

HROHep03 Cells | 300197

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1. Product identifier:**
Frozen and Living Cell Cultures (Biosafety Level, BSL 1 and 2), whereas BSL2 cell lines were categorized according to TRBA 468 and German IfSG (Infektions-Schutz-Gesetz, Germany).
- 1.2. Relevant identified uses of the mixture and uses advised against:**
For in vitro research use only. For professional, industrial use.
Not for use in human, therapeutic or diagnostic applications.
- 1.3. Details of the supplier of the safety data sheet:**
Information about the distributor/manufacturer: CLS Cell Lines Service GmbH
Dr.-Eckener-Str. 8
69214
Eppelheim
Germany
Tel: +49(0)6221-700799
- 1.3.1. Responsible person:** Jonathan
SteubingE-mail: info@cls.shop
- 1.4. Emergency telephone number:** +49(0)6221-700799

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the

mixture: Biological Hazards:

For Biosafety Level 1 Cell Cultures

Handle as a potentially biohazardous material at least under Biosafety Level 1 containment. Although the material is not known to cause disease in healthy humans, this cannot be excluded. The material has not been screened for Hepatitis B, human immunodeficiency viruses or other adventitious agents, unless otherwise reported on the Certificate of Analysis or the product information sheet. However, personal protective equipment (PPE) and procedures should be followed at all means when working with such material.

For Biosafety Level 2 Cell Cultures

Handle as a potentially biohazardous material at least under Biosafety Level 2 containment. This material is virally transformed or intrinsically carries Epstein-Barr-Virus particles, which may be associated with human disease, hazards include percutaneous injury, ingestion, mucous membrane exposure. The material has not been screened for Hepatitis B, human immunodeficiency viruses or other adventitious agents, unless otherwise reported on the Certificate of Analysis or the product information sheet. Personal protective equipment (PPE) and procedures MUST be followed at all means when working with such material.

Chemical Hazards:

Frozen cell cultures may contain 5 to 10% (v/v) dimethyl sulphoxide (DMSO). DMSO may be harmful and toxic if in contact with skin or ingested, (R23/24/25), irritating to eyes and respiratory system (R36/37/38).

HROHep03 Cells | 300197

Avoid skin contact, eye contact, digestive, and respiratory epithelium (S24/25) if thawed. Person handling the cells should wear PPE (S36/37).

Physical Hazards:

There is a small risk that frozen vials may be pressurized, because of the trapped liquid nitrogen, and could explode on warming. Such a risk will be increased if the vial has been shipped to the customer in a liquid nitrogen container (dry shipper). Wear protective equipment when handling such packages.

Classification according to Regulation (EC) No 1272/2008 (CLP):

Not considered as hazardous mixture.

Hazard statements: No hazard statements.

2.2. Label elements:

Hazard statements: No hazard statements.

Precautionary statements: No precautionary statements.

2.3. Other hazards:

Results of PBT and vPvB assessment: No data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances:

Not applicable.

3.2. Mixtures:

Description:

Various animal and human cell cultures at Biosafety level 1 or 2

Frozen or growing cells are shipped in a yellow or pink liquid cell culture medium (pH 6-8) which may contain inorganic salts, vitamins, amino acids, carbohydrates, other nutrients and phenol red dissolved in water. Frozen cultures may also contain 5-10% DMSO as a cryoprotectant.

Unit: cryovial; frozen liquid in a small plastic container (vial)or

Flask: living cell culture in a plastic

flaskHazardous ingredients:

Description	CAS number	EC number / ECHA list number	REACH registration number	Conc. (%)	Classification according to Regulation (EC) No 1272/2008 (CLP)		
					Pictogram, signal word code(s)	Hazard class and category code(s)	Hazard statement code(s)
Dimethyl					GHS06	Acute Tox. 3 Acute Tox. 3	H301 1

*: Classification specified by the manufacturer; the substance is not listed in Annex VI of the Regulation (EC) No 1272/2008.

HROHep03 Cells | 300197

Non-Hazardous Ingredient(s)	Percentage
Cell culture media, supplemented for freezing	60-80
FBS (Fetal Bovine Serum)	0-20
Cells	1

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures: **INGESTION:**

Measures:

- If the material was swallowed, rinse the mouth with water.
- If the person is unconscious seek emergency medical attention.
- Avoid vomiting unless directed by a medical doctor.

INHALATION:

Measures:

- If the person is unconscious seek emergency medical attention.
- Remove person to fresh air.

SKIN CONTACT:

Measures:

- Wash off immediately with plenty of water and soap.
- Remove all contaminated clothing.

