



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

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| Product Formal Name | VSPERM FREEZE |
| Product Form | Mixture |
| Product Use | For professional use only. |
| Manufacturer | VITROMED GmbH – Raiffeisenstr. 15a - 40764 Langenfeld-Germany |
| For Emergency Assistance | Phone +49-2173-2004130 Mail support@vitromed.com |

SECTION 2 – HAZARDS IDENTIFICATION

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| Regulation (EC) No 1272/2008 | Non-dangerous |
| Potential Acute Health Effects | May be harmful by swallow; cause skin or eye irritation, be irritating to mucous membranes and upper respiratory tract. |
| Potential Chronic Health Effects | No additional information available |
| Adverse physicochemical, human health and environmental effects | No additional information available |
| Other hazards | No additional information available |

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

The mixture does not contain any raw materials with 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

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| 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

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| 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 firefighting 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

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| Personal Precautions | Evacuate unnecessary personnel. Equip cleanup crew with proper protection. Ventilate area. |
| Environmental Precautions | Notify authorities if liquid enters sewers or public waters. |
| Methods for Cleaning Up | Collect spillage. Store away from other materials. |

SECTION 7 – HANDLING AND STORAGE

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| 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 |
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VSPERM FREEZE

Safety Data Sheet

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| | 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 re-sterilized after opening. |
| Specific Use | See instructions for use delivered with the device. For professional use only. |
| Incompatible products | Strong bases. Strong acids. |
| Incompatible materials | Sources of ignition. Direct sunlight. |
| Storage temperature | 2 - 8 °C |

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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| 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. |
| 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

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| Appearance and Odor | VGRAD with gentamicin – Colorless hazy liquid, odorless VGRAD with gentamicin and phenol red – Reddish hazy 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 | Highly soluble in water |
| Solubility in Water | Complete |
| Viscosity | Not available |
| Evaporation Rate | Not available |

SECTION 10 – STABILITY AND REACTIVITY

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Safety Data Sheet

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| Stability | Stable. Stable after transport (max. 5 days) at elevated temperature ($\leq 37^{\circ}\text{C}$). 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 – TOXICOLOGICAL INFORMATION

May cause skin irritation. May be harmful if absorbed through the skin. May cause eye irritation. May be harmful if inhaled. Material may be irritating to mucus membranes and upper respiratory tract. May be harmful if swallowed. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

SECTION 12 – ECOLOGICAL INFORMATION

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| 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

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

SECTION 14 – TRANSPORT INFORMATION

Not classified as hazardous for transport.

SECTION 15 – REGULATORY INFORMATION

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.

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| Information shown on the Label | ISO 15223-1 |
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SECTION 16 – OTHER INFORMATION

The information contained herein is furnished without warranty of any kind. Users should consider these data only as a supplement to other information gathered by them and must take independent determinations of the suitability and completeness of information from all other sources to assure proper use and disposal of these materials and the safety and health of employees and customers. VITROMED GmbH shall not be held liable for any damage resulting from handling or from contact with its products.