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

1.1 Product identifier	
Trade name	: CellGenix® GMP rh IL-1 beta
Product code	: 1011-050
Substance name	: CellGenix® rh IL-1 beta - Interleukin-1 beta - recombinant human
1.2 Relevant identified uses of t	he substance or mixture and uses advised against
Use of the Sub- stance/Mixture	: Cell Culture component. For further manufacturing use (GMP grade) or for preclinical ex vivo use (preclinical grade).
Recommended restrictions on use	: Not intended for human in vivo application.
1.3 Details of the supplier of the	e safety data sheet
Company	: Sartorius CellGenix GmbH Am Flughafen 16 79108 Freiburg Germany
Telephone	: +49 761 888 89-0
Telefax	: +49 761 888 89-830
E-mail address of person responsible for the SDS	: CA-FM Department: Environment@sartorius.com

1.4 Emergency telephone number

UK/Europe/Global: +44.1865.407.333 (Sartorius 29003) United States: +1.866.928.0789 (Toll free), (Sartorius 29003) Canada: +1.800.579.7421 (Toll free), (Sartorius 29003) United States & Canada (geographic): +1.202.464.2554 (Sartorius 29003) Asia-Pacific/East & South East Asia (without China): +65.3158.1074 (Sartorius 29003) Japan: +81.3.4578.9341 (Sartorius 29003) Indonesia: 007.803.011.0293 (Toll free Indonesia), (Sartorius 29003) Malaysia: +60.3.6207.4347 (Sartorius 29003) Thailand: 001.800.120.666.751 (Toll free Thailand), (Sartorius 29003) India: 000.800.100.7479 (Toll free India) or +65.3158.1198 (Sartorius 29003) South Korea: +82.2.3479.8401 (Sartorius 29003) Australia: +61.2.8014.4558 (Sartorius 29003)



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New Zealand: +64.9.929.1483 (Sartorius 29003) Middle East/Africa: +44.1235.239671 (Sartorius 29003)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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

2.2 Label elements

Labelling REGULATION (EC) No 1272/2008

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

2.3 Other hazards

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

Cytokines and growth factors are highly bioactive proteins involved in cell signaling. Up to now, there are no test data available which would allow to classify them into one of the hazard classes according to the CLP-regulation (EU) No. 1272/2008. However, considering their bioactivity, any unintended exposure should be avoided. Therefore, in the case of any exposure, medical advice should be seeked.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature

: Mixture powdered form

Hazardous components

Remarks

: No dangerous ingredients according to Regulation (EC) No. 1907/2006

SECTION 4: First aid measures

4.1 Description of first aid	measures
General advice	: Show this safety data sheet to the doctor in attendance.
If inhaled	: Move out of dangerous area. If breathed in, move person into fresh air.
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			y tract clear. cial respiration if needed. rsist, call a physician.	
In ca	se of skin contact	Wash off immed removing all co	liately adhering matter. diately with soap and plenty of water while ntaminated clothes and shoes. ention if irritation develops and persists.	
In ca	se of eye contact		contact, remove contact lens and rinse imme- nty of water, also under the eyelids, for at least i immediately.	
If swallowed		0,	: Thoroughly rinse mouth with water. After rinsing, drink large amounts of water.	
		If symptoms pe	rsist, call a physician.	
	important symptoms a known.	and effects, both acu	ite and delayed	
4.3 Indica	ation of any immediate	medical attention a	nd special treatment needed	
Trea	tment	: Treat symptoma	atically.	
SECTIO	N 5: Firefighting mea			

SECTION 5: Firefighting measures

5.1 Extinguishing media Suitable extinguishing media	: Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Water Carbon dioxide (CO2) Dry powder Foam		
Unsuitable extinguishing media	: None known.		
5.2 Special hazards arising from the substance or mixture Specific hazards during fire- fighting : Do not allow run-off from fire fighting to enter drains or water courses.			
5.3 Advice for firefighters Special protective equipment for firefighters : Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear.			
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Speci ods	fic extinguishing meth-		g measures that are appropriate to local cir- the surrounding environment.
SECTION 6: Accidental release measures			

6.1 Personal precautions, protective equipment and emergency procedures Personal precautions : Ensure adequate ventilation. Avoid any contact with the substance.			
6.2 Environmental precautions			
Environmental precautions	: The product should not be allowed to enter drains, water courses or the soil.		
6.3 Methods and material for conta	inment and cleaning up		
Methods for cleaning up	 Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal. Do not create a powder cloud by using a brush or compressed air. 		

