

# Kit SDS Cover Sheet FGM Bullet Kit

Version 3.0	Revision Date 16.12.2021	Print Date 20.07.2022
Product Information		
Product name :	FGM Bullet Kit	
Material number	: CC-3130	
Components		
FBM Basal Medium		SDS attached
CC-4134 FGM Sing	leQuot Kit Suppl&Growth Factors	
	GA-1000	SDS attached
	Recombinant human insulin 0.5%	SDS attached
	HFGF-B GF FOR FGM SQ KIT	SDS attached



according to Regulation (EC) No. 1907/2006

## **FBM Basal Medium**

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SECTION 1: Identification of the s	substance/mixture and of the company	y/undertaking
1.1 Product identifier Product name	: FBM Basal Medium	
1.2 Relevant identified uses of the su	bstance or mixture and uses advised ag	ainst
Use of the Substance/Mixture	: For Research Use Only. Not for use	in diagnostic procedures.
1.3 Details of the supplier of the safe	ty data sheet	
Company	: Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81	11
	<b>Lonza Verviers Sprl</b> Parc Industriel de Petit-Rechain BE-4800 Verviers, Belgium Business Telephone: +32 8732 1612	1
	<b>Lonza Cologne GmbH</b> Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 19	990
	<b>Lonza Copenhagen ApS</b> Strandhaven 12 DK-2665 Vallensbaek Strand, Denm Business Telephone: + 45 4356 740	
E-mail address Responsible/issuing person	sds@lonza.com	
1.4 Emergency telephone number		
Emergency telephone number	: Lonza Ltd, CH-4002 Basel, Switzerla Telephone: +41 61 313 94 94 (24h)	and

## **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.

Ref. / 00000027312



# FBM Basal Medium

#### 2.3 Other hazards

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

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

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

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

# Components

Remarks

: No hazardous ingredients

## **SECTION 4: First aid measures**

4.1 Description of first aid measures	No special precautions required.
	No special precadions required.
In case of skin contact :	Wash with water and soap as a precaution. If skin irritation persists, call a physician.
In case of eye contact :	Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.
If swallowed :	Immediately give large quantities of water to drink. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
4.2 Most important symptoms and effects,	both acute and delayed
Symptoms :	No information available.

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

Treatment

: No information available.



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SECTION 5: Firefighting measures			
5.1 Extinguishing media			
Suitable extinguishing media	:	Water spray Dry powder Foam	
5.2 Special hazards arising from the su	bst	ance 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 b	preathing apparatus.
Further information	:	Use water spray to cool unopened conta	iiners.
SECTION 6: Accidental release mea	su	res	
6.1 Personal precautions, protective eq	uip	oment 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 containme	ent	and cleaning up	
Methods for cleaning up	:	Contain spillage, and then collect with no absorbent material, (e.g. sand, earth, dia vermiculite) and place in container for dis local / national regulations (see section 1	atomaceous earth, sposal according to
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 st	atic discharges.
Hygiene measures	:	Handle in accordance with good industria	al hygiene and safety
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	practice.	
7.2 Conditions for safe storage, inclu	ding any incompatibilities	
Requirements for storage areas ar containers	d : No special storage conditions r	equired.
7.3 Specific end use(s)		
Specific use(s)	: No information available.	
SECTION 8: Exposure controls/pe	rsonal protection	
8.1 Control parameters		
Occupational Exposure Limits		
Contains no substances with	ccupational 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 accord	
	concentration of the dangerous No special protective equipmer	
Respiratory protection	<ul> <li>No personal respiratory protect required.</li> </ul>	live equipment normally

## 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	red



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# **FBM Basal Medium**

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Odour	: no data available	
Melting point/freezing point	: no data available	
Initial boiling point and boiling range	: no data available	
Flammability	: no data available	
Upper explosion limit / upper flammability limit	: no data available	
Lower explosion limit / Lower flammability limit	: no data available	
Flash point	: no data available	
Auto-ignition temperature	: no data available	
Decomposition temperature Decomposition temperature	: no data available	
рН	: 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	

no data available

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Stable under recommended storage conditions.



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10.2 Chemical stability		
Stable under normal conditions.		
10.3 Possibility of hazardous reactions		
Hazardous reactions	: Stable under normal conditions.	
10.4 Conditions to avoid		
Conditions to avoid	: no data available	
10.5 Incompatible materials		
Materials to avoid	: Strong oxidizing agents	
<b>10.6 Hazardous decomposition products</b> No decomposition if stored normally.	5	

## **SECTION 11: Toxicological information**

Ref.

