

Kit SDS Cover Sheet

KGM-2 Bullet Kit

Version 3.0

Revision Date 16.12.2021

Print Date 08.11.2022

Product Information

Product name : KGM-2 Bullet Kit

Material number : CC-3107

Components

| | |
|--|--------------|
| KBM-2 Basal Medium | SDS attached |
| CC-4152 KGM-2 SingleQuot Kit Suppl&Growth Factor | |
| BPE Low Protein - non specific | SDS attached |
| HEGF FOR USE IN KGM-2 KIT | SDS attached |
| Recombinant human insulin 0.5% | SDS attached |
| Hydrocortisone solution | SDS attached |
| Transferrin | SDS attached |
| Epinephrine | SDS attached |
| GA-1000 | SDS attached |

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : KBM-2 Basal Medium

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

Use of the Substance/Mixture : For Research Use Only. Not for use in diagnostic procedures.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

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practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : red

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| | | |
|--|---|-------------------|
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | 7,25 - 7,65 |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

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STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according

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to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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RID : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class** : Not applicable
 14.4 **Packing group** : Not applicable
 14.5 **Environmental hazards** : no

DOT : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class** : Not applicable
 14.4 **Packing group** : Not applicable
 14.5 **Environmental hazards** : no

TDG : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class** : Not applicable
 14.4 **Packing group** : Not applicable
 14.5 **Environmental hazards** : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex : Not applicable

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XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL -

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Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : Hydrocortisone solution

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Flammable liquids, Category 2 H225: Highly flammable liquid and vapour.
Eye irritation, Category 2 H319: Causes serious eye irritation.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

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| | | |
|--------------------------|---|---|
| Hazard pictograms | : |   |
| Signal word | : | Danger |
| Hazard statements | : | H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. |
| Precautionary statements | : | Prevention: P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/ eye protection/ face protection. Response: P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P337 + P313 If eye irritation persists: Get medical advice/ attention. P370 + P378 In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish. |

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. REACH Registration Number | Classification | Concentration (% w/w) |
|---------------|--|--------------------|--------------------------|
| Ethanol | 64-17-5 | Flam. Liq. 2; H225 | >= 90 - <= 100 |

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| | | | |
|--|--|---|--|
| | 200-578-6 603-002-00-5 01-2119457610-43-XX XX | Eye Irrit. 2; H319 specific concentration limit 2A; H319 > 50 % | |
|--|--|---|--|

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- If inhaled : Remove to fresh air.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Consult a physician.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Call a physician immediately.
- If swallowed : If accidentally swallowed obtain immediate medical attention.
Clean mouth with water and drink afterwards plenty of water.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Dry powder
Water spray
Foam

5.2 Special hazards arising from the substance or mixture

- Hazardous combustion products : Carbon oxides (Cox)

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5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use respirator when performing operations involving potential exposure to vapour of the product.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms. Avoid contact with skin and eyes.

Advice on protection against fire and explosion : Highly flammable. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

Hygiene measures : Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep away from sources of ignition - No smoking. Keep containers tightly closed in a cool, well-ventilated place.

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Switzerland

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|-------|
| Ethanol | 64-17-5 | TWA | 500 ppm 960 mg/m ³ | SMAK |
| | | STEL | 1 000 ppm 1 920 mg/m ³ | SMAK |

Germany

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---------|---|----------------------------------|----------|
| Ethanol | 64-17-5 | MAK | 200 ppm 380 mg/m ³ | DFG MAK |
| Peak-limit: excursion factor (category) | | Peak-limit: excursion factor (category) 4 | | |
| | | | 200 ppm 380 mg/m ³ | TRGS 900 |
| Peak-limit: excursion factor (category) | | Peak-limit: excursion factor (category) 4 | | |

Belgium

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|--------|
| Ethanol | 64-17-5 | TWA | 1 000 ppm 1 907 mg/m ³ | BE/OEL |

Denmark

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|---------|
| Ethanol | 64-17-5 | GV | 1 000 ppm 1 900 mg/m ³ | GV (DK) |