6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling	7.1 Precautions for safe handling			
Advice on safe handling	: Avoid creating dust. Do not breathe vapours/dust. Avoid contact with skin, eyes and clothing. If syringes are used to handle the product, be careful to avoid injuries with injection needles.			
Advice on protection against fire and explosion	: The product is flammable but not readily ignited.			
Hygiene measures	: Keep container tightly closed. When using, do not eat, drink or smoke. Wash hands and face before breaks and immediately after handling the product.			
7.2 Conditions for safe storage, in	cluding any incompatibilities			
Further information on stor- age conditions	: -8020 °C (Shipping at ambient temperature.)			
Storage class (TRGS 510)	: 10-13, German Storage Class 10 to 13			
7.3 Specific end use(s)				
Specific use(s)	: Cell Culture component. For further manufacturing use (GMP			
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grade) or for preclinical ex vivo use (preclinical grade).

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No data available

8.2 Exposure controls

Engineering measures

none

Personal protective equipment

Eye protection Hand protection Material		Safety glasses with side-shields conforming to EN166 Nitrile rubber Latex gloves
Skin and body protection Respiratory protection		Change working clothes after each workshift. No personal respiratory protective equipment normally re- quired.
Protective measures	:	Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	: powder : white : odourless : No data available
рН	: not determined
Melting point/range	: No data available
Boiling point/boiling range Flash point	: Not applicable : No data available
Evaporation rate Upper explosion limit	: Not applicable : No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available



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	Relative	e vapour density	:	No data available	2
	Relative density Density		:	No data available	
			: No data available		
	Bulk de	nsity	:	No data available	
	Solubility(ies) Water solubility Solubility in other solvents		-	soluble not determined	
	octanol	n coefficient: n- /water nition temperature		No data available	
	Decomposition temperature Viscosity Viscosity, dynamic		:	No data available	
				Not applicable	
	Visco	osity, kinematic	:	Not applicable	
	Flow tin	ne	:	Not applicable	
		ve properties ng properties		Not applicable No data available	
9.2	Self-hea Impact	formation ating substances sensitivity lar weight	:	No data available Not applicable 17,5 kg/mol	

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions

: None known.

Stable under recommended storage conditions. No decomposition if used as directed.



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10.4 Conditions to avoid Conditions to avoid		: Not applicable			
	npatible materials ials to avoid	: Strong oxidizing	agents		
10.6 Hazardous decomposition products					

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:	
Acute oral toxicity	: Remarks: No data available
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available
Acute toxicity (other routes of administration)	: Remarks: No data available

Skin corrosion/irritation

Product:

Remarks: No data available

Serious eye damage/eye irritation

Product:

Remarks: No data available

Respiratory or skin sensitisation

Product:

Remarks: No data available

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available



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Genotoxicity in vivo :

: Remarks: No data available

Carcinogenicity

Product:

Remarks: This information is not available.

Reproductive toxicity

Product:

Effects on fertility

: Remarks: No data available

STOT - single exposure

Product:

Remarks: No data available

STOT - repeated exposure

Product: Remarks: No data available

Repeated dose toxicity

Product:

Remarks: This information is not available.

Experience with human exposure

Product:

General Information	:	Remarks: No data available
Inhalation	:	Remarks: This information is not available.
Skin contact	:	Remarks: This information is not available.
Eye contact	:	Remarks: This information is not available.
Ingestion	:	Remarks: This information is not available.

Neurological effects

Product:

Remarks: No data available

Further information

Product:

Remarks: No data available



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SECTION 12: Ecological information

12.1 Toxicity

<u>Product:</u> Toxicity to fish	: Remarks: No data available
Toxicity to daphnia and other	: Remarks: No data available
aquatic invertebrates Toxicity to algae	: Remarks: No data available
Toxicity to fish (Chronic tox- icity)	: Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chron-	: Remarks: No data available
ic toxicity) Toxicity to bacteria	: Remarks: No data available
Sediment toxicity	: Remarks: No data available

12.2 Persistence and degradability

Product:

Biodegradability	: Remarks: No data available
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12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

Product:

Mobility	
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: Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

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

12.6 Other adverse effects

Product:

Further information	: The substance/mixture does not contain components consid-
	ered to have endocrine disrupting properties according to
	REACH Article 57(f) or Commission Delegated regulation



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Additi matio	ional ecological infor- n	(EU) 2017/2100 levels of 0.1% o : Remarks: No da	•		
SECTION 13: Disposal considerations					

13.1 Waste treatment methods

Product	: In accordance with local and national regulations. Empty the packaging completely prior to disposal. Handle uncleaned empty containers as full ones.
Contaminated packaging	: Clean container with water.
	Retain and dispose of contaminated wash water.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user Not applicable

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Water hazard class (Germa-	:	WGK 3 highly hazardous to water
ny)		Remarks: (own classification)



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15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture.

SECTION 16: Other information

Further information

Other information

: For this mixture, a safety data sheet is legally not required, neither due to REACH art. 31(1) nor due to REACH art. 31(3). Therefore, the compilation of this safety data sheet is done voluntarily and the safety data sheet does't have to fit the requirements of REACH annex II to the full extent.

These safety instructions also apply to empty packaging which may still contain product residues.

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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