EYE CONTACT:

Measures:

- Flush eyes immediately with water for 10-15 minutes.

4.2. **Most important symptoms and effects, both acute and delayed:**

See Section 11.

4.3. **Indication of any immediate medical attention and special treatment needed:**

No special treatment needed; treat symptomatically.

If exposed or concerned: Report to your Safety Officer and seek Medical Advice immediately.

SECTION 5: FIREFIGHTING MEASURES

5.1. **Extinguishing media:**

5.1.1. **Suitable extinguishing media:**

Choose extinguishing media depending on surrounding fire.

5.1.2. **Unsuitable extinguishing media:**

No data available.

5.2. **Special hazards arising from the substance or mixture:**

During a fire, irritating and toxic gases may be generated by thermal decomposition. The inhalation of such combustion products can have serious adverse effects on health.

5.3. **Advice for firefighters:**

Wear full protective clothing and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

HROHep03 Cells | 300197

- 6.1. Personal precautions, protective equipment and emergency procedures:**
- 6.1.1. For non-emergency personnel:**
Allow only well-trained experts wearing suitable protective clothing to abide in the field of accident.
- 6.1.2. For emergency responders:**
Use personal protective equipment when working with the cell lines, including safety glasses, laboratory gloves and appropriate laboratory clothing to prevent skin exposure.
Do not open primary containers if not authorized.
- 6.2. Environmental precautions:**
Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or groundwater. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.
- 6.3. Methods and material for containment and cleaning up:**
Clean contaminated surface thoroughly.
Autoclave before disposal into appropriated containers. If spilled, follow appropriate cleaning procedure.
Use absorbent material and disinfect.
Wash contaminated clothing separately.
Wash with soap and water. Additional personal protective equipment for cleaning may be mandatory.
- 6.4. Reference to other sections:**
For further and detailed information see Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. Precautions for safe handling:**
Observe conventional hygiene precautions.
Handle and store according to instructions on product information sheet.
Technical measures:
Follow established laboratory procedures when handling. Open only under a sterile workbench.
Wear protective equipment.
Handle as if containing infectious material.
Precautions against fire and explosion:
No special measures required.
- 7.2. Conditions for safe storage, including any incompatibilities: Technical measures and storage condition:**
Handle and store according to instructions on product information sheet. Keep cryovial at -150°C (freezer) or at -196°C (liquid nitrogen vapour phase). **Incompatible materials:** See Section 10.5
Packaging material: No special prescriptions.
- 7.3. Specific end use(s):**
No specific instructions available.

HROHep03 Cells | 300197

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters:

Occupational exposure limit values (Commission Directive (EC) No 2000/39 of 8 June 2000): The components of the mixture are not regulated with exposure limit value.

DNEL values	Oral exposure			Dermal exposure		Inhalative exposure	
	Short term (acute)		Long term (chronic)	Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)
Consumer	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data
Worker	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data

PNEC values		
Compartment	Value	Note(s)
Freshwater	no data	no notes
Marine water	no data	no notes
Freshwater sediment	no data	no notes
Marine water sediment	no data	no notes
Sewage Treatment Plant (STP)	no data	no notes
Intermittent release	no data	no notes
Secondary poisoning	no data	no notes
Soil	no data	no notes

8.2. Exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1. Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin.

8.2.2. Individual protection measures, such as personal protective equipment:

Avoid the contact with skin, eyes, and clothing. Keep away from food and drinks.
Wash hands immediately after handling the product.

HROHep03 Cells | 300197

1. **Eye/face protection:** Use appropriate protective glasses (EN 166).
2. **Skin protection:**
 - a. **Hand protection:** Use appropriate protective gloves (EN 374).
 - b. **Other:** Wear a lab coat while handling the product.
3. **Respiratory protection:** Normally, no respiratory protective equipment is required. Use fume hood to keep airborne concentrations low. No exposure limits are known. European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.
4. **Thermal hazards:** No thermal hazards known.

8.2.3. Environmental exposure controls:

No specific prescription.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions, an expert's advice is necessary before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Parameter	Value / Test method / Remarks
1. Appearance:	frozen or liquid, no information available for cell cultures
2. Odour:	no data*
3. Odour threshold:	no data*
4. pH:	no data*
5. Melting point/freezing point:	no data*
6. Initial boiling point and boiling range:	no data*
7. Flash point:	no data*
8. Evaporation rate:	no data*
9. Flammability (solid, gas):	no data*
10. Upper/lower flammability or explosive limits:	no data*
11. Vapour pressure:	no data*
12. Vapour density:	no data*
13. Relative density:	no data*
14. Solubility(ies):	no data*
15. Partition coefficient: n-octanol/water:	no data*
16. Auto-ignition temperature:	no data*
17. Decomposition temperature:	no data*
18. Viscosity:	no data*
19. Explosive properties:	no data*
20. Oxidizing properties:	no data*

9.2. Other information:

Chemical Properties:

Frozen cell cultures may contain DMSO.

