

Kit SDS Cover Sheet FGM® 3 SingleQuots®

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

Product Information

Commercial Product Name	: Clonetics®
Product name	: FGM® 3 SingleQuots®
Material number	: CC-4525

Components

GA-1000	SDS attached
Fetal Bovine Serum	SDS attached
Recombinant human insulin 0.5%	SDS attached
rhFGF-B	SDS attached



according to Regulation (EC) No. 1907/2006

GA-1000

Version 2.0 Revision Date 12.12.2018 Print Date 10.03.2021 SECTION 1: Identification of the substance/mixture and of the company/undertaking **1.1 Product identifier** <02GCG_BRAND1[D:Product Name]> FGM® 3 SingleQuots® Product name : 1.2 Relevant identified uses of the substance or mixture and uses advised against Use of the Substance/Mixture : Scientific research and development 1.3 Details of the supplier of the safety data sheet Company : Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81 11 Lonza Verviers Sprl Parc Industriel de Petit-Rechain **BE-4800** Verviers, Belgium Business Telephone: +32 8732 1611 Lonza Cologne GmbH Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 1990 Lonza Copenhagen ApS Strandhaven 12 DK-2665 Vallensbaek Strand, Denmark Business Telephone: + 45 4356 7400 E-mail address sds@lonza.com Responsible/issuing person **1.4 Emergency telephone number** Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)



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Hazard pictograms		
Signal word	: Danger	
Hazard statements	: H317 May cause an allergic skin H334 May cause allergy or asthn difficulties if inhaled.	
Precautionary statements	 Prevention: P261 Avoid breathing dust/ fume P280 Wear protective gloves. P284 Wear respiratory protection Response: P304 + P340 IF INHALED: Remo keep comfortable for breathing. P333 + P313 If skin irritation or ra advice/ attention. P342 + P311 If experiencing resp POISON CENTER/doctor. 	n. ove person to fresh air and ash 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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
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.



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If inhaled	:	Move to fresh air.	
		Call a physician immediately.	the factor of the factor f
		If breathing is irregular or stopped, a respiration.	dminister artificial
In case of skin contact	:	After contact with skin, wash immed	iately with plenty of soap
		and water.	
		Wash clothing before reuse. Get medical attention if irritation dev	elons and nersists
In case of eye contact	:	In the case of contact with eyes, rins	e immediately with plenty
		of water and seek medical advice.	
		If eye irritation persists, consult a sp	ecialist.
If swallowed	:	Immediately give plenty of water (if p	
		Do not induce vomiting without med	
		Never give anything by mouth to an Take victim immediately to hospital.	unconscious person.
2 Most important symptoms and effe	ects,	both acute and delayed	
Symptoms	:	Allergic appearance	
		sensitising effects	
3 Indication of any immediate medic	al at	tention and special treatment need	ed
	:	Treat symptomatically.	
Treatment			
Ireatment	-		
	;		
ECTION 5: Firefighting measures	5		
ECTION 5: Firefighting measures	:	Not combustible.	
ECTION 5: Firefighting measures	;	Use extinguishing measures that are	
ECTION 5: Firefighting measures	;		
ECTION 5: Firefighting measures	:	Use extinguishing measures that are circumstances and the surrounding	
ECTION 5: Firefighting measures 1 Extinguishing media Suitable extinguishing media	: ubst	Use extinguishing measures that are circumstances and the surrounding	environment.
ECTION 5: Firefighting measures 1 Extinguishing media Suitable extinguishing media 2 Special hazards arising from the s Specific hazards during firefighting	: ubst	Use extinguishing measures that are circumstances and the surrounding ance or mixture	environment.
ECTION 5: Firefighting measures 1 Extinguishing media Suitable extinguishing media 2 Special hazards arising from the s Specific hazards during firefighting 3 Advice for firefighters	: ubst	Use extinguishing measures that are circumstances and the surrounding ance or mixture Heating or fire can release toxic gas	environment.
 ECTION 5: Firefighting measures 1 Extinguishing media Suitable extinguishing media 2 Special hazards arising from the s Specific hazards during firefighting 	: ubst	Use extinguishing measures that are circumstances and the surrounding ance or mixture	environment.

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.	