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

Acute toxicity	
Acute oral toxicity	: Remarks: no data available
Acute inhalation toxicity	: Remarks: no data available
Acute dermal toxicity	: Remarks: no data available
Skin corrosion/irritation	Remarks: no data available
Serious eye damage/eye irritation	Remarks: no data available
Respiratory or skin sensitisation	Remarks: no data available
Germ cell mutagenicity	
Genotoxicity in vitro	: Remarks: no data available
Carcinogenicity	Remarks: no data available
Reproductive toxicity	
Effects on fertility	: Remarks: no data available
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STOT - single exposure	Remarks: no data available	
	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 considered to have endocrine di to REACH Article 57(f) or Comm (EU) 2017/2100 or Commission levels of 0.1% or higher.	isrupting properties according nission Delegated regulation
Further information		
	Remarks: No data is available o	n the product itself.
<b>12.1 Toxicity</b> 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 assessn	nent	
Assessment	: This substance/mixture contains be either persistent, bioaccumul persistent and very bioaccumula higher.	ative and toxic (PBT), or very
12.6 Endocrine disrupting properties		
Endocrine disrupting potential	: The substance/mixture does not considered to have endocrine d	
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		to REACH Article 57(f) or Cor	nmission Delegated regulation on Regulation (EU) 2018/605 at
12.7 O	ther adverse effects		
Er	ndocrine disrupting potential	<ul> <li>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.</li> </ul>	
Ad	dditional ecological information	: no data available	
SECT	ION 13: Disposal consideration	ns	
	aste treatment methods	: Dispose of in accordance with	n local regulations.
SECT	ION 14: Transport informatior		
ΙΑΤΑ		Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
IMDG	-CODE	Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Marine pollutant: no</li> </ul>	
ADR		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	



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Versior	3.0	Revision Date 16.12.2021	Print Date 20.07.2022
RID		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
DOT		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
TDG		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	

#### 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

n the : Not applicable reparations
n Concern : Not applicable
(Annex Not applicable



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XIV)			
Regulation (EC) No 1005/2009 on sub ozone layer	ostances that deplete the	Not applicable	
Regulation (EU) 2019/1021 on persist (recast)	ent organic pollutants	Not applicable	
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable			
National regulatory information			
Water hazard class (Germany)	: WGK 1 slightly hazardo Remarks: Classification	us to water according to AwSV, Annex 1 (5.2)	
15.2 Chemical safety assessment			
not required		_	

# SECTION 16: Other information

#### Full text of other abbreviations

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



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

#### **Further information**

Date format

dd.mm.yyyy

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

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

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# GA-1000

Version 3.0	Revision Date 16.12.2021	Print Date 20.07.2022
SECTION 1: Identification of the s	ubstance/mixture and of the company/un	dertaking
1.1 Product identifier		
Product name	: GA-1000	
1.2 Relevant identified uses of the su	bstance or mixture and uses advised against	
Use of the Substance/Mixture	: Scientific research and development	
1.3 Details of the supplier of the safe	ty data sheet	
Company	: Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81 11	
	<b>Lonza Verviers Sprl</b> Parc Industriel de Petit-Rechain BE-4800 Verviers, Belgium Business Telephone: +32 8732 1611	
	<b>Lonza Cologne GmbH</b> Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 1990	
	<b>Lonza Copenhagen ApS</b> Strandhaven 12 DK-2665 Vallensbaek Strand, Denmark Business Telephone: + 45 4356 7400	
E-mail address Responsible/issuing person	sds@lonza.com	
<b>1.4 Emergency telephone number</b> Emergency telephone number	: Lonza Ltd, CH-4002 Basel, Switzerland Telephone: +41 61 313 94 94 (24h)	

## **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)			
Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.		
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.		



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## GA-1000

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2.2 Label elements		
Labelling (REGULATION (E	C) No 1272/2008)	
Hazard pictograms		
Signal word	: Danger	
Hazard statements	: H317 May cause an allergic skin H334 May cause allergy or asthr difficulties if inhaled.	
Precautionary statements	P280 Wear protective gloves. P284 Wear respiratory protection <b>Response:</b>	ove person to fresh air and rash occurs: Get medical

Hazardous components which must be listed on the label:

Gentamicin, sulfate (salt)

#### 2.3 Other hazards

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

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

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

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration



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sion 3.0	Revision Date 16.12.2021		Print Date 20.07.20	
	EC-No. Index-No. REACH Registration Number		(% w/w)	
Gentamicin, sulfate (salt)	1405-41-0	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 3 - < 5	

