

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Human Cryopreserved Kupffer Cells

Version 2.0

Revision Date 07.12.2018

Print Date 10.02.2021

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

Product name : Human Cryopreserved Kupffer Cells
Material number : HLKC

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

Use of the Substance/Mixture : For Research Use Only. Not for use in diagnostic procedures.

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.

Human Cryopreserved Kupffer Cells

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 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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : 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.

Further information : Use water spray to cool unopened containers.

Human Cryopreserved Kupffer Cells

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Wear protective gloves/protective clothing/eye protection/face protection.
 Ensure adequate ventilation.
 Wear respiratory protection when its use is identified for certain contributing scenario.
 Wash contaminated clothing before re-use.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Clean with disinfectants.

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

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/m3	SMAK

Human Cryopreserved Kupffer Cells

		TWA	50 ppm 160 mg/m ³	SMAK
--	--	-----	---------------------------------	------

Germany

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Dimethyl sulfoxide	67-68-5	MAK	50 ppm 160 mg/m ³	DFG MAK
Peak-limit: excursion factor (category)		Peak-limit: excursion factor (category) 2		
			50 ppm 160 mg/m ³	TRGS 900
Peak-limit: excursion factor (category)		Peak-limit: excursion factor (category) 2		

Denmark

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Dimethyl sulfoxide	67-68-5	GV	50 ppm 160 mg/m ³	GV (DK)

Sweden

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Dimethyl sulfoxide	67-68-5	TWA	50 ppm 150 mg/m ³	SWO
		STEL	150 ppm 500 mg/m ³	SWO

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
	Workers	Skin contact	Long-term systemic effects	400 mg/kg
	Consumers	Skin contact	Long-term systemic effects	200 mg/kg
	Consumers	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
	Consumers	Inhalation	Long-term local effects	47 mg/m ³
	Consumers	Dermal	Long-term systemic effects	100 mg/kg
	Consumers	Oral	Long-term systemic effects	60 mg/kg

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

Human Cryopreserved Kupffer Cells

	Sewage treatment plant	11 mg/l
	Soil	3,02 mg/kg
	Sediment	13,4 mg/kg
	Marine water	1,7 mg/l

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection 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 : dark yellow, light red

Odour : no data available

Odour Threshold : no data available

pH : 7

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

Vapour pressure : no data available

Relative vapour density : no data available

Relative density : no data available

Density : no data available

Human Cryopreserved Kupffer Cells

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 decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

Human Cryopreserved Kupffer Cells

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 Other adverse effects

Additional ecological information : no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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 : 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 : 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 : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

Human Cryopreserved Kupffer Cells

RID	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
DOT	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
TDG	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
14.6 Special precautions for user	:	none
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	:	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 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 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

Human Cryopreserved Kupffer Cells

(Germany)

Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Other information : Product should be handled at the Biological Safety Level 2 to minimize exposure of potentially infectious products, as recommended in the CDC-NIH Manual, "Biosafety in Microbiological and Biomedical laboratories".

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

Human Cryopreserved Kupffer Cells

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.

99 / EN