DMSO is stable. It is incompatible with a very wide range of materials, including acid chlorides, strong acids, strong oxidizing agents, strong reducing agents, phosphorus halides, moisture, copperwool + trichloroacetic acid, hygroscopic.

HROHep03 Cells | 300197

*: The manufacturer did not carry out any tests on this parameter for the product or the results of the tests are not available at the time of publication of the data sheet.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:**
No reactivity known.
- 10.2. Chemical stability:**
Stable under normal conditions.
- 10.3. Possibility of hazardous reactions:**
Hazardous polymerization: will not occur.
- 10.4. Conditions to avoid:**
No conditions to avoid known.
- 10.5. Incompatible materials:**
No incompatible materials known.
- 10.6. Hazardous decomposition products:**
No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Information on toxicological effects:**
 - Acute toxicity:** Based on available data, the classification criteria are not met.
 - Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
 - Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
 - Respiratory or skin sensitisation:** Based on available data, the classification criteria are not met.
 - Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
 - Carcinogenicity:** Based on available data, the classification criteria are not met.
 - Reproductive toxicity:** Based on available data, the classification criteria are not met.
 - STOT-single exposure:** Based on available data, the classification criteria are not met.
 - STOT-repeated exposure:** Based on available data, the classification criteria are not met.
 - Aspiration hazard:** Based on available data, the classification criteria are not met.
- 11.1.1. Summaries of the information derived from the test conducted:**
No data available.
- 11.1.2. Relevant toxicological properties:**
Toxicity data for DMSO:

ORL-RAT LD50 14500 mg kg ⁻¹	ORL-MAM LD50 21400 mg kg ⁻¹
kg ⁻¹ IVN-MAN TDLO 686 mg kg ⁻¹	IPR-RAT LD50 8200 mg kg ⁻¹
IVN-MUS LD50 3100 mg kg ⁻¹	ORL-BWD LD50 100 mg kg ⁻¹
IVN-DOG LD50 2500 mg kg	
- 11.1.3. Information on likely routes of exposure:**
Ingestion, inhalation, skin contact, eye contact.
- 11.1.4. Symptoms related to the physical, chemical, and toxicological characteristics:**
No data available.

HROHep03 Cells | 300197

11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:

No data available.

11.1.6. Interactive effects:

No data available.

11.1.7. Absence of specific data:

The toxicological properties have not been fully reported.

11.1.8. Other information:

No toxic or exposure data available for cell lines, however general protection procedures occur. Wear appropriate protection equipment.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity:

No data available.

12.2. Persistence and degradability:

No data available.

12.3. Bioaccumulative potential:

No data available.

12.4. Mobility in soil:

No data available.

12.5. Results of PBT and vPvB assessment:

No data available.

12.6. Other adverse effects:

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods:

Disposal according to the local regulations.

13.1.1. Information regarding the disposal of the product:

Follow established procedures for Containment (Biosafety) Level 1 and 2. Hazardous waste generators are required.

Please check if discarded chemical is classified as a hazardous waste. Follow all national, regional and local regulations.

List of Waste Code:

No waste disposal key according to the List of Waste Code (LoW code) can be determined for this product, as only the purpose of application defined by the user enables an allocation. The LoW codenumber must be determined after a discussion with a waste disposal specialist.

13.1.2. Information regarding the disposal of the packaging:

Dispose of in accordance with applicable regulations.

13.1.3. Physical/chemical properties that may affect waste treatment options shall be specified:

No data available.

13.1.4. Sewage disposal:

No data available.

13.1.5. Special precautions for any recommended waste treatment:

No data available.

SECTION 14: TRANSPORT INFORMATION

HROHep03 Cells | 300197

ADR/RID; ADN; IMDG; IATA:

Not subject to the conventions of carriage of dangerous goods.

14.1. UN Number:

No UN Number.

14.2. UN proper shipping name:

No proper shipping name.

14.3. Transport hazard class(es):

No transport hazard classes.

14.4. Packing group:

No packing group.

14.5. Environmental hazards:

No relevant information available.