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice	: When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	<ul> <li>Move to fresh air.</li> <li>Call a physician immediately.</li> <li>If breathing is irregular or stopped, administer artificial respiration.</li> </ul>
In case of skin contact	<ul> <li>After contact with skin, wash immediately with plenty of soap and water.</li> <li>Wash clothing before reuse.</li> <li>Get medical attention if irritation develops and persists.</li> </ul>
In case of eye contact	<ul> <li>In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.</li> <li>If eye irritation persists, consult a specialist.</li> </ul>
If swallowed	<ul> <li>Immediately give plenty of water (if possible charcoal slurry).</li> <li>Do not induce vomiting without medical advice.</li> <li>Never give anything by mouth to an unconscious person.</li> <li>Take victim immediately to hospital.</li> </ul>
4.2 Most important symptoms ar	d effects, both acute and delayed
Symptoms	: Allergic appearance sensitising effects
4.3 Indication of any immediate r	nedical attention and special treatment needed
Treatment	: Treat symptomatically.
SECTION 5: Firefighting meas	sures

# SE

5.1	Extin	guishing	) media
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Suitable extinguishing media	:	Not combustible.
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		Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
5.2 Special hazards arising from the s	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-contai	ned breathing apparatus.	
Further information	: Use water spray to cool unopened	containers.	

## **SECTION 6: Accidental release measures**

<b>6.1 Personal precautions, protective equ</b> Personal precautions	ip: :	ment and emergency procedures Use respirator when performing operations involving potential exposure to vapour of the product. Refer to protective measures listed in sections 7 and 8.
6.2 Environmental precautions		
Environmental precautions	:	No special environmental precautions required.
6.3 Methods and material for containmer	nt a	and cleaning up
Methods for cleaning up	:	Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).
6.4 Reference to other sections		
For personal protection see section 8.		
SECTION 7: Handling and storage		
7.1 Precautions for safe handling		In case of insufficient ventilation, wear suitable respiratory

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



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Hygiene measures		n the skin and the eyes. Avoid Wash hands before breaks and ne product.
7.2 Conditions for safe storage, inc	luding any incompatibilities	
Requirements for storage areas a containers	and : Keep frozen or refrigerated.	
7.3 Specific end use(s)		
Specific use(s)	: No information available.	
SECTION 8: Exposure controls/p	personal protection	
8.1 Control parameters		
Occupational Exposure Limits		
Contains no substances with	occupational exposure limit values.	
8.2 Exposure controls		
<b>Engineering measures</b> Provide sufficient air exchange ar	nd/or exhaust in work rooms.	
Personal protective equipment		
Eye protection	: Safety glasses Safety goggles	
Hand protection		
Material Rate of permeability	: Nitrile rubber : > 480 min	
Nate of permeability	. 7400 mm	
Skin and body protection	: Choose body protection accor concentration of the dangero Complete suit protecting aga	ous substance at the work place.
Respiratory protection	: In case of mist, spray or aero personal respiratory protection	
	Respirator with ABEK filter. Respirator with combination 1 141)	filter for vapour/particulate (EN

# **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties



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

no data available



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SECTION 10: Stability and reactivity	y		
<b>10.1 Reactivity</b> Stable under recommended storage	cor	nditions.	
<b>10.2 Chemical stability</b> Stable under normal conditions.			
<b>10.3 Possibility of hazardous reactions</b> Hazardous reactions	:	Stable under normal conditions.	
<b>10.4 Conditions to avoid</b> Conditions to avoid	:	None known.	
<b>10.5 Incompatible materials</b> Materials to avoid	:	Strong oxidizing agents	
10.6 Hazardous decomposition product	ts		
11.1 Information on hazard classes as o			
SECTION 11: Toxicological informa 11.1 Information on hazard classes as o 11.2 Information on other hazards			
SECTION 11: Toxicological informa			ng properties according Delegated regulation
SECTION 11: Toxicological informa 11.1 Information on hazard classes as o 11.2 Information on other hazards Endocrine disrupting properties		The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul	ng properties according Delegated regulation ation (EU) 2018/605 at
SECTION 11: Toxicological informa 11.1 Information on hazard classes as o 11.2 Information on other hazards Endocrine disrupting properties Assessment Further information	def :	The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul- levels of 0.1% or higher.	ng properties according Delegated regulation ation (EU) 2018/605 at
SECTION 11: Toxicological informa 11.1 Information on hazard classes as o 11.2 Information on other hazards Endocrine disrupting properties Assessment	def :	The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul- levels of 0.1% or higher.	ng properties according Delegated regulation ation (EU) 2018/605 at
SECTION 11: Toxicological informa 11.1 Information on hazard classes as o 11.2 Information on other hazards Endocrine disrupting properties Assessment Further information SECTION 12: Ecological information	def :	The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul- levels of 0.1% or higher.	ng properties according Delegated regulation ation (EU) 2018/605 at
SECTION 11: Toxicological informa 11.1 Information on hazard classes as o 11.2 Information on other hazards Endocrine disrupting properties Assessment Further information SECTION 12: Ecological information 12.1 Toxicity Toxicity to fish 12.2 Persistence and degradability	def :	The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul levels of 0.1% or higher. Remarks: No data is available on the p	ng properties according Delegated regulation ation (EU) 2018/605 at
SECTION 11: Toxicological informa 11.1 Information on hazard classes as a 11.2 Information on other hazards Endocrine disrupting properties Assessment Further information SECTION 12: Ecological information 12.1 Toxicity Toxicity to fish	def :	The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul levels of 0.1% or higher. Remarks: No data is available on the p	ng properties according Delegated regulation ation (EU) 2018/605 at