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		Refer to protective measures listed	d in sections 7 and 8.
6.2 Environmental precautions			
Environmental precautions	:	No special environmental precauti	ons required.
6.3 Methods and material for containme	nt	and cleaning up	
Methods for cleaning up	:	Contain spillage, soak up with non material, (e.g. sand, earth, diatoma and transfer to a container for disp national regulations (see section 1	aceous earth, vermiculite) osal according to local /
6.4 Reference to other sections			
For personal protection see section 8.			
SECTION 7: Handling and storage			
7.1 Precautions for safe handling			
Advice on safe handling	:	In case of insufficient ventilation, we equipment. Avoid exposure - obtain special insuface only in area provided with app Avoid contact with skin and eyes.	structions before use.
Advice on protection against fire and explosion	:	Stable under normal conditions.	
Hygiene measures	:	DANGER! Avoid contact with the s breathing dust or spray mist. Wash immediately after handling the pro	n hands before breaks and
	ng	any incompatibilities	
7.2 Conditions for safe storage, includin		Koon frazen ar refrigerated	
7.2 Conditions for safe storage, includir Requirements for storage areas and containers	:	Keep frozen of reingerated.	
Requirements for storage areas and	:	Keep frozen of reingerated.	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

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



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Personal protective equipment		
Eye protection	: Safety glasses Safety goggles	
Hand protection		
Material	: Nitrile rubber	
Rate of permeability	: > 480 min	
Skin and body protection	: Choose body protection accordin concentration of the dangerous s Complete suit protecting against	substance at the work place.
Respiratory protection	: In case of mist, spray or aerosol of personal respiratory protection ar	•
	Respirator with ABEK filter. Respirator with combination filter 141)	for vapour/particulate (EN

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	Aqueous solution
Colour	:	light yellow
Odour	:	odourless
Odour Threshold	:	no data available
рН	:	no data available
Freezing point	:	0°C
Boiling point/boiling range	:	no data available
Flash point	:	Does not sustain combustion.
Evaporation rate	:	no data available
Flammability (solid, gas)	:	no data available
Upper explosion limit	:	no data available
Lower explosion limit	:	no data available
Vapour pressure	:	no data available
Relative vapour density	:	no data available
Relative density	:	no data available
Solubility(ies)		



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Water solubility	:	soluble	
Partition coefficient: n-octanol/water	:	no data available	
Auto-ignition temperature	:	no data available	
Decomposition temperature	:	no data available	
Viscosity	:	no data available	
Explosive properties	:	no data available	
Oxidizing properties	:	no data available	
9.2 Other information no data available			
SECTION 10: Stability and reactivity	/		
10.1 Reactivity Stable under recommended storage of	cor	nditions.	
10.2 Chemical stability Stable under normal conditions.			
10.3 Possibility of hazardous reactions Hazardous reactions	:	Stable under normal conditions.	
10.4 Conditions to avoid Conditions to avoid		None known.	
	•	NOTE KIOWI.	
10.5 Incompatible materials Materials to avoid	:	Strong oxidizing agents	
10.6 Hazardous decomposition product Nitrogen oxides (NOx) Carbon dioxide (CO2) Carbon monoxide	ts		
SECTION 11: Toxicological informa	tio	on	
11.1 Information on toxicological effect	ts		
Further information			
		Remarks: No data is available on the produ	

SECTION 12: Ecological information

- 12.1 Toxicity
 - Toxicity to fish

: Remarks: no data available



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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 assess	nent	
Assessment	: This substance/mixture contains be either persistent, bioaccumu persistent and very bioaccumula higher.	llative and toxic (PBT), or very
12.6 Other adverse effects Additional ecological information	: No data is available on the proc	duct itself.
SECTION 13: Disposal considerati	ons	
13.1 Waste treatment methods		
Product	: Dispose of in accordance with le	ocal regulations.
Contaminated packaging	: Dispose of as unused product.	
SECTION 14: Transport informatio	n	
ΙΑΤΑ	Not dangerous goods	
 14.1 UN number 14.2 Proper shipping name 14.3 Transport hazard class 14.4 Packing group 14.5 Environmental hazards 	 Not applicable Not applicable Not applicable Not applicable no 	

