

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Cryo Human Hepatocytes

Version 4.0

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

Product name : Cryo Human Hepatocytes

Synonyms : Cryo Human Hpctyes, Pltable, Q:. Ind

Material number : HUCPG

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

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

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

1.3 Details of the supplier of the safety data sheet

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

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

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

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

1.4 Emergency telephone 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

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

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
- Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Heating or fire can release toxic gas.
- Hazardous combustion products : Carbon oxides (CO_x)
Sulphur oxides (SO_x)

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

- Environmental precautions : Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : No special precautions required.
For personal protection see section 8.
- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep container tightly closed. Keep in a well-ventilated place. To maintain product quality, do not store in heat or direct sunlight.
- Advice on common storage : No special restrictions on storage with other products.
- Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

- Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Dimethyl sulfoxide	67-68-5	STEL	100 ppm 320 mg/m ³	CH SUVA
		TWA	50 ppm 160 mg/m ³	CH SUVA

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Dimethyl sulfoxide	Workers	Inhalation	Long-term systemic effects	394 mg/m ³
		Skin contact	Long-term systemic effects	400 mg/kg
	Consumers	Skin contact	Long-term systemic effects	200 mg/kg
		Oral	Long-term systemic effects	100 mg/kg
	Consumers	Inhalation	Long-term systemic effects	70 mg/m ³
		Workers	Inhalation	Long-term systemic effects
	Workers		Inhalation	Long-term local effects
	Workers	Dermal	Long-term systemic effects	200 mg/kg
	Consumers	Inhalation	Long-term systemic effects	120 mg/m ³
			Long-term local effects	47 mg/m ³
		Dermal	Long-term systemic effects	100 mg/kg
			Oral	Long-term systemic effects
	Calcium chloride dihydrate	Workers	Inhalation	Long-term local effects
Consumers		Inhalation	Acute local effects	5 mg/m ³

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	Consumers	Inhalation	Long-term local effects	2,5 mg/m ³
	Workers	Inhalation	Acute local effects	10 mg/m ³
Potassium dihydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	4,07 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	3,04 mg/m ³

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

Substance name	Environmental Compartment	Value
Dimethyl sulfoxide	Fresh water	17 mg/l
	Oral	700 mg/kg
	Sewage treatment plant	11 mg/l
	Soil	3,02 mg/kg
	Sediment	13,4 mg/kg
Potassium dihydrogenorthophosphate	Marine water	1,7 mg/l
	Fresh water	0,05 mg/l
	Marine water	0,0005 mg/l
	Intermittent use/release	0,5 mg/l
	Sewage treatment plant	50 mg/l

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Physical state : liquid
- Appearance : Aqueous solution
- Colour : light brown
- Odour : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available

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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 flash
Auto-ignition temperature	:	No data available
Decomposition temperature Decomposition temperature	:	No data available
pH	:	6,8 - 7,2
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

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

Conditions to avoid	:	Heat
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents Strong acids and strong bases
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10.6 Hazardous decomposition products

No decomposition if used as directed.

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

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

Aspiration toxicity

No aspiration toxicity classification

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

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

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levels of 0.1% or higher.

Further information

Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

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

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SECTION 14: Transport information

IATA : Not dangerous goods

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

IMDG : Not dangerous goods

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

ADR : Not dangerous goods

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

RID : Not dangerous goods

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

DOT : Not dangerous goods

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

TDG : Not dangerous goods

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

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation

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

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

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

Water hazard class (Germany) : WGK 2 obviously hazardous to water

15.2 Chemical safety assessment

not required
not required

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

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

Further information

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

Date format : dd.mm.yyyy

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