France

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|-------|
| Ethanol | 64-17-5 | VME | 1 000 ppm 1 900 mg/m ³ | FVL |
| | | VLE | 5 000 ppm 9 500 mg/m ³ | FVL |

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Italy

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------|----------|
| Ethanol | 64-17-5 | STEL | 1 000 ppm | OEL (IT) |

Netherlands

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------|---------|-------------------------------|-------------------------|--------|
| Ethanol | 64-17-5 | TGG | 260 mg/m ³ | NL OEL |
| Further information | | Effective date: 01 Oct 2008 | | |
| | | TGG 15 | 1 900 mg/m ³ | NL OEL |
| Further information | | Effective date: 01 Oct 2008 | | |

Spain

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|-------|
| Ethanol | 64-17-5 | STEL | 1 000 ppm 1 910 mg/m ³ | VLA |

Sweden

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|-------|
| Ethanol | 64-17-5 | TWA | 500 ppm 1 000 mg/m ³ | SWO |
| | | STEL | 1 000 ppm 1 900 mg/m ³ | SWO |

United Kingdom

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|------------|---------|-------------------------------|--------------------------------------|----------|
| Ethanol | 64-17-5 | TWA | 1 000 ppm 1 920 mg/m ³ | EH40 WEL |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|-----------|-----------------|----------------------------|-----------------------|
| Ethanol | Consumers | Oral | Long-term systemic effects | 87 mg/kg |
| | Consumers | Dermal | Long-term systemic effects | 206 mg/kg |
| | Consumers | Inhalation | Long-term systemic effects | 114 mg/m ³ |
| | Workers | Inhalation | Long-term systemic effects | 950 mg/m ³ |
| | Workers | Dermal | Long-term systemic effects | 343 mg/kg |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-----------|
| Ethanol | Fresh water | 0,96 mg/l |

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| | | |
|--|------------------------|------------|
| | Soil | 0,63 mg/kg |
| | Fresh water sediment | 3,6 mg/kg |
| | Marine water | 0,79 mg/l |
| | Sewage treatment plant | 580 mg/l |
| | Marine sediment | 2,9 mg/kg |
| | Oral | 380 mg/kg |

8.2 Exposure controls**Engineering measures**

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection

: In the case of vapour formation use a respirator with an approved filter.

Respirator with a vapour filter (EN 141)

Respirator with ABEK filter.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Colour : colourless

Odour : alcohol-like

Melting point/freezing point : -114,5 - -114 °C

Information refers to the main component.

Initial boiling point and boiling range : 78 °C Information refers to the main component.

Flammability : no data available

Upper explosion limit / upper

flammability limit

: 15,0 %(V)
Information refers to the main component.

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| | | |
|--|---|---|
| Lower explosion limit / Lower flammability limit | : | 3,5 %(V) Information refers to the main component. |
| Flash point | : | 12 °C Information refers to the main component. |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity | | |
| Viscosity, dynamic | : | 1,17 - 1,2 mPa.s (20 °C) |
| Solubility(ies) | | |
| Water solubility | : | completely miscible |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | 0,79 g/cm ³ (20 °C) |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : Keep away from heat and sources of ignition.

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10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****11.2 Information on other hazards****Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

The following toxicological data refer to:**Ethanol** (CAS-No.: 64-17-5)**Acute toxicity**

Acute oral toxicity : LD50 (Rat): > 5 000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 403

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritationSpecies: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation**Serious eye damage/eye irritation**Species: Rabbit
Assessment: Mild eye irritation
Result: Moderate eye irritation

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Respiratory or skin sensitisationExposure routes: Dermal
Species: Mouse
Result: not sensitizing**Germ cell mutagenicity**Genotoxicity in vitro : Test Type: Ames test
Result: negative
: Test Type: gene mutation test
Species: mouse lymphoma cells
Result: negative**Reproductive toxicity**Effects on fertility : Remarks: no data available
Species: Mouse
Application Route: Oral
Method: OECD Test Guideline 416**Repeated dose toxicity**Species: Rat, male and female
NOAEL: 1 730 mg/kg
LOAEL: 3 200 mg/kg
Application Route: Oral
Exposure time: 14 Weeks

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

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12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.
Contact waste disposal services.