according to Regulation (EC) No. 1907/2006

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12.3 Bioaccumulative potential		
Bioaccumulation	: Remarks: no data available	
12.4 Mobility in soil		
Distribution among environmental compartments	: Remarks: no data available	
12.5 Results of PBT and vPvB assessn	nent	
Assessment	: This substance/mixture contains no be either persistent, bioaccumulativ persistent and very bioaccumulative higher.	e and toxic (PBT), or very
12.6 Endocrine disrupting properties		
Endocrine disrupting potential	: The substance/mixture does not considered to have endocrine disrut to REACH Article 57(f) or Commiss (EU) 2017/2100 or Commission Relevels of 0.1% or higher.	pting properties according ion Delegated regulation
12.7 Other adverse effects		
Endocrine disrupting potential	<ul> <li>The substance/mixture does not considered to have endocrine disrut to REACH Article 57(f) or Commiss (EU) 2017/2100 or Commission Relevels of 0.1% or higher.</li> </ul>	pting properties according ion Delegated regulation
Additional ecological information	: No data is available on the product	itself.

# **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Dispose of as unused product.



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Revision Date 16.12.2021

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## **SECTION 14: Transport information**

#### ΙΑΤΑ Not dangerous goods 14.1 **UN number** Not applicable 14.2 Proper shipping name Not applicable 14.3 **Transport hazard class** Not applicable 14.4 Packing group Not applicable 14.5 **Environmental hazards** ÷ no **IMDG-CODE** Not dangerous goods 14.1 **UN number** Not applicable **Proper shipping name** Not applicable 14.2 1 Not applicable 14.3 Transport hazard class • 14.4 Packing group Not applicable ÷ 14.5 **Environmental hazards** Marine pollutant: no · ADR Not dangerous goods 14.1 **UN number** Not applicable 14.2 Proper shipping name Not applicable 14.3 **Transport hazard class** Not applicable 1 Packing group Not applicable 14.4 2 14.5 **Environmental hazards** 2 no 1 RID Not dangerous goods 14.1 **UN number** : Not applicable Proper shipping name Not applicable 14.2 Not applicable 14.3 Transport hazard class Packing group Not applicable 14.4 2 14.5 **Environmental hazards** 5 no DOT 2 Not dangerous goods 14.1 **UN number** Not applicable 5 14.2 **Proper shipping name** Not applicable : 14.3 Transport hazard class Not applicable 5 14.4 Packing group Not applicable ÷ 14.5 **Environmental hazards** ÷ no



according to Regulation (EC) No. 1907/2006

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	Print Date 20.07.2022
: Not dangerous goods	
<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>	
	: Not applicable : Not applicable : Not applicable

#### 14.6 Special precautions for user

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

#### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture REACH - Restrictions on the manufacture, placing on the : Not applicable market and use of certain dangerous substances, preparations and articles (Annex XVII) REACH - Candidate List of Substances of Very High Concern : Not applicable for Authorisation (Article 59). REACH - List of substances subject to authorisation (Annex Not applicable XIV) Regulation (EC) No 1005/2009 on substances that deplete the Not applicable ozone layer Regulation (EU) 2019/1021 on persistent organic pollutants Not applicable (recast) Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable National regulatory information Water hazard class (Germany) WGK 1 slightly hazardous to water 2 Remarks: Classification according to AwSV, Annex 1 (5.2)

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#### 15.2 Chemical safety assessment

not required

## **SECTION 16: Other information**

Classification of the	ne mixture:	Classification procedure:
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
Full text of H-State	ements	
H317		: May cause an allergic skin reaction.
H334		: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Full text of other a	bbreviations	
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;



according to Regulation (EC) No. 1907/2006

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

#### **Further information**

Date format

dd.mm.yyyy

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#### 99 / EN

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

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according to Regulation (EC) No. 1907/2006