IMDG

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

Not dangerous goods



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Versior	n 2.0 F	Revision Date 12.12.2018	Print Date 10.03.2021
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	 Not applicable Not applicable Not applicable Not applicable no 	
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	 Not applicable Not applicable Not applicable Not applicable no 	
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	 Not applicable Not applicable Not applicable Not applicable no 	
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	 Not applicable Not applicable Not applicable Not applicable no 	
14.6	Special precautions for user	: none	
14.7	Transport in bulk according to Annex II of Marpol and the IBC Coc	: Not applicable le	

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture						
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable				
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable				
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable				



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Regulation (EC) No 10 ozone layer	005/2009 on substand	es that deplete the : Not applie	cable	
Regulation (EC) No 85	50/2004 on persistent	organic pollutants : Not appli	cable	
Seveso III: Directive 2 major-accident hazard	s involving dangerous	opean Parliament and of the Cours s substances. ot applicable	ncil on the control of	
National regulatory in	formation			
Water contaminating c (Germany)		GK 1 slightly hazardous to water lassification according to AwSV, A		
15.2 Chemical safety ass	essment			
not required				
SECTION 16: Other infe	ormation			
Classification of the	mixture:	Classification p	procedure:	
Resp. Sens. 1	H334	Calculation meth		
Skin Sens. 1	H317	Calculation meth	nod	
Full text of H-Statem	ents			
H317		ay cause an allergic skin reaction		
H334	H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.			

Further 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

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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

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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according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 2.0 Revision Date 12.12.2018 Print Date 10.03.2021 SECTION 1: Identification of the substance/mixture and of the company/undertaking **1.1 Product identifier** <02GCG_BRAND1[D:Product Name]> FGM® 3 SingleQuots® Product name : 1.2 Relevant identified uses of the substance or mixture and uses advised against Use of the Substance/Mixture : Scientific research and development 1.3 Details of the supplier of the safety data sheet Company : Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81 11 Lonza Verviers Sprl Parc Industriel de Petit-Rechain **BE-4800** Verviers, Belgium Business Telephone: +32 8732 1611 Lonza Cologne GmbH Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 1990 Lonza Copenhagen ApS Strandhaven 12 DK-2665 Vallensbaek Strand, Denmark Business Telephone: + 45 4356 7400 E-mail address sds@lonza.com Responsible/issuing person **1.4 Emergency telephone number** Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

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.

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 effe	cts	, both acute and delayed
Symptoms	:	No information available.
4.3 Indication of any immediate medicate	al a	ttention and special treatment needed
Treatment	ai a	No information available.
Hoamon	•	
SECTION 5: Firefighting measures		
5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Dry powder Foam
5.2 Special hazards arising from the su	ubs	tance or mixture
		Heating or fire can release toxic gas.
5.3 Advice for firefighters		
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.
Pof /00000016003		



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Further information	: Use water spray to cool unopene	ed containers.
SECTION 6: Accidental release mea	sures	
6.1 Personal precautions, protective eq	uipment and emergency procedure	es
Personal precautions	: Use personal protective equipme	ent.
6.2 Environmental precautions		
Environmental precautions	: Prevent product from entering dr	ains.
6.3 Methods and material for containme	nt and cleaning up	
Methods for cleaning up	: Contain spillage, and then collect absorbent material, (e.g. sand, evermiculite) and place in contained local / national regulations (see s	arth, diatomaceous earth, er for disposal 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	: No special precautions required.	
Hygiene measures	: Handle in accordance with good practice.	industrial hygiene and safety
7.2 Conditions for safe storage, includir	ng any incompatibilities	
Requirements for storage areas and containers	: Keep tightly closed.	
	Store in cool place.	
7.3 Specific end use(s)		
Specific use(s)	: No information available.	



