity at 20 °C: Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

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169 ºC

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Kinematic viscosity at 20 ºC: Not relevant * Kinematic viscosity at 40 °C: Not relevant * Concentration: Not relevant * pH: 10,4 (at 1 %) Vapour density at 20 ºC: Not relevant 3 Partition coefficient n-octanol/water 20 ºC: Not relevant * Solubility in water at 20 °C: 800 kg/m³ Solubility properties: Not relevant * Not relevant * Decomposition temperature:

Flammability:

Melting point/freezing point:

Flash Point:

Flammability (solid, gas):

Autoignition temperature:

Lower flammability limit:

Upper flammability limit:

Not relevant *

Not relevant *

Not relevant *

Explosive (Solid):

Lower explosive limit:

Upper explosive limit:

Not relevant *

Not relevant *

Particle characteristics:

Median equivalent diameter: Not relevant *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:

Oxidising properties:

Not relevant *

Corrosive to metals:

Heat of combustion:

Aerosols-total percentage (by mass) of flammable components:

Not relevant *

Other safety characteristics:

Surface tension at 20 $^{\circ}$ C: Not relevant * Refraction index: Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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SECTION 10: STABILITY AND REACTIVITY (continued)

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

- A- Ingestion (acute effect):
 - Acute toxicity: Based on available data, the classification criteria are not met
 - Corrosivity/Irritability: Based on available data, the classification criteria are not met
- B- Inhalation (acute effect):
 - Acute toxicity: Based on available data, the classification criteria are not met
 - Corrosivity/Irritability: Based on available data, the classification criteria are not met
- C- Contact with the skin and the eyes (acute effect):
 - Contact with the skin: Based on available data, the classification criteria are not met
 - Contact with the eyes: Based on available data, the classification criteria are not met
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
 - Carcinogenicity: Based on available data, the classification criteria are not met IARC: Not relevant
 - Mutagenicity: Based on available data, the classification criteria are not met
 - Reproductive toxicity: Based on available data, the classification criteria are not met
- E- Sensitizing effects:
 - Respiratory: Based on available data, the classification criteria are not met
 - Skin: Based on available data, the classification criteria are not met
- F- Specific target organ toxicity (STOT) single exposure:

Based on available data, the classification criteria are not met

- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
 - Skin: Based on available data, the classification criteria are not met
- H- Aspiration hazard:

Based on available data, the classification criteria are not met

Other information:

Not relevant

Product-specific toxicological information:

	Acute toxicity	Genus		
LD50 oral	5800 mg/kg	Rat		

Specific toxicology information on the substances:

Not relevant

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met

12.1 Toxicity:

Not relevant

12.2 Persistence and degradability:

Not relevant

12.3 Bioaccumulative potential:

Not relevant

12.4 Mobility in soil:

Not relevant

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Type of waste (Regulation (EU) No 1357/2014):

Not relevant

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC, The Waste Regulations 2011, 2011 No. 988). As under 15 01 (2014/955/EU) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant

- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

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SECTION 15: REGULATORY INFORMATION (continued)

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Not relevant

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009), SI 2009 No 1348

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, 2011 No. 1885

Control of Substances Hazardous to Health Regulations 2002 (as amended)

EH40/2005 Workplace exposure limits

The Waste Regulations 2011, 2011 No. 988

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

COMMISSION REGULATION (EU) 2020/878

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Not relevant

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://echa.europa.eu

http://eur-lex.europa.eu

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

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The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

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