## Recombinant human insulin 0.5%

Version 3.0	Revision Date 16.12.2021	Print Date 20.07.2022
SECTION 1: Identification of the subs	tance/mixture and of the company/unde	ertaking
1.1 Product identifier		
Product name	Recombinant human insulin 0.5%	
1.2 Relevant identified uses of the substa	ance or mixture and uses advised against	
Use of the Substance/Mixture	Scientific research and development	
1.3 Details of the supplier of the safety da	ata sheet	
Company	: Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81 11	
	<b>Lonza Verviers Sprl</b> Parc Industriel de Petit-Rechain BE-4800 Verviers, Belgium Business Telephone: +32 8732 1611	
	<b>Lonza Cologne GmbH</b> Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 1990	
	<b>Lonza Copenhagen ApS</b> Strandhaven 12 DK-2665 Vallensbaek Strand, Denmark Business Telephone: + 45 4356 7400	
E-mail address Responsible/issuing person	sds@lonza.com :	
1.4 Emergency telephone number		
Emergency telephone number	: Lonza Ltd, CH-4002 Basel, Switzerland Telephone: +41 61 313 94 94 (24h)	

## **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

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

## 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

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

Ref. 45004.4 / 00000015292



## Recombinant human insulin 0.5%

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#### 2.3 Other hazards

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

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

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

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

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components
------------

Remarks

: No hazardous ingredients

## **SECTION 4: First aid measures**

4.1 Description of first aid measures				
If inhaled	:	No special precautions required.		
In case of skin contact	:	Wash with water and soap as a precaution. If skin irritation persists, call a physician.		
In case of eye contact	:	Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.		
If swallowed	:	Immediately give large quantities of water to drink. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.		
4.2 Most important symptoms and effects, both acute and delayed				
Symptoms	:	No information available.		
4.3 Indication of any immediate medical attention and special treatment peeded				



according to Regulation (EC) No. 1907/2006

# Recombinant human insulin 0.5%

			Print Date 20.07.202
SECTION 5: Firefighting measures			
5.1 Extinguishing media			
Suitable extinguishing media	:	Water spray Dry powder Foam	
5.2 Special hazards arising from the su	ubst	ance 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-contain	ed breathing apparatus.
Further information	:	Use water spray to cool unopened co	ontainers.
SECTION 6: Accidental release mea	asu	res	
6.1 Personal processions, protective of	~	ment and amorganov procedures	
5.1 Personal precautions, protective en Personal precautions	quip :		
	•		
6.2 Environmental precautions			
Environmental precautions	:	No special environmental precaution	s required.
6.3 Methods and material for containm	ent	and cleaning up	
Methods for cleaning up	:	Wipe up with absorbent material (e.g Dispose of in accordance with local r	
6.4 Reference to other sections			
For personal protection see section 8	3.		
SECTION 7: Handling and storage			
7.1 Precautions for safe handling			
Advice on safe handling	:	No special precautions required.	
Advice on protection against fire and explosion	:	No special precautions required.	
Hygiene measures	:	Handle in accordance with good indupractice.	ustrial hygiene and safety



## Recombinant human insulin 0.5%

/ersion 3.0	F	Revision Date 16.12.2021	Print Date 20.07.2022
7.2 Conditions for safe storage, incl	uding a	iny incompatibilities	
Requirements for storage areas a containers	nd :	No special storage conditions required.	
7.3 Specific end use(s)			
Specific use(s)	:	No information available.	
SECTION 8: Exposure controls/p	ersona	al protection	
3.1 Control parameters			
Occupational Exposure Limits			
Contains no substances with	occupa	itional exposure limit values.	
3.2 Exposure controls			
<b>Engineering measures</b> Use only in area provided with ap	propriat	e exhaust ventilation.	
Personal protective equipment			
Eye protection	:	Tightly fitting safety goggles	
Hand protection			
Material Rate of permeability	:	Nitrile rubber > 480 min	
Skin and body protection	:	Choose body protection according to the concentration of the dangerous substance. No special protective equipment required	e at the work place.
Respiratory protection	:	No personal respiratory protective equipn required.	nent normally

#### **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



according to Regulation (EC) No. 1907/2006

# Recombinant human insulin 0.5%

Version 3.0		Revision Date 16.12.2021	Print Date 20.07.2022
Melting point/freezing point	:	no data available	
Initial boiling point and boiling range	:	no data available	
Flammability	:	no data available	
Upper explosion limit / upper flammability limit	:	no data available	
Lower explosion limit / Lower flammability limit	:	no data available	
Flash point	:	Water	
Auto-ignition temperature	:	no data available	
Decomposition temperature Decomposition temperature	:	no data available	
рН	:	2 - 4	
Viscosity Viscosity, kinematic	:	no data available	
Solubility(ies) Water solubility	:	completely soluble	
Partition coefficient: n-octanol/water	:	no data available	
Vapour pressure	:	no data available	
Relative density	:	no data available	
Density	:	no data available	
Relative vapour density	:	no data available	
Particle characteristics	:	no data available	

## 9.2 Other information

no data available

## **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Stable under recommended storage conditions.

## 10.2 Chemical stability

Stable under normal conditions.

