

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended

Cryo Human Hepatocytes

Version 5.0

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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, Susp'n Q:, 10-DP

Material number : HUUCS10P

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 Spri
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

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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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.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray

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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 (COx)
Sulphur oxides (SOx)

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.

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.

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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	484 mg/m ³
	Workers	Inhalation	Long-term local effects	265 mg/m ³	
	Workers	Dermal	Long-term systemic effects	200 mg/kg	
	Consumers	Inhalation	Long-term systemic effects	120 mg/m ³	
		Inhalation	Long-term local effects	47 mg/m ³	
		Dermal	Long-term systemic effects	100 mg/kg	
		Oral	Long-term systemic effects	60 mg/kg	
	Calcium chloride dihydrate	Workers	Inhalation	Long-term local effects	5 mg/m ³
			Consumers	Inhalation	Acute local effects
Consumers		Inhalation	Long-term local effects	2,5 mg/m ³	
Potassium	Workers	Inhalation	Acute local effects	10 mg/m ³	
		Inhalation	Long-term systemic	4,07 mg/m ³	

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dihydrogenorthophosphate			effects	
	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
	Marine water	1,7 mg/l
Potassium dihydrogenorthophosphate	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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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 : 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

Density : No data available

Relative vapour density : No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.
No hazardous decomposition products are known.

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

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

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considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Remarks : No data available

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

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

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)	:	Conditions of restriction for the following entries should be considered: Number on list 75
		If you intend to use this product as tattoo ink, please contact your vendor.
International Chemical Weapons Convention (CWC) Schedules of Toxic Chemicals and Precursors	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors	:	Neither banned nor restricted
SIN (Substitute it Now!) List (ChemSec)	:	Not listed
Community rolling action plan (CORAP) List of Substances	:	Not listed
EU Dual-Use export controls regulation 2021/821 (Annex I, 1C350 and 1C450) as amended	:	Not applicable
Council Regulation (EC) No 273/2004 on drug precursors	:	Not applicable
U.S. EPA PFAS List of Lists	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	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

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Water hazard class (Germany) : WGK 2 obviously hazardous to water
Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or

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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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