SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product Formal Name	**VSPERMFREEZE**
Product Form	Mixture
Product Use	For professional use only. Medium for freezing human sperm including epididymal or testicular sperm.
Manufacturer	**VITROMED GmbH – Hans-Knöll-Str. 6 – 07745 Jena – Germany**
For Emergency Assistance	**Phone** +49 3641 5 39 19 76 **Mail** support@vitromed.com

SECTION 2 – HAZARDS IDENTIFICATION

Regulation (EC) No. 1272/2008	Not classified
Potential Acute Health Effects	No additional information available
Potential Chronic Health Effects	No additional information available
Adverse physicochemical, human health and environmental effects	No additional information available
Labelling according to Regulation (EC) No. 1272/2008 [CLP]	No labelling applicable
Other hazards	No additional information available

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Substance	Not applicable
Mixture	Classification of substances in the mixture according to Regulation (EC) No. 1272/2008 [CLP]: < 1% Phenol red sodium salt, CAS-No. 34487-61-1, Skin Irrit. 2, H315; Eye Irrit. 2, H319, STOT SE 3, H335 Full text of H-statements: see section 16
Comments	The mixture does not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk.

SECTION 4 – FIRST AID MEASURES

Measures general	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
Inhalation	Remove to fresh air. Allow the victim to rest. If breathing becomes difficult, call a physician.
Eyes	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
Skin	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
Ingestion	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. **Seek medical attention if any discomfort should occur.**
Symptoms/effects	Not expected to present a significant hazard under anticipated conditions of normal use

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing Media	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Special Firefighting Procedure	Do not use a heavy water stream. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment. Do not enter fire area without proper protective equipment, including respiratory protection.
Unusual Fire and Explosion Hazards	Emits toxic fumes under fire conditions.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear chemical safety goggles. Wear rubber gloves. Avoid contact with skin, eyes and clothing.
Environmental Precautions	Prevent entry to sewers and public waters.
Methods for Cleaning Up	Rinse spill area with water. Dispose with laboratory waste.

SECTION 7 – HANDLING AND STORAGE

Handling	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
Storage	Keep only in the original container away from direct (sun)light. Do not freeze. Do not use after expiry date. After opening the container, the product can be used up to 7 days when sterile conditions are maintained and the products are stored at 2 - 8°C. Cannot be resterilized after opening.
Specific Use	See instructions for use delivered with the device.
Incompatible products	Strong bases. Strong acids.
Incompatible materials	Sources of ignition. Direct sunlight.
Storage temperature	2 - 8°C

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls (Occupational)	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
Personal protective equipment	Wear fire/flame resistant/retardant clothing.
Skin protection	Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.
Hand protection	Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.
Eye/Face protection	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
Respiratory protection	Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor	Reddish transparent liquid, odorless
pH	7.2 – 7.9
Boiling Point	Not available
Flash Point	Not available
Flammability	Non-flammable
Explosive Properties	Not available
Oxidizing Properties	Not available
Vapor Pressure	Not available
Relative density	Not available

Solubility	Not available
Solubility in Water	Not available
Viscosity	Not available
Evaporation Rate	Not available

SECTION 10 – STABILITY AND REACTIVITY

Stability	Stable. Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 18 months from date of manufacture.
Conditions to Avoid	Direct (sun)light, extremely high or low temperatures.
Materials to Avoid	Strong acids and bases.
Hazardous Decomposition Products	Fume, Carbon monoxide and dioxide.

SECTION 11 – TOXICOLOGIAL INFORMATION

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Not classified
Acute toxicity (inhalation)	Not classified.
Additional information	Extensive data on Sperm Survival tests have demonstrated that the medium is not toxic.
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.
Potential adverse human health effects and symptoms	Based on available data, the classification criteria are not met.
Other information	Human Albumin Solution: The plasma which is the source of the human serum albumin is tested for antibodies to HIV and HCV and non-reactive for HbsAg, HBV RNA, HCV RNA, HIV-1 RNA and syphilis. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety. Route of exposure: In normal use, there is no contact between the media and the patient.

SECTION 12 – ECOLOGICAL INFORMATION

Hazardous to the aquatic environment, short-term (acute)	Not classified
Hazardous to the aquatic environment, long-term (chronic)	Not classified
Persistence and degradability	Not established
Bioaccumulative potential	Not established
Mobility in soil	No additional information available
Results of PBT and vPvB assessment	No additional information available
Other adverse effects	Avoid release to the environment

SECTION 13 – DISPOSAL CONSIDERATIONS

Product/Packaging disposal recommendations	Dispose in a safe manner in accordance to with local and national regulations and avoid release to the environment.
Ecology - waste materials	Avoid release to the environment.

SECTION 14 – TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / AND

UN number	
UN-No. (ADR)	Not applicable
UN-No. (IMDG)	Not applicable
UN-No. (IATA)	Not applicable
UN-No. (ADN)	Not applicable
UN-No. (RID)	Not applicable
UN proper shipping name	
Proper Shipping Name (ADR)	Not applicable
Proper Shipping Name (IMDG)	Not applicable
Proper Shipping Name (IATA)	Not applicable
Proper Shipping Name (ADN)	Not applicable
Proper Shipping Name (RID)	Not applicable
Transport hazard class(es)	
ADR	Not applicable
IMDG	Not applicable
IATA	Not applicable
ADN	Not applicable
RID	Not applicable
Dangerous for the environment	No
Marine pollutant	No
Other information	supplementary information available
Overland transport	Not applicable
Transport by sea	Not applicable
Air transport	Not applicable
Inland waterway transport	Not applicable
Rail transport	Not applicable

SECTION 15 – REGULATORY INFORMATION

EU-Regulations	Contains no REACH substances with Annex XVII restrictions Contains no substance on the REACH candidate list Contains no REACH Annex XIV substances Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals. Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants ISO 15223-1 & 93/42/EEC
National regulations Germany	Water hazard class (WGK) : WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1) Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

This product does not contain any ingredients which have been determined to be health hazardous pursuant to U.S. OSHA regulations, and which comprise 1 % or more (0.1 % for carcinogens) of the mixture.

SECTION 16 – OTHER INFORMATION

Data sources	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 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements

Skin Irrit. 2	Skin corrosion/irritation, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation
H315 _H_315_EU	Causes skin irritation
H319 _H_319_EU	Causes serious eye irritation
H335 _H_335_EU	May cause respiratory irritation

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