

Kit SDS Cover Sheet

FGM-2 Bullet Kit

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

Product Information

Product name : FGM-2 Bullet Kit

Material number : CC-3132

Components

FBM Basal Medium

SDS attached

CC-4126 FGM-2 SingleQuotKit Suppl&Growth Factors

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Product name : FBM 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.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

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

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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
		No data available
Auto-ignition temperature	:	No data available
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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

ADR	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	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(es)	:	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(es)	:	Not applicable
14.4 Packing group	:	Not applicable
TDG	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class(es)	:	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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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

Water hazard class (Germany) : WGK 1 slightly hazardous to water

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

FBM Basal Medium

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

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

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)**

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.

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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. EC-No. Index-No.	Classification	Concentration (% w/w)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

	REACH Registration Number		
Gentamicin, sulfate (salt)	1405-41-0 215-778-9	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 or poison control centre immediately.
If unconscious, place in recovery position and seek medical advice.
Keep respiratory tract clear.
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.
- After contact with skin, wash immediately with plenty of soap and water.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician.
- 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.
- Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Allergic appearance

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

sensitising effects

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.
Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Not combustible.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Water spray

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Heating or fire can release toxic gas.

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.
Use personal protective equipment.

Further information : Use a water spray to cool fully closed 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.
Use personal protective equipment.
Ensure adequate ventilation.
Use respirator when performing operations involving potential exposure to vapour of the product.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

Prevent further leakage or spillage if safe to do so.

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.

For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of aerosol.
Avoid exposure - obtain special instructions before use.
Do not breathe vapours/dust.
Avoid contact with skin and eyes.
Smoking, eating and drinking should be prohibited in the application area.
For personal protection see section 8.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.

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

Normal measures for preventive fire protection.

Hygiene measures : Wash hands before breaks and at the end of workday. Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

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

Observe label precautions. Keep container tightly closed. Keep in a well-ventilated place. To maintain product quality, do not store in heat or direct sunlight.

Further information on storage stability : No decomposition if stored and applied as directed.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 : Safety glasses

Hand protection

Material : Nitrile rubber

Remarks : Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
Impervious gloves Break through time : > 480 min
The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Impervious clothing

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)

Respirator with a vapour filter (EN 141)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 Decomposition temperature	: No data available
pH	: No data available
Viscosity Viscosity, kinematic	: 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information

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

Acute toxicity

Acute oral toxicity : Acute toxicity estimate: 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

Repeated dose toxicity

Remarks: No data available

Aspiration toxicity

No aspiration toxicity classification

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.

Neurological effects

Remarks: No data available

Further information

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

12.2 Persistence and degradability

Biodegradability : Remarks: 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

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 contents/container in accordance with local regulation.
Contact waste disposal services.
Do not dispose of waste into sewer.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : 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(es) : 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(es) : 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(es) : Not applicable
 14.4 Packing group : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

TDG : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : 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 - Candidate List of Substances of Very High Concern : Not applicable
 for Authorisation (Article 59).

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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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

Water hazard class (Germany) : WGK 1 slightly hazardous to water

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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;

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GA-1000

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Other information : This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.

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.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

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

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 | : | Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician. |
| In case of skin contact | : | Wash with water and soap as a precaution.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician. |
| In case of eye contact | : | Flush eyes with water as a precaution.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist. |
| If swallowed | : | Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician. |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Heating or fire can release toxic gas.

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.
Use personal protective equipment.

Further information : Use a water spray to cool fully closed 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.
Try to prevent the material from entering drains or water courses.

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.

Use neutralizing agents.
Neutralize with chalk, alkali solution or ammonia.
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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.
For personal protection see section 8.

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

Normal measures for preventive fire protection.

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 container tightly closed. Keep in a well-ventilated place.
To maintain product quality, do not store in heat or direct sunlight.

Advice on common storage : No special restrictions on storage with other products.

Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : No information available.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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	: Safety glasses
Hand protection	
Remarks	: Wear protective gloves. Break through time : > 480 min
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place. Lightweight protective clothing
Respiratory protection	: No personal respiratory protective equipment normally required. In the case of vapour formation use a respirator with an approved filter.

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
Melting point/freezing point	: No data available
Boiling point/boiling range	: No data available
Flammability	: No data available
Upper explosion limit / Upper	: No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

flammability limit

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

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

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

Remarks: No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

STOT - repeated exposure

Remarks: No data available

Aspiration toxicity

No aspiration toxicity classification

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: 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.

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish

: Remarks: No data available

12.2 Persistence and degradability

Biodegradability

: Remarks: 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 : Solutions with low pH-value must be neutralized before discharge.
Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : 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(es) : 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(es) : 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(es) : Not applicable
 14.4 Packing group : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

TDG : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : 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 - Candidate List of Substances of Very High Concern : Not applicable
 for Authorisation (Article 59).

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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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

Water hazard class (Germany) : nwg not water endangering

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Other information : This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Product name : HFGF-B GF FOR FGM-2 SQ 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 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

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.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 practice.

7.2 Conditions for safe storage, including any incompatibilities

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Odour : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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
		No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

STOT - single exposure

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

RID : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : 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(es)** : Not applicable
 14.4 **Packing group** : Not applicable

TDG : Not dangerous goods

14.1 **UN number** : Not applicable
 14.2 **Proper shipping name** : Not applicable
 14.3 **Transport hazard class(es)** : 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 - Candidate List of Substances of Very High Concern : Not applicable
 for Authorisation (Article 59).

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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

Water hazard class (Germany) : WGK 1 slightly hazardous to water

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 –

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

HFGF-B GF FOR FGM-2 SQ KIT

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Product name : Fetal Bovine Serum

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

Use of the Substance/Mixture : For research use only.

Recommended restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

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

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 | : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician. |
| In case of skin contact | : Wash with water and soap as a precaution.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician. |
| In case of eye contact | : Flush eyes with water as a precaution.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist. |
| If swallowed | : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician. |

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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 : Water spray

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Heating or fire can release toxic gas.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefightersSpecial protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Further information : Use a water spray to cool fully closed 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 : Try to prevent the material from entering drains or water courses.

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.

For disposal considerations see section 13.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.
For personal protection see section 8.

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

Normal measures for preventive fire protection.

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 container tightly closed. Keep in a well-ventilated place.
To maintain product quality, do not store in heat or direct sunlight.

Advice on common storage : No special restrictions on storage with other products.

Further information on storage stability : No decomposition if stored and applied as directed.

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 : Safety glasses

Hand protection : Wear protective gloves. Break through time : > 480 min
Remarks

Skin and body protection : Choose body protection according to the amount and

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

	concentration of the dangerous substance at the work place. Lightweight protective clothing
Respiratory protection	: No personal respiratory protective equipment normally required. In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: liquid
Appearance	: Aqueous solution
Colour	: brown
Odour	: No data available
Melting point/freezing point	: No data available
Boiling point/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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

No aspiration toxicity classification

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 available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Remarks: 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

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : 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(es) : 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(es) : 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(es) : Not applicable
 14.4 Packing group : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

TDG : Not dangerous goods

- 14.1 **UN number** : Not applicable
- 14.2 **Proper shipping name** : Not applicable
- 14.3 **Transport hazard class(es)** : 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 - Candidate List of Substances of Very High Concern : Not applicable
for Authorisation (Article 59).

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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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

Water hazard class (Germany) : WGK 1 slightly hazardous to water

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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

Other information : This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 4.0

Revision Date 01.05.2024

Print Date 11.05.2024

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.

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.