Ref. 45004.4 / 00000015292



# Recombinant human insulin 0.5%

Revision Date 16.12.2021	Print Date 20.07.2022
: Stable under normal conditions.	
: no data available	
: Strong oxidizing agents	
	<ul> <li>Stable under normal conditions.</li> <li>no data available</li> </ul>

## 10.6 Hazardous decomposition products

No decomposition if stored normally.

# **SECTION 11: Toxicological information**

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

Acute toxicity Acute oral toxicity	:	Remarks: no data available
Acute inhalation toxicity	:	Remarks: no data available
Acute dermal toxicity	:	Remarks: no data available
Skin corrosion/irritation		Assessment: No skin irritation
Serious eye damage/eye irritation		Assessment: No eye irritation
Respiratory or skin sensitisation		Remarks: no data available
Germ cell mutagenicity Genotoxicity in vitro	:	Remarks: no data available
Carcinogenicity		Remarks: no data available
<b>Reproductive toxicity</b> Effects on fertility	:	Remarks: no data available
STOT - single exposure		



according to Regulation (EC) No. 1907/2006

# Recombinant human insulin 0.5%

	Revision Date 16.12.2021	Print Date 20.07.2022
	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 co considered to have endocrine disru to REACH Article 57(f) or Commiss (EU) 2017/2100 or Commission Re- levels of 0.1% or higher.	pting properties according ion Delegated regulation
Further information		
	Remarks: No data is available on th	ne product itself.
	Remarks: Insulin: may cause hypog Insulin is inactivated in the gastro-ir ingested. May cause central nervous system May induce sweating, pallor or visus	depression.
SECTION 12: Ecological informatic	n	
12.1 Toxicity	<ul> <li>Remarks: no data available</li> </ul>	
<b>12.1 Toxicity</b> Toxicity to fish		
<b>12.1 Toxicity</b> Toxicity to fish		
<ul> <li>12.1 Toxicity Toxicity to fish</li> <li>12.2 Persistence and degradability Biodegradability</li> </ul>	: Remarks: no data available	
<b>12.1 Toxicity</b> Toxicity to fish <b>12.2 Persistence and degradability</b> Biodegradability	: Remarks: no data available	
<ul> <li>12.1 Toxicity Toxicity to fish</li> <li>12.2 Persistence and degradability Biodegradability</li> <li>12.3 Bioaccumulative potential Bioaccumulation</li> </ul>	<ul><li>Remarks: no data available</li><li>Result: no data available</li></ul>	
<ul> <li>12.1 Toxicity Toxicity to fish</li> <li>12.2 Persistence and degradability Biodegradability</li> <li>12.3 Bioaccumulative potential Bioaccumulation</li> </ul>	<ul><li>Remarks: no data available</li><li>Result: no data available</li></ul>	
<ul> <li>12.2 Persistence and degradability Biodegradability</li> <li>12.3 Bioaccumulative potential Bioaccumulation</li> <li>12.4 Mobility in soil Distribution among environmental</li> </ul>	<ul> <li>: Remarks: no data available</li> <li>: Result: no data available</li> <li>: Remarks: no data available</li> <li>: Remarks: no data available</li> </ul>	



## **Recombinant human insulin 0.5%**

Version 3.0	Revision Date 16.12.2021	Print Date 20.07.2022
12.6 Endocrine disrupting properties		
Endocrine disrupting potential	<ul> <li>The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul levels of 0.1% or higher.</li> </ul>	ng properties according Delegated regulation
12.7 Other adverse effects		
Endocrine disrupting potential	<ul> <li>The substance/mixture does not conta considered to have endocrine disruptir to REACH Article 57(f) or Commission (EU) 2017/2100 or Commission Regul levels of 0.1% or higher.</li> </ul>	ng properties according Delegated regulation
Additional ecological information	: no data available	

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product

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

# **SECTION 14: Transport information**

ΙΑΤΑ		Not dangerous goods
14.1 14.2 14.3 14.4 14.5	Proper shipping name Transport hazard class Packing group	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>
IMDG	CODE	Not dangerous goods
14.1 14.2 14.3 14.4		Not applicable Not applicable Not applicable Not applicable