Contaminated packaging : Dispose of as unused product.

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SECTION 14: Transport information**IATA**

14.1 **UN number** : 1170
14.2 **Proper shipping name** : Ethanol solution
14.3 **Transport hazard class** : 3
14.4 **Packing group** : II
Labels : 3
14.5 **Environmental hazards** : no

IMDG-CODE

14.1 **UN number** : 1170
14.2 **Proper shipping name** : Ethanol solution
14.3 **Transport hazard class** : 3
14.4 **Packing group** : II
Labels : 3
EmS Number 1 : F-E
EmS Number 2 : S-D
14.5 **Environmental hazards** : Marine pollutant: no

ADR

14.1 **UN number** : 1170
14.2 **Proper shipping name** : ETHANOL SOLUTION
14.3 **Transport hazard class** : 3
14.4 **Packing group** : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
14.5 **Environmental hazards** : no

RID

14.1 **UN number** : 1170
14.2 **Proper shipping name** : ETHANOL SOLUTION
14.3 **Transport hazard class** : 3
14.4 **Packing group** : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
14.5 **Environmental hazards** : no

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DOT

| | | | |
|------|-------------------------------------|---|-------------------|
| 14.1 | UN number | : | 1170 |
| 14.2 | Proper shipping name | : | Ethanol solutions |
| 14.3 | Transport hazard class | : | 3 |
| 14.4 | Packing group | : | II |
| | Labels | : | 3 |
| | Emergency Response Guidebook Number | : | 127 |
| 14.5 | Environmental hazards | : | no |

TDG

| | | | |
|------|------------------------|---|------------------|
| 14.1 | UN number | : | 1170 |
| 14.2 | Proper shipping name | : | ETHANOL SOLUTION |
| 14.3 | Transport hazard class | : | 3 |
| 14.4 | Packing group | : | II |
| | Labels | : | 3 |
| 14.5 | Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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Regulation (EU) 2019/1021 on persistent organic pollutants (recast) Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

| | | | |
|-----|-------------------|-----------------------|------------------------|
| P5c | FLAMMABLE LIQUIDS | Quantity 1 5 000 t | Quantity 2 50 000 t |
|-----|-------------------|-----------------------|------------------------|

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Code Number: 96
Remarks: Classification according to AwSV, Annex 1 (4)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Classification of the mixture:

Flam. Liq. 2 H225
Eye Irrit. 2 H319

Classification procedure:

Based on product data or assessment
Calculation method

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous

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Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

99 / EN

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : GA-1000

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

: Danger

Hazard statements

: H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

: **Prevention:**

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

P280 Wear protective gloves.

P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Gentamicin, sulfate (salt)

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. | Classification | Concentration |
|---------------|---------|----------------|---------------|
|---------------|---------|----------------|---------------|

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| | EC-No. Index-No. REACH Registration Number | | (% w/w) |
|----------------------------|---|---|------------|
| Gentamicin, sulfate (salt) | 1405-41-0 | Resp. Sens. 1; H334 Skin Sens. 1; H317 | >= 3 - < 5 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : Move to fresh air.
Call a physician immediately.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Wash clothing before reuse.
Get medical attention if irritation develops and persists.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give plenty of water (if possible charcoal slurry).
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Allergic appearance
sensitising effects

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Not combustible.

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Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use respirator when performing operations involving potential exposure to vapour of the product.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : In case of insufficient ventilation, wear suitable respiratory equipment.
Avoid exposure - obtain special instructions before use.
Use only in area provided with appropriate exhaust ventilation.
Avoid contact with skin and eyes.

Advice on protection against fire and explosion : Stable under normal conditions.

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Hygiene measures : DANGER! Avoid contact with the skin and the eyes. Avoid breathing dust or spray mist. Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep frozen or refrigerated.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Eye protection : Safety glasses
Safety goggles

Hand protection

Material : Nitrile rubber
Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Complete suit protecting against chemicals

Respiratory protection : In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.