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SECTION 8: Exposure of	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 Rate of permeability	:	Nitrile rubber > 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

Appearance	:	Aqueous solution
Colour	:	brown
Odour	:	no data available
Odour Threshold	:	no data available
рН	:	6,8 - 8,3
Freezing point	:	no data available
Boiling point/boiling range	:	no data available
Flash point	:	does not flash
Evaporation rate	:	no data available
Flammability (solid, gas)	:	no data available
Upper explosion limit	:	no data available
Lower explosion limit	:	no data available



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Vapour pressure	: no data available			
Relative vapour density	: no data available			
Relative density	: no data available			
Density	: no data available			
Solubility(ies) Water solubility	: soluble			
Partition coefficient: n-octanol/water	: no data available			
Auto-ignition temperature	: no data available			
Decomposition temperature	: no data available			
Viscosity	: no data available			
Explosive properties	: no data available			
Oxidizing properties	: no data available			
9.2 Other information				

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials Materials to avoid

: Strong oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Further information



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	Remarks: No data is available on t	he product itself.
SECTION 12: Ecological information	n	
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 assessi	nent	
Assessment	: This substance/mixture contains no be either persistent, bioaccumulati persistent and very bioaccumulativ higher.	ve and toxic (PBT), or very
12.6 Other adverse effects		
Additional ecological information	: no data available	

13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations.



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Not dangerous goods

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SECTION 14: Transport information

IATA

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



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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	 Not applicable Not applicable Not applicable Not applicable no 	
14.6	Special precautions for user	: none	
14.7	Transport in bulk according to Annex II of Marpol and the IBC Co	: Not applicable	

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 (EC) No 850/2004 on persistent 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 contaminating class : WGK 1 slightly hazardous to water (Germany)
15.2 Chemical safety assessment

not required

SECTION 16: Other information

Full text of H-Statements

Further information

Full text of other abbreviations



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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

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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SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Fetal Bovine Serum

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

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.



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0

Revision Date 12.12.2018

: FGM® 3 SingleQuots®

Print Date 10.03.2021

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

1.1 Product identifier

<02GCG_BRAND1[D:Product Name]>

Product name

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

- Use of the Substance/Mixture
- : Scientific research and development

1.3 Details of the supplier of the safety data sheet

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



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

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.

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 Descript	tion 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.
meannenn		

SECTION 5: Firefighting measures

5.1 Extinguishing media Suitable extinguishing media	:	Water spray Dry powder Foam	
5.2 Special hazards arising from the su Specific hazards during firefighting			
5.3 Advice for firefighters Special protective equipment for	:	In the event of fire, wear self-contained breathing apparatus.	



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0		Revision Date 12.12.2018	Print Date 10.03.2021
firefighters			
Further information	:	Use water spray to cool unopened conta	ainers.
SECTION 6: Accidental release mea	su	ires	
6.1 Personal precautions, protective eq	uiŗ	oment and emergency procedures	
Personal precautions	:	Use personal protective equipment.	
6.2 Environmental precautions			
Environmental precautions	:	No special environmental precautions re	equired.
6.3 Methods and material for containme	nt	and cleaning un	
Methods for cleaning up	:	Wipe up with absorbent material (e.g. cl Dispose of in accordance with local regi	
6.4 Reference to other sections			
For personal protection see section 8			
SECTION 7: Handling and storage			
7.1 Precautions for safe handling			
Advice on safe handling	:	No special precautions required.	
Advice on protection against fire and explosion	:	No special precautions required.	
Hygiene measures	:	Handle in accordance with good industr practice.	ial hygiene and safety
7.2 Conditions for safe storage, includir	ng	any incompatibilities	
_	-	No special storage conditions required.	
7.3 Specific end use(s)			
Specific use(s)	:	No information available.	



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0	Revision Date 12.12.2018	Print Date 10.03.2021				
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	: 7	Fightly fitting safety goggles		
Hand protection Material Rate of permeability		Nitrile rubber > 480 min		
Skin and body protection	C	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 equired.		

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	Aqueous solution
Colour	:	colourless
Odour	:	odourless
Odour Threshold	:	no data available
рН	:	2 - 4
Freezing point	:	no data available
Boiling point/boiling range	:	no data available
Flash point	:	Water
Evaporation rate	:	no data available
Flammability (solid, gas)	:	no data available
Upper explosion limit	:	no data available
Lower explosion limit	:	no data available



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0	Revision Date 12.12.2018	Print Date 10.03.2021
Vapour pressure	: no data available	
Relative vapour density	: no data available	
Relative density	: no data available	
Density	: no data available	
Solubility(ies) Water solubility	: completely soluble	
Partition coefficient: n-octanol/water	: no data available	
Auto-ignition temperature	: no data available	
Decomposition temperature	: no data available	
Viscosity	: no data available	
Explosive properties	: no data available	
Oxidizing properties	: no data available	
9.2 Other information		