14.6. Special precautions for user:

Additional information may occur for the carriage of Dangerous Goods by road and air, regarding classification, packaging, and labelling, as cryovials (deep-frozen ampoules) must be shipped on dry ice or liquid nitrogen. The package will indicate all required information.

Please contact the manufacturer in case of any questions regarding the transport.

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:

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive (EC) No 1999/45 and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive (EEC) No 76/769 and Commission Directives (EEC) No 91/155, (EEC) No 93/67, (EC) No 93/105 and (EC) No 2000/21

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives (EEC) No 67/548 and (EC) No 1999/45, and amending Regulation (EC) No 1907/2006

COMMISSION REGULATION (EU) No 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

All necessary licenses for import, holding, transfer and export are in place from CLS. Recipient only must provide evidence of permits and licenses required by law for receiving and handling. Substances are for research use only.

15.2. Chemical safety assessment: No information.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet: No information.

HROHep03 Cells | 300197

Literature references / data sources:

Safety data sheet issued by the manufacturer (October 2020, English).

Methods used for the classification according to Regulation (EC) No 1272/2008:

Not considered as a hazardous mixture.

Relevant hazard statements (code and full text) of Sections 2 and 3:

H301 – Toxic if swallowed.

H311 – Toxic in contact with skin.

H319 – Causes serious eye irritation.

H335 – May cause respiratory irritation.

Training advice: No data available.

Full text of the abbreviations in the safety data sheet:

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road. ATE: Acute Toxicity Estimate.

AOX: Adsorbable organic

halides. BCF: Bioconcentration factor.

BOD: Biological Oxygen Demand.

CAS number: Chemical Abstract Service number.

CLP: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

CMR effects: Carcinogenic, mutagenic, reprotoxic effects. COD: Chemical Oxygen Demand.

CSA: Chemical Safety

Assessment. CSR: Chemical Safety Report.

DNEL: Derived-No-Effect-Level.

ECHA: European Chemical Agency. EC: European Community.

EC number: EINECS and ELINCS numbers (see also EINECS and ELINCS). EEC: European Economic Community.

EEA: European Economic Area (EU + Iceland, Liechtenstein, and Norway). EINECS: European Inventory of Existing Commercial Chemical Substances. ELINCS: European List of Notified Chemical Substances.

EN: European Norm.

EU: European Union.

EWC: European Waste Catalogue (replaced by LoW – see below).

GHS: Globally Harmonized System of Classification and Labelling of Chemicals. IATA: International Air Transport Association.

ICAO-TI: Technical Instructions for the Safe Transport of Dangerous Goods by Air. IMDG: International Maritime Dangerous Goods.

IMSBC: International Maritime Solid Bulk Cargoes.

IUCLID: International Uniform Chemical Information Database. IUPAC: International Union of Pure and Applied Chemistry.

Kow: n-Octanol - Water Partition Coefficient.

LC50: Lethal concentration resulting in 50 % mortality.

LD50: Lethal dose resulting in 50 % mortality (median lethal dose). LoW: List of Waste.

HROHep03 Cells | 300197

LOEC: Lowest Observed Effect

Concentration.LOEL: Lowest Observed Effect Level.

NOEC: No Observed Effect

Concentration.NOEL: No Observed Effect Level.

NOAEC: No Observed Adverse Effect

Concentration.NOAEL: No Observed Adverse Effect Level.

OECD: Organization for Economic Cooperation and Development.OSHA: Occupational Safety and Health Administration.

PBT: Persistent, Bioaccumulative and

Toxic.PNEC: Predicted No Effect Concentration.

QSAR: Quantitative Structure Activity Relationship.

REACH: Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.SCBA: Self Contained Breathing Apparatus.

SDS: Safety Data Sheet.

STOT: Specific Target Organ Toxicity.

SVHC: Substances of Very High

Concern.UN: United Nations.

UVCB: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials.

VOC: Volatile Organic Compound.

vPvB: very Persistent and very Bioaccumulative.

This safety data sheet had been prepared by MSDS-Europe (International branch of Toxinfo Kft. on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations. Professional help regarding the explanation of the safety data sheet: +36 70 335 8480; info@msds-europe.com www.msds-europe.com. The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources, and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information. The MSDS shall be used only as a guide for handling the product; while handling and using the product other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their circumstances and purposes and assume all risk associated with the use of this product.

It is the responsibility of the user to fully comply with local, national, and international regulations concerning the use of this product. Biological material may be hazardous and should be used with caution. CLS Cell Lines Service GmbH shall not be held liable for any damage resulting from handling or from contact with the product.