Respirator with ABEK filter.
Respirator with combination filter for vapour/particulate (EN 141)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

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| | | |
|--|---|------------------------------|
| Physical state | : | liquid |
| Appearance | : | Aqueous solution |
| Colour | : | light yellow |
| Odour | : | odourless |
| Melting point/freezing point | : | 0 °C |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | Does not sustain combustion. |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity | : | no data available |
| Solubility(ies) Water solubility | : | soluble |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

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SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition productsNo decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****11.2 Information on other hazards****Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further informationRemarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

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12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Dispose of as unused product.

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SECTION 14: Transport information**IATA** Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

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15.2 Chemical safety assessment

not required

SECTION 16: Other information**Classification of the mixture:**

Resp. Sens. 1 H334

Skin Sens. 1 H317

Classification procedure:

Calculation method

Calculation method

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Full text of other abbreviations

Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations;

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VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : Recombinant human insulin 0.5%

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheetCompany : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11**Lonza Verviers Sprl**
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611**Lonza Cologne GmbH**
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990**Lonza Copenhagen ApS**
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Insulin: may cause hypoglycaemia.

Insulin is inactivated in the gastro-intestinal tract when ingested.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : No special precautions required.
- In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Dispose of in accordance with local regulations.

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : No special precautions required.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Use only in area provided with appropriate exhaust ventilation.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : colourless

Odour : odourless

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| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | Water |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | 2 - 4 |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | completely soluble |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

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10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Assessment: No skin irritation

Serious eye damage/eye irritation

Assessment: No eye irritation

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

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Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

Remarks: Insulin: may cause hypoglycaemia. Insulin is inactivated in the gastro-intestinal tract when ingested.

May cause central nervous system depression.

May induce sweating, pallor or visual disturbances.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Contact waste disposal services.
Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

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|------------------------------------|---|---------------------|
| ADR | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : nwg not water endangering
Remarks: Classification according to AwSV, Annex 1 (4)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test

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population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : HEGF FOR USE IN KGM-2 KIT

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheetCompany : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11**Lonza Verviers Sprl**
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611**Lonza Cologne GmbH**
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990**Lonza Copenhagen ApS**
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

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practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : no data available

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| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

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STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according

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to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex : Not applicable

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XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL -

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Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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Transferrin

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : Transferrin

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : No special precautions required.
- In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

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practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : no data available

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| | | |
|--|---|-------------------|
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

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STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according

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to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex : Not applicable

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XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : nwg not water endangering
Remarks: Classification according to AwSV, Annex 1 (2.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL -

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Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Epinephrine

Version 3.0

Revision Date 16.12.2021

Print Date 08.11.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : Epinephrine

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheetCompany : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11**Lonza Verviers Sprl**
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611**Lonza Cologne GmbH**
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990**Lonza Copenhagen ApS**
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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Epinephrine

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

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practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : no data available

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| | | |
|--|---|-------------------|
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

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STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according

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to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex : Not applicable

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XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL -

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Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : BPE Low Protein - non specific

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheetCompany : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11**Lonza Verviers Sprl**
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611**Lonza Cologne GmbH**
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990**Lonza Copenhagen ApS**
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : No special precautions required.
- In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

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practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : no data available

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| | | |
|--|---|-------------------|
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

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STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according

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to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex) : Not applicable

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XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : nwg not water endangering
Remarks: Classification according to AwSV, Annex 1 (2.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL -

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according to Regulation (EC) No. 1907/2006

BPE Low Protein - non specific

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Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

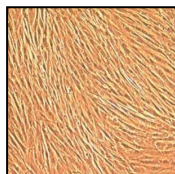
Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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Clonetics™ Lung Fibroblast Cell Systems

NHLF & DHLF

Table of Contents:

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I. Introduction

Clonetics™ Lung Fibroblast Cell Systems contain Normal Human Lung Fibroblasts (NHLF) or Diseased Human Lung Fibroblasts (DHLF) and optimized medium for their growth. Each System can quickly generate NHLF or DHLF cultures for the study of stimulation and response in pulmonary inflammation and fibrosis in normal or diseased cells. Clonetics™ Lung Fibroblast Cell Systems are convenient and easy to use, allowing the researcher to focus on results. There are four types of DHLF available: cells isolated from donors with cystic fibrosis, asthma, COPD, and idiopathic pulmonary fibrosis (iPF). Cryopreserved NHLF and DHLF are shipped second passage. Proliferating NHLF and DHLF are shipped as third passage cultures.

Clonetics™ Cells, Medium and Reagents are quality tested together and guaranteed to give optimum performance as a complete “cell system”.

II. Cell System Components (need to be purchased separately)

- One Lung Fibroblast Cell Product – Normal or Diseased (Cryopreserved or Proliferating)

- One Fibroblast Cell Medium BulletKit™ - 500 ml
- Clonetics™ FGM™ -2 BulletKit™ (CC-3132) contains one 500 ml bottle of Fibroblast Cell Basal Medium and the following growth supplements: hFGF-B, 0.5 ml; Insulin, 0.5 ml; FBS, 10 ml; GA-1000, 0.5 ml.
- One ReagentPack™ (CC-5034) containing:

| | |
|--------------------------------|--------|
| Trypsin/EDTA | 100 ml |
| Trypsin Neutralizing Solution | 100 ml |
| HEPES Buffered Saline Solution | 100 ml |

III. Characterization of Cells

Routine characterization of NHLF and DHLF includes morphological observation throughout serial passages. Cells stain negative for smooth muscle α -actin, cytokeratin 18, cytokeratin 19 and von Willebrand (Factor VIII).

IV. Performance

| | |
|---|--|
| Recommended seeding density for subculture | 2,500 cells/cm ² |
| Typical time from subculture to confluent monolayer | 6 - 9 days |
| NHLF additional population doublings guaranteed using Clonetics™ System | 15 |
| DHLF additional population doublings guaranteed using Clonetics™ System | Tested through 3 passages for information only |

V. Quality Control

All cells are performance assayed and tested for HIV-1, Hepatitis-B, Hepatitis-C, mycoplasma, bacteria, yeast and fungi. Cell viability, morphology and proliferative capacity are measured after

recovery from cryopreservation. Clonetics™ Media are formulated for optimal growth of specific types of normal human cells. Certificates of Analysis (COA) for each cell strain are shipped with each order. COAs for all other products are available upon request.

VI. Ordering Information

Cryopreserved Cells

| Cat. No. | Product | Size |
|----------|---------------------------|-----------------|
| CC-2512 | NHLF | ≥ 500,000 cells |
| 00194843 | DHLF-CF (cystic fibrosis) | ≥ 500,000 cells |
| 00194912 | DHLF-AS (asthma) | ≥ 500,000 cells |
| 0195277 | DHLF-COPD | ≥ 500,000 cells |
| CC-7231 | DHLF-iPF | ≥ 500,000 cells |

Proliferating formats are available. Refer to the Lonza website or contact Scientific Support for details.

| Cat. No. | Product | Size |
|----------|---|--------|
| CC-3132 | FGM -2™ BulletKit, FBM™ Plus SingleQuots™ of Growth Supplements | 500 ml |
| CC-3131 | FBM™, Fibroblast Basal Medium | 500 ml |
| CC-4126 | FGM -2 SingleQuots™ Formulates FBM™ to FGM™ -2 | |
| CC-5034 | ReagentPack™ | |
| | Trypsin/EDTA Solution | 100 ml |
| | Trypsin Neutralizing Solution | 100 ml |
| | HEPES Buffered Saline Solution | 100 ml |

When placing an order or for Scientific Support, please refer to the product numbers and descriptions listed above. For a complete listing of all Clonetics™ Products, refer to the Lonza website or the current Lonza catalog. To obtain a catalog, additional information or Scientific Support you may contact Lonza by web, e-mail, telephone, fax or mail.