- 14.4 Packing group
- **Environmental hazards** 14.5

: Marine pollutant: no



## Recombinant human insulin 0.5%

Version	3.0	Revision Date 16.12.2021	Print Date 20.07.2022
ADR		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
RID		Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
DOT		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
TDG		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	

#### 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

Ref. 45004.4 / 00000015292



## Recombinant human insulin 0.5%

Version 3.0	Revision Date 16.12.2021		Print Date 20.07.2022
REACH - Restrictions on the manuface market and use of certain dangerous s and articles (Annex XVII)		Not applicable	
REACH - Candidate List of Substance for Authorisation (Article 59).	es of Very High Concern :	Not applicable	
REACH - List of substances subject to XIV)	authorisation (Annex	Not applicable	
Regulation (EC) No 1005/2009 on sub ozone layer	ostances that deplete the	Not applicable	
Regulation (EU) 2019/1021 on persist (recast)	ent organic pollutants	Not applicable	
Seveso III: Directive 2012/18/EU of th major-accident hazards involving dang		of the Council on th	e control of
National regulatory information			
Water hazard class (Germany)	: nwg not water endan Remarks: Classification		Annex 1 (4)
15.2 Chemical safety assessment			

not required

## **SECTION 16: Other information**

#### Full text of other abbreviations

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



## Recombinant human insulin 0.5%

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	ose); LOFT - Danish Threshold Limit Value; MAK	

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

#### Further information

Date format

: dd.mm.yyyy

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#### 99 / EN

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## HFGF-B GF FOR FGM SQ KIT

Version 3.0	Revision Date 16.12.2021	Print Date 20.07.2022
SECTION 1: Identification of the s	substance/mixture and of the company/un	dertaking
1.1 Product identifier		
Product name	: HFGF-B GF FOR FGM SQ KIT	
1.2 Relevant identified uses of the su	bstance or mixture and uses advised against	
Use of the Substance/Mixture	: Scientific research and development	
1.3 Details of the supplier of the safe	ty data sheet	
Company	: Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81 11	
	<b>Lonza Verviers Sprl</b> Parc Industriel de Petit-Rechain BE-4800 Verviers, Belgium Business Telephone: +32 8732 1611	
	<b>Lonza Cologne GmbH</b> Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 1990	
	<b>Lonza Copenhagen ApS</b> Strandhaven 12 DK-2665 Vallensbaek Strand, Denmark Business Telephone: + 45 4356 7400	
E-mail address Responsible/issuing person	sds@lonza.com	
1.4 Emergency telephone number		
Emergency telephone number	: Lonza Ltd, CH-4002 Basel, Switzerland Telephone: +41 61 313 94 94 (24h)	

#### **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

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

## 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

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

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#### 2.3 Other hazards

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

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

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

## **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

# Components

Remarks

: No hazardous ingredients

## **SECTION 4: First aid measures**

4.1 Description of first aid measures	No special precautions required.
In case of skin contact :	Wash with water and soap as a precaution. If skin irritation persists, call a physician.
In case of eye contact :	Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.
If swallowed :	Immediately give large quantities of water to drink. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
4.2 Most important symptoms and effects,	both acute and delayed
Symptoms :	No information available.

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

Treatment

: No information available.



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SECTION 5: Firefighting measure	S		
5.1 Extinguishing media			
Suitable extinguishing media	:	Water spray Dry powder Foam	
5.2 Special hazards arising from the	subst	ance or mixture	
Hazardous combustion products	:	No hazardous combustion products	s are known
5.3 Advice for firefighters			
Special protective equipment for firefighters	:	In the event of fire, wear self-conta	ined breathing apparatus.
Further information	:	Use water spray to cool unopened	containers.
SECTION 6: Accidental release m	easu	res	
6.1 Personal precautions, protective	equip	ment and emergency procedures	
Personal precautions	:	Use personal protective equipment	<u>.</u>
6.2 Environmental precautions			
Environmental precautions	:	Prevent product from entering drain	ns.
6.3 Methods and material for contain	ment	and cleaning up	
6.3 Methods and material for contain Methods for cleaning up	ment :	and cleaning up Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container local / national regulations (see sec	th, diatomaceous earth, for disposal according to
Methods for cleaning up	ment :	Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container	th, diatomaceous earth, for disposal according to
Methods for cleaning up	:	Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container	th, diatomaceous earth, for disposal according to
Methods for cleaning up 6.4 Reference to other sections	: 1 8.	Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container	th, diatomaceous earth, for disposal according to
Methods for cleaning up 6.4 Reference to other sections For personal protection see sectior	: 1 8.	Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container	th, diatomaceous earth, for disposal according to
Methods for cleaning up 6.4 Reference to other sections For personal protection see sectior SECTION 7: Handling and storage	: 1 8.	Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container	th, diatomaceous earth, for disposal according to
Methods for cleaning up 6.4 Reference to other sections For personal protection see section SECTION 7: Handling and storage 7.1 Precautions for safe handling	: n 8. <b>.</b> :	Contain spillage, and then collect w absorbent material, (e.g. sand, ear vermiculite) and place in container local / national regulations (see sec	th, diatomaceous earth, for disposal according to ction 13).



