Safety Data Sheet

Insulin, Human recombinant, Solution (5 mg/ml) | 831103

Section 1: identification of the mixture and of the company/undertaking

1.1. Product identifier: Various cell culture media supplied by Cytion GmbH. Cytion Catalog Number: Various
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.

1.2. 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)6221-40578-0
- **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

Emergency telephone numbers:

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

Section 2: hazards identification

2.1. Classification of the mixture:

- Categorized as noninfectious and non-toxic
- **GHS Symbol:** NA
- **Signal Word:** NA
- **HMIS Rating:**
  - Health: 0
  - Flammability: 0
  - Reactivity: 0
- **NFPA Rating:**
  - Health: 0
  - Flammability: 0
  - Reactivity: 0
- **Biological Hazards:** NA
- **Chemical Hazards:** NA
- **Physical Hazards:** NA
- **Classification according to Regulation (EC) No 1272/2008 (CLP):**

- **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:

- Cell culture media are clear transparent or yellow to red liquids (pH 6-8), containing inorganic salts, vitamins, amino acids, carbohydrates, and other nutrients dissolved in water.
- Yellow to red liquids contain phenol red additionally.
- Ready-to-use media may contain Fetal Bovine Serum (FBS) and may be further supplemented with non-hazardous substances or mixtures for cell proliferation (according to EU-CLP or Regulation (EC) No 1272/2008 and GHS standards).

Hazardous ingredients:

- None listed in Annex VI of Regulation (EC) No 1272/2008.

Non-Hazardous Ingredient(s):

- Cell culture media
- FBS (Fetal Bovine Serum)

Section 4: first aid measures

4.1. Description of first aid measures:
Ingestion:

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

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:

- 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 the 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

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 remain in the accident area.

6.1.2. For emergency responders:

- Use personal protective equipment when working with 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 spillage and resulting waste according to applicable environmental regulations.
- Do not allow the product or resulting waste to enter sewers, soil, or surface/groundwater.
- Notify respective authorities immediately in case of environmental pollution.

6.3. Methods and material for containment and cleaning up:

- Clean contaminated surfaces thoroughly.
- Autoclave before disposal into appropriate containers.
- If spilled, follow appropriate cleaning procedures.
- 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 bottles tightly closed in a dry place.
- Store at +2-8°C.

Incompatible materials:

- See Section 10.5.

Packaging material:

- No special prescriptions.

7.3. Specific end use(s):

- For in vitro research use only.
- For professional, industrial use.
- Not intended for clinical or diagnostic applications.

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 values.

8.2. Exposure controls:

- In case of hazardous materials with no controlled concentration limit, it is the employer's duty to minimize concentration levels using existing scientific and technological means, ensuring no harm to workers.

8.2.1. Appropriate engineering controls:

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

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 a fume hood to keep airborne concentrations low.
- No exposure limits are known.
- Follow European Standard EN 149 whenever workplace conditions warrant respirator use.

4. Thermal hazards:

- No thermal hazards known.

8.2.3. Environmental exposure controls:

- No specific prescription.

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*

Parameter	Value / Test Method / Remarks
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 / / *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:

- Cell culture media are clear transparent or yellow to red liquids (pH 6-8), containing inorganic salts, vitamins, amino acids, carbohydrates, other nutrients, and phenol red (except transparent liquids, phenol-red-free) dissolved in water.
- Ready-to-use media may contain FBS.

*: 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 sensitization:** 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
  - 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-1

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:

- Disposal according to 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.
- Verify if the 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.

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

- **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 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:

- **REGULATION (EC) No 1907/2006:**

  - Concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.
- **REGULATION (EC) No 1272/2008:**
  - On classification, labelling, and packaging of substances and mixtures.
- **COMMISSION REGULATION (EU) No 2015/830:**
  - Amending Regulation (EC) No 1907/2006 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.

Section 16: other information

Information regarding the revision of the safety data sheet:

- No information.

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 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.
- **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.

Disclaimer:
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

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