VII. Product Warranty

CULTURES HAVE A FINITE LIFESPAN *IN VITRO*. Lonza guarantees the performance of its cells only if Clonetics™ Media and Reagents are used exclusively, and the recommend protocols are followed. The performance of cells is not guaranteed if any modifications are made to the complete Cell System. Cryopreserved NHLF and DHLF are assured to be viable and functional when thawed and maintained properly.

THESE PRODUCTS ARE FOR RESEARCH USE ONLY. Not approved for human or veterinary use, for application to humans or animals, or for use in clinical or *in vitro* procedures.

WARNING: CLONETICS™ AND POIETICS™ PRODUCTS CONTAIN HUMAN SOURCE MATERIAL, TREAT AS POTENTIALLY INFECTIOUS. Each donor is tested and found non-reactive by an FDA approved method for the presence of HIV-1, Hepatitis B Virus and Hepatitis C Virus. Where donor testing is not possible, cell products are tested for the presence of viral nucleic acid from HIV, Hepatitis B Virus, and Hepatitis C Virus. Testing can not offer complete assurance that HIV-1, Hepatitis B Virus, and Hepatitis C Virus are absent. All human sourced products should be handled at the Biological Safety Level 2 to minimize exposure of potentially infectious products, as recommended in the CDC-NIH Manual, [Biosafety in Microbiological and Biomedical Laboratories](#), 5th Edition. If you require further information, please contact your site Safety Officer or Scientific Support.

All trademarks herein are marks of Lonza Groups or its subsidiaries.

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according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 3.0

Revision Date 11.12.2021

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : FBM Basal Medium

Material number : CC-3131

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

Use of the Substance/Mixture : For Research Use Only. Not for use in diagnostic procedures.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

FBM Basal Medium

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

FBM Basal Medium

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Use water spray to cool unopened containers.
-

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

- Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

- Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

- For personal protection see section 8.
-

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Advice on safe handling : No special precautions required.
- Advice on protection against fire and explosion : Take precautionary measures against static discharges.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

- Specific use(s) : No information available.

FBM Basal Medium

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

| | | |
|--------------------------|---|--|
| Eye protection | : | Tightly fitting safety goggles |
| Hand protection | | |
| Material | : | Nitrile rubber |
| Rate of permeability | : | > 480 min |
| Skin and body protection | : | Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required. |
| Respiratory protection | : | No personal respiratory protective equipment normally required. |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|--|---|-------------------|
| Physical state | : | liquid |
| Appearance | : | Aqueous solution |
| Colour | : | red |
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |

FBM Basal Medium

| | |
|--|---------------------|
| Decomposition temperature | |
| Decomposition temperature | : no data available |
| pH | : 7,4 - 7,7 |
| Viscosity | |
| Viscosity, kinematic | : no data available |
| Solubility(ies) | |
| Water solubility | : no data available |
| Partition coefficient: n-octanol/water | : no data available |
| Vapour pressure | : no data available |
| Relative density | : no data available |
| Density | : no data available |
| Relative vapour density | : no data available |
| Particle characteristics | : no data available |

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

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Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

Aspiration toxicity

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

FBM Basal Medium

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Additional ecological information : no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

IMDG-CODE : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : Marine pollutant: no

FBM Basal Medium

ADR : Not dangerous goods

- 14.1 **UN number** : Not applicable
- 14.2 **Proper shipping name** : Not applicable
- 14.3 **Transport hazard class** : Not applicable
- 14.4 **Packing group** : Not applicable
- 14.5 **Environmental hazards** : no

RID : Not dangerous goods

- 14.1 **UN number** : Not applicable
- 14.2 **Proper shipping name** : Not applicable
- 14.3 **Transport hazard class** : Not applicable
- 14.4 **Packing group** : Not applicable
- 14.5 **Environmental hazards** : no

DOT : Not dangerous goods

- 14.1 **UN number** : Not applicable
- 14.2 **Proper shipping name** : Not applicable
- 14.3 **Transport hazard class** : Not applicable
- 14.4 **Packing group** : Not applicable
- 14.5 **Environmental hazards** : no