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	practice.	
7.2 Conditions for safe storage, in	cluding any incompatibilities	
Requirements for storage areas containers	and : No special storage conditions requ	iired.
7.3 Specific end use(s)		
Specific use(s)	: No information available.	
SECTION 8: Exposure controls	/personal protection	
8.1 Control parameters		
Occupational Exposure Limit	5	
Contains no substances wi	th occupational exposure limit values.	
8.2 Exposure controls		
Engineering measures Avoid splashes.		
Personal protective equipmer	ht	
Eye protection	: Tightly fitting safety goggles	
Hand protection		
Material Rate of permeability	: Nitrile rubber : > 480 min	
Rate of permeability	. > 400 11111	
Skin and body protection	: Choose body protection according concentration of the dangerous sul No special protective equipment re	bstance at the work place.
Respiratory protection	: No personal respiratory protective required.	equipment normally

## 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	no data available



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

no data available

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Stable under recommended storage conditions.



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10.2 Chemical stability		
Stable under normal conditions.		
10.3 Possibility of hazardous reactions		
Hazardous reactions :	Stable under normal conditions.	
10.4 Conditions to avoid		
Conditions to avoid :	no data available	
10.5 Incompatible materials		
Materials to avoid :	Strong oxidizing agents	

No decomposition if stored normally.

## **SECTION 11: Toxicological information**

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

Acute toxicity	
Acute oral toxicity	: Remarks: no data available
Acute inhalation toxicity	: Remarks: no data available
Acute dermal toxicity	: Remarks: no data available
Skin corrosion/irritation	
	Remarks: no data available
Serious eye damage/eye irritation	
	Remarks: no data available
Respiratory or skin sensitisation	
	Remarks: no data available
Germ cell mutagenicity	
Genotoxicity in vitro	: Remarks: no data available
Carcinogenicity	
	Remarks: no data available
Reproductive toxicity	
Effects on fertility	: Remarks: no data available
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0707		
STOT - single exposure	Remarks: no data available	
	Remarks. no data avaliable	
STOT - repeated exposure		
	Remarks: no data available	
1.2 Information on other hazards		
Endocrine disrupting properties		
Assessment	: The substance/mixture does not considered to have endocrine di to REACH Article 57(f) or Comm (EU) 2017/2100 or Commission levels of 0.1% or higher.	srupting properties according hission Delegated regulation
Further information		
	Remarks: No data is available o	n the product itself.
<b>12.1 Toxicity</b> Toxicity to fish	: Remarks: no data available	
12.2 Perciptones and degradability		
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 assessr	nent	
Assessment	: This substance/mixture contains be either persistent, bioaccumula persistent and very bioaccumula higher.	ative and toxic (PBT), or very
12.6 Endocrine disrupting properties		
Endocrine disrupting potential	: The substance/mixture does not considered to have endocrine di	
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			ommission Delegated regulation ion Regulation (EU) 2018/605 at
12.7 O	ther adverse effects		
Er	ndocrine disrupting potential	<ul> <li>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.</li> </ul>	
Ad	dditional ecological information	: no data available	
SECT	ION 13: Disposal considerati	ons	
	· · · · · · · · · · · · · · · · · · ·		
-	aste treatment methods		
Pr	roduct	: Dispose of in accordance wit	in local regulations.
SECT	ION 14: Transport informatio	n	
ΙΑΤΑ		Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
IMDG-CODE		Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Marine pollutant: no</li> </ul>	
ADR		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	



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RID		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
DOT 14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not dangerous goods</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	
TDG		: Not dangerous goods	
14.1 14.2 14.3 14.4 14.5	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>no</li> </ul>	

#### 14.6 Special precautions for user

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

#### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex		Not applicable
REACH - List of substances subject to authorisation (Annex		Not applicable

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stances that deplete the	Not applicable			
ent organic pollutants	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				
any) : WGK 1 slightly hazardous to water Remarks: Classification according to AwSV, Annex 1 (5.2)				
	ent organic pollutants European Parliament and erous substances. Not applicable : WGK 1 slightly hazardou			

# **SECTION 16: Other information**

## Full text of other abbreviations

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



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

#### **Further information**

Date format

dd.mm.yyyy

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

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