9.2 Other information

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: Stable under normal conditions.
---------------------	-----------------------------------

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials Materials to avoid

: Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Skin corrosion/irritation



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0		Revision Date 12.12.2018	Print Date 10.03.2021
		Assessment: No skin irritation	
Serious eye damage/eye irritation			
		Assessment: No eye irritation	
Further information			
		Remarks: No data is available on the pro	oduct itself.
		Remarks: Insulin: may cause hypoglycae Insulin is inactivated in the gastro-intesti ingested. May cause central nervous system depr May induce sweating, pallor or visual dis	nal tract when ession.
SECTION 12: Ecological informatio	n		
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 assessn	nen	t	
Assessment	:	This substance/mixture contains no com be either persistent, bioaccumulative and persistent and very bioaccumulative (vPv higher.	d toxic (PBT), or very
12.6 Other adverse effects			
Additional ecological information	:	no data available	

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0

Revision Date 12.12.2018

Not dangerous goods

Print Date 10.03.2021

SECTION 14: Transport information

IATA

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



according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Versior	n 2.0	Revision Date 12.12.2018	Print Date 10.03.2021
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	 Not applicable Not applicable Not applicable Not applicable no 	
14.6	Special precautions for user	: none	
14.7	Transport in bulk according to Annex II of Marpol and the IBC Co	: Not applicable ode	

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 for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament ar major-accident hazards involving dangerous substances. Not applicable	nd c	of the Council on the control of

National regulatory information

Water contaminating class : nwg not water endangering (Germany)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Full text of H-Statements

Further information

Full text of other abbreviations

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

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

Date format

dd.mm.yyyy

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according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

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

rhFGF-B

Version 2.0 Revision Date 12.12.2018 Print Date 10.03.2021 SECTION 1: Identification of the substance/mixture and of the company/undertaking **1.1 Product identifier** <02GCG_BRAND1[D:Product Name]> FGM® 3 SingleQuots® Product name : 1.2 Relevant identified uses of the substance or mixture and uses advised against Use of the Substance/Mixture : Scientific research and development 1.3 Details of the supplier of the safety data sheet Company : Lonza Ltd Muenchensteinerstrasse 38 CH-4002 Basel, Switzerland Business Telephone: +41 61 316 81 11 Lonza Verviers Sprl Parc Industriel de Petit-Rechain **BE-4800** Verviers, Belgium Business Telephone: +32 8732 1611 Lonza Cologne GmbH Nattermannallee 1 DE-50829 Köln, Germany Business Telephone: + 49 221 99 1990 Lonza Copenhagen ApS Strandhaven 12 DK-2665 Vallensbaek Strand, Denmark Business Telephone: + 45 4356 7400 E-mail address sds@lonza.com Responsible/issuing person 1.4 Emergency telephone number Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland Telephone: +41 61 313 94 94 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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



according to Regulation (EC) No. 1907/2006

rhFGF-B

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

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.

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 effe	cts	, both acute and delayed
Symptoms	:	No information available.
4.3 Indication of any immediate medica	al at	ttention and special treatment needed
Treatment	:	No information available.
SECTION 5: Firefighting measures		
5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Dry powder Foam
5.2 Special hazards arising from the su	ibst	tance or mixture
Specific hazards during firefighting		
5.3 Advice for firefighters		
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.
Ref. / 00000028974		SDK EU/EN Page



according to Regulation (EC) No. 1907/2006

rhFGF-B

		Print Date 10.03.20
:	Use water spray to cool unopened c	containers.
easu	res	
equip	ment and emergency procedures	
:	Use personal protective equipment.	
:	Prevent product from entering drains	S.
ment	and cleaning up	
:	Contain spillage, and then collect wi absorbent material, (e.g. sand, earth vermiculite) and place in container for local / national regulations (see sect	n, diatomaceous earth, or disposal according to
n 8.		
e		
:	No special precautions required.	
nd :	Take precautionary measures again	st static discharges.
:	Handle in accordance with good ind practice.	ustrial hygiene and safety
uding	any incompatibilities	
nd :	No special storage conditions requir	ed.
:	No information available.	
	equip : : : ment : nd : : uding	easures equipment and emergency procedures : Use personal protective equipment. : Prevent product from entering drain ment and cleaning up : Contain spillage, and then collect wi absorbent material, (e.g. sand, earth vermiculite) and place in container f local / national regulations (see sect n 8. e : No special precautions required. nd : Take precautionary measures again : Handle in accordance with good ind practice. uding any incompatibilities nd : No special storage conditions required