TDG : Not dangerous goods

- 14.1 **UN number** : Not applicable
- 14.2 **Proper shipping name** : Not applicable
- 14.3 **Transport hazard class** : Not applicable
- 14.4 **Packing group** : Not applicable
- 14.5 **Environmental hazards** : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

FBM Basal Medium

| | |
|---|----------------|
| REACH - List of substances subject to authorisation (Annex XIV) | Not applicable |
|---|----------------|

| | |
|---|----------------|
| Regulation (EC) No 1005/2009 on substances that deplete the ozone layer | Not applicable |
|---|----------------|

| | |
|---|----------------|
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | Not applicable |
|---|----------------|

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

FBM Basal Medium**SECTION 16: Other information****Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Kit SDS Cover Sheet

FGM® 2 SingleQuots®

Version 3.0

Revision Date 16.12.2021

Print Date 09.11.2022

Product Information

Commercial Product Name : Clonetics®
Product name : FGM® 2 SingleQuots®
Material number : CC-4126

Components

| | |
|--------------------------------|--------------|
| Recombinant human insulin 0.5% | SDS attached |
| HFGF-B GF FOR FGM-2 SQ KIT | SDS attached |
| GA-1000 | SDS attached |
| Fetal Bovine Serum | SDS attached |

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according to Regulation (EC) No. 1907/2006

GA-1000

Version 3.0

Revision Date 16.12.2021

Print Date 09.11.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Commercial Product Name : Clonetics®
Product name : FGM® 2 SingleQuotes®

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com
Responsible/issuing person :

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear protective gloves.
P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Gentamicin, sulfate (salt)

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. | Classification | Concentration |
|---------------|---------|----------------|---------------|
|---------------|---------|----------------|---------------|

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| | EC-No. Index-No. REACH Registration Number | | (% w/w) |
|----------------------------|---|---|------------|
| Gentamicin, sulfate (salt) | 1405-41-0 | Resp. Sens. 1; H334 Skin Sens. 1; H317 | >= 3 - < 5 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : Move to fresh air.
Call a physician immediately.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Wash clothing before reuse.
Get medical attention if irritation develops and persists.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give plenty of water (if possible charcoal slurry).
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Allergic appearance
sensitising effects

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Not combustible.

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Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use respirator when performing operations involving potential exposure to vapour of the product.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : In case of insufficient ventilation, wear suitable respiratory equipment.
Avoid exposure - obtain special instructions before use.
Use only in area provided with appropriate exhaust ventilation.
Avoid contact with skin and eyes.

Advice on protection against fire and explosion : Stable under normal conditions.

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Hygiene measures : DANGER! Avoid contact with the skin and the eyes. Avoid breathing dust or spray mist. Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep frozen or refrigerated.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Eye protection : Safety glasses
Safety goggles

Hand protection
Material : Nitrile rubber
Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Complete suit protecting against chemicals

Respiratory protection : In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.

Respirator with ABEK filter.
Respirator with combination filter for vapour/particulate (EN 141)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

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| | | |
|--|---|------------------------------|
| Physical state | : | liquid |
| Appearance | : | Aqueous solution |
| Colour | : | light yellow |
| Odour | : | odourless |
| Melting point/freezing point | : | 0 °C |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | Does not sustain combustion. |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity | : | no data available |
| Solubility(ies) Water solubility | : | soluble |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

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SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition productsNo decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****11.2 Information on other hazards****Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further informationRemarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

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12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Dispose of as unused product.

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SECTION 14: Transport information**IATA** Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

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15.2 Chemical safety assessment

not required

SECTION 16: Other information**Classification of the mixture:**

Resp. Sens. 1 H334

Skin Sens. 1 H317

Classification procedure:

Calculation method

Calculation method

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Full text of other abbreviations

Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations;

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VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Commercial Product Name : Clonetics®
Product name : FGM® 2 SingleQuotes®

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com
Responsible/issuing person :

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Insulin: may cause hypoglycaemia.

