Safety Data Sheet

ARPE-19-celler | 305025

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)
- BSL2 cell lines 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:

German Headquarters:

- **Company Name:** Cytion GmbH
- **Address:** Dr.-Eckener-Str. 8, 69214 Eppelheim, Germany
- **Telephone:** +49(0)6221-405780
- **Email:** info@cytion.com
- **Responsible person:** Jonathan Steubing

US Office:

- **Company Name:** Cell Lines Service LLC, d/b/a Cytion
- **Address:** 6330 S Western Ave #140, Sioux Falls, SD 57108, United States
- **Telephone:** +1 605-800-7310
- **Email:** contact@us.cytion.com
- **Responsible person:** Oliver Goernhardt

1.4. Emergency telephone number:

- **Germany:** +49 6221-405-780
- **United States:** +1 605-800-7310

Section 2: Hazards identification

2.1. Classification of the mixture:

- **Biological hazards:**
  - **Biosafety Level 1 Cell Cultures:** Handle as potentially biohazardous under Biosafety Level 1 containment. Although not known to cause disease in healthy humans, this cannot be excluded. The material has not been screened for Hepatitis B, HIV, or other adventitious agents unless stated on the Certificate of Analysis or product information sheet. Use personal protective equipment (PPE) as necessary.
  - **Biosafety Level 2 Cell Cultures:** Handle as potentially biohazardous under Biosafety Level 2 containment. This material is virally transformed or contains Epstein-Barr-Virus particles, which may be associated with human disease. Hazards include percutaneous injury, ingestion, and mucous membrane exposure. The material has not been screened for Hepatitis B, HIV, or other adventitious agents unless stated on the Certificate of Analysis or product information sheet. PPE and strict procedures MUST be followed.

- **Chemical hazards:**
  - Frozen cell cultures may contain 5 to 10% (v/v) dimethyl sulphoxide (DMSO). DMSO may be harmful if in contact with skin or ingested and is irritating to eyes and the respiratory system. Avoid contact with skin, eyes, digestive, and respiratory systems if thawed. PPE is required.
- **Physical hazards:**
  - Frozen vials may be pressurized due to trapped liquid nitrogen, posing a risk of explosion upon warming, especially if shipped in a liquid nitrogen container. Wear protective equipment when handling such packages.

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

- Not considered a hazardous mixture. No hazard statements.

2.2. Label elements:

- **Hazard statements:** None.
- **Precautionary statements:** None.

2.3. Other hazards:

- **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) containing 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) or flask (living cell culture in a plastic flask).
- **Hazardous ingredients:**

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:**
  - Rinse the mouth with water.
  - If the person is unconscious, seek emergency medical attention.
  - Avoid inducing vomiting unless directed by a medical professional.
- **Inhalation:**

    - If the person is unconscious, seek emergency medical attention.
    - Remove the person to fresh air.
- **Skin contact:**
    - Wash off immediately with plenty of water and soap.
    - Remove all contaminated clothing.
- **Eye contact:**
    - Flush eyes immediately with water for 10-15 minutes.

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

- Refer to 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:

- **Suitable extinguishing media:** Choose extinguishing media based on surrounding fire.
- **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

6.1. Personal precautions, protective equipment, and emergency procedures:

- **For non-emergency personnel:** Allow only well-trained experts wearing suitable protective clothing to remain in the field of accident.
- **For emergency responders:** Use personal protective equipment, 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 resulting waste according to applicable environmental regulations. Do not allow the product or resulting waste to enter sewers, soil, surface, or groundwater. Notify respective authorities in case of environmental pollution immediately.

6.3. Methods and material for containment and cleaning up:

- Clean contaminated surfaces thoroughly.
- Autoclave before disposal into appropriate containers. Follow appropriate cleaning procedures if spilled.
- 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 the 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 conditions:** Handle and store according to instructions on the product information sheet. Keep cryovials at -150°C (freezer) or at -196°C (liquid nitrogen vapor phase).
- **Incompatible materials:** See Section 10.5
- **Packaging material:** No special prescriptions.

7.3. Specific end use(s):

- No specific instructions available.

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:

Exposure	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
Consumer (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
Worker (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:

- **Appropriate engineering controls:** In pursuance of work, proper foresight is needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin.
- **Individual protection measures, such as personal protective equipment:** Avoid contact with skin, eyes, and clothing. Keep away from food and drinks. Wash hands immediately after handling the product.
    - **Eye/face protection:** Use appropriate protective glasses (EN 166).
    - **Skin protection:**
        - **Hand protection:** Use appropriate protective gloves (EN 374).
        - **Other:** Wear a lab coat while handling the product.
    - **Respiratory protection:** Normally, no respiratory protective equipment is required. Use a 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.
    - **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, expert advice is necessary before deciding on further protective measures.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Parameter	Value / Test method / Remarks
Appearance	Frozen or liquid; no information available for cell cultures
Odour	No data*
Odour threshold	No data*
pH	No data*
Melting point/freezing point	No data*
Initial boiling point and boiling range	No data*
Flash point	No data*
Evaporation rate	No data*
Flammability (solid, gas)	No data*
Upper/lower flammability or explosive limits	No data*
Vapour pressure	No data*
Vapour density	No data*

Parameter	Value / Test method / Remarks
Relative density	No data*
Solubility(ies)	No data*
Partition coefficient: n-octanol/water	No data*
Auto-ignition temperature	No data*
Decomposition temperature	No data*
Viscosity	No data*
Explosive properties	No data*
Oxidizing properties	No data*

9.2. Other information:

- **Chemical Properties:** Frozen cell cultures may contain DMSO. DMSO is stable and incompatible with a wide range of materials, including acid chlorides, strong acids, strong oxidizing agents, strong reducing agents, phosphorus halides, moisture, copper wool + trichloroacetic acid, and hygroscopic materials.

*: 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:**

Route	LD50 (mg/kg)	Species
ORL-RAT	14500	Rat
ORL-MAM	21400	Mammal
IVN-MAN	686	Human
IPR-RAT	8200	Rat
IVN-MUS	3100	Mouse
ORL-BWD	100	Bird
IVN-DOG	2500	Dog

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.

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 apply. 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:

- **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 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 code number must be determined after a discussion with a waste disposal specialist.
- **Information regarding the disposal of the packaging:** Dispose of in accordance with applicable regulations.
- **Physical/chemical properties that may affect waste treatment options:** No data available.
- **Sewage disposal:** No data available.
- **Special precautions for any recommended waste treatment:** No data available.

Section 14: Transport information

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 be provided for the carriage of Dangerous Goods by road and air, regarding classification, packaging, and labeling, 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 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:

- **Applicable Regulations:**
    - 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, labeling, 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 Cytion. The recipient 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 available.

Section 16: Other information

Information regarding the revision of the safety data sheet:

- No information available.

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, labeling, 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 Labeling 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.
- **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, Authorization, 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 has been prepared by MSDS-Europe (International branch of Toxinfo Kft.) on the basis of information provided by the manufacturer/supplier and conforms to the relevant regulations. For professional help regarding the explanation of the safety data sheet, please contact: +36 70 335 8480; info@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 risks 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. Cytion GmbH shall not be held liable for any damage resulting from handling or from contact with the product.