according to Regulation (EC) No. 1907/2006

rhFGF-B

Version 2.0	Revision Date 12.12.2018	Print Date 10.03.2021			

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 Rate of permeability	:	Nitrile rubber > 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

Appearance	:	Aqueous solution
Colour	:	no data available
Odour	:	no data available
Odour Threshold	:	no data available
рН	:	no data available
Freezing point	:	no data available
Boiling point/boiling range	:	no data available
Flash point	:	does not flash
Evaporation rate	:	no data available
Flammability (solid, gas)	:	no data available
Upper explosion limit	:	no data available
Lower explosion limit	:	no data available



according to Regulation (EC) No. 1907/2006

rhFGF-B

Version 2.0	Revision Date 12.12.2018	Print Date 10.03.2021
Vapour pressure	: no data available	
Relative vapour density	: no data available	
Relative density	: no data available	
Density	: no data available	
Solubility(ies) Water solubility	: soluble	
Partition coefficient: n-octanol/water	: no data available	
Auto-ignition temperature	: no data available	
Decomposition temperature	: no data available	
Viscosity	: no data available	
Explosive properties	: no data available	
Oxidizing properties	: no data available	
9.2 Other information		

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable und	er 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 toxicological effects

Further information



according to Regulation (EC) No. 1907/2006

rhFGF-B

Version 2.0	Revision Date 12.12.2018	Print Date 10.03.202		
	Remarks: No data is available on the product itself.			
SECTION 12: Ecological information	on			
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 assess	ment			
Assessment	: This substance/mixture contains n be either persistent, bioaccumulat persistent and very bioaccumulativ higher.	ive and toxic (PBT), or very		
12.6 Other adverse effects				
Additional ecological information	: no data available			

13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations.



according to Regulation (EC) No. 1907/2006

rhFGF-B

Version 2.0

Revision Date 12.12.2018

Not dangerous goods

Print Date 10.03.2021

SECTION 14: Transport information

IATA

14.1 14.2 14.3 14.4 14.5 IMDG	UN number Proper shipping name Transport hazard class Packing group Environmental hazards		Not applicable Not applicable Not applicable Not applicable no
14.1 14.2 14.3 14.4 14.5 ADR	UN number Proper shipping name Transport hazard class Packing group Environmental hazards	· · · · · · · · · · · · · · · · · · ·	Not applicable Not applicable Not applicable Not applicable Marine pollutant: no Not dangerous goods
14.1 14.2 14.3 14.4 14.5 RID	UN number Proper shipping name Transport hazard class Packing group Environmental hazards		Not applicable Not applicable Not applicable Not applicable no
14.1 14.2 14.3 14.4 14.5 DOT	UN number Proper shipping name Transport hazard class Packing group Environmental hazards		Not applicable Not applicable Not applicable Not applicable no 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	: : : :	Not applicable Not applicable Not applicable Not applicable no



according to Regulation (EC) No. 1907/2006

rhFGF-B

Versio	n 2.0	Revision Date 12.12.2018	Print Date 10.03.2021
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	 Not applicable Not applicable Not applicable Not applicable no 	
14.6	Special precautions for user	: none	
14.7	Transport in bulk according to Annex II of Marpol and the IBC Co	: Not applicable de	

SECTION 15: Regulatory information

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

 ould y, health and environmental regulations/registation sp		
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament ar major-accident hazards involving dangerous substances. Not applicable	nd d	of the Council on the control of

National regulatory information

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

15.2 Chemical safety assessment

not required



according to Regulation (EC) No. 1907/2006

rhFGF-B

Version 2.0

Revision Date 12.12.2018

Print Date 10.03.2021

SECTION 16: Other information

Full text of H-Statements

Further 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

Date format

: dd.mm.yyyy

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