Insulin is inactivated in the gastro-intestinal tract when ingested.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : No special precautions required.
- In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**Suitable extinguishing media : Water spray
Dry powder
Foam**5.2 Special hazards arising from the substance or mixture**

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning upMethods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Dispose of in accordance with local regulations.**6.4 Reference to other sections**

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : No special precautions required.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Use only in area provided with appropriate exhaust ventilation.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber
Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : colourless

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| | | |
|--|---|--------------------|
| Odour | : | odourless |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | Water |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | 2 - 4 |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | completely soluble |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

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SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition productsNo decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Assessment: No skin irritation

Serious eye damage/eye irritation

Assessment: No eye irritation

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

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Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility

: Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

Remarks: Insulin: may cause hypoglycaemia.
Insulin is inactivated in the gastro-intestinal tract when ingested.
May cause central nervous system depression.
May induce sweating, pallor or visual disturbances.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish

: Remarks: no data available

12.2 Persistence and degradability

Biodegradability

: Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation

: Remarks: no data available

12.4 Mobility in soil

Distribution among environmental

: Remarks: no data available

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compartments

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Contact waste disposal services.
Dispose of in accordance with local regulations.

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SECTION 14: Transport information**IATA** Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

RID Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

DOT Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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| | | |
|------------------------------------|---|---------------------|
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : nwg not water endangering
Remarks: Classification according to AwSV, Annex 1 (4)

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15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Recombinant human insulin 0.5%

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Commercial Product Name : Clonetics®
Product name : FGM® 2 SingleQuotes®

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com
Responsible/issuing person :

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : No special precautions required.
- In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

Colour : no data available

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| | | |
|--|---|-------------------|
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | no data available |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

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SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition productsNo decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

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Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility

: Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards

Endocrine disrupting properties

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish

: Remarks: no data available

12.2 Persistence and degradability

Biodegradability

: Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation

: Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments

: Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or

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higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : Marine pollutant: no

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| | | |
|------------------------------------|---|---------------------|
| ADR | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test

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population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Commercial Product Name : Clonetics®
Product name : FGM® 2 SingleQuotes®

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com
Responsible/issuing person :

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

- If inhaled : No special precautions required.
- In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

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SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Further information : Use water spray to cool unopened containers.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.
Advice on protection against fire and explosion : No special precautions required.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep tightly closed.

Store in cool place.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection

: No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : liquid

Appearance : Aqueous solution

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| | | |
|--|---|-------------------|
| Colour | : | brown |
| Odour | : | no data available |
| Melting point/freezing point | : | no data available |
| Initial boiling point and boiling range | : | no data available |
| Flammability | : | no data available |
| Upper explosion limit / upper flammability limit | : | no data available |
| Lower explosion limit / Lower flammability limit | : | no data available |
| Flash point | : | no data available |
| Auto-ignition temperature | : | no data available |
| Decomposition temperature Decomposition temperature | : | no data available |
| pH | : | 6,8 - 8,3 |
| Viscosity Viscosity, kinematic | : | no data available |
| Solubility(ies) Water solubility | : | no data available |
| Partition coefficient: n-octanol/water | : | no data available |
| Vapour pressure | : | no data available |
| Relative density | : | no data available |
| Density | : | no data available |
| Relative vapour density | : | no data available |
| Particle characteristics | : | no data available |

9.2 Other information

no data available

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SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition productsNo decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

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Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or

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higher.

12.6 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : no data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG-CODE Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

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| | | |
|------------------------------------|---|---------------------|
| ADR | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| RID | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| DOT | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |
| TDG | : | Not dangerous goods |
| 14.1 UN number | : | Not applicable |
| 14.2 Proper shipping name | : | Not applicable |
| 14.3 Transport hazard class | : | Not applicable |
| 14.4 Packing group | : | Not applicable |
| 14.5 Environmental hazards | : | no |

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (4)

15.2 Chemical safety assessment

not required

SECTION 16: Other information**Full text of other abbreviations**

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test

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population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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