



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

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| Product Formal Name | VONESTEP |
| Product Form | Mixture |
| Product Use | For professional use only |
| 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

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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 | Not available |

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

VONESTEP contains albumin, a derivative of human blood. All donors used in its manufacture were individually tested and found to be nonreactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods. Donors of the source material have been screened for Creutzfeldt-Jakob disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for the transmission of CJD is also considered extremely remote. No cases of viral disease or CJD have ever been identified for albumin.

SECTION 4 – FIRST AID MEASURES

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| Inhalation | Remove to fresh air. If breathing becomes difficult, call a physician. |
| Eyes | Flush with plenteous amounts of water for at least 15 minutes. Insure adequate flushing by separating the eyelids with fingers. |
| Skin | Wash after each contact. |
| Ingestion | Wash out with water provided person in conscious. Call a physician. Seek medical attention if any discomfort should occur. |

SECTION 5 – FIREFIGHTING MEASURES

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| Extinguishing Media | Water spray, carbon dioxide, dry chemical powder or appropriate foam. |
| Special Firefighting Procedure | Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. |
| Unusual Fire and Explosion Hazards | Emits toxic fumes under fire conditions. |

SECTION 6 – ACCIDENTAL RELEASE MEASURES

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| 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

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| Handling | Refer Section 8. |
| Storage | Store at 2 - 8°C. Do not freeze before use. Keep the product in the original packaging or shield from light while not in use. Do not use after expiry date. Keep away from sunlight. |
| Specific Use | See instructions for use delivered with the device. For professional use only. |

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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| Exposure Controls (Occupational) | Wear chemical safety goggles. Wear rubber gloves. Avoid contact with skin, eyes and clothing. Avoid inhalation. Avoid mouth pipetting. |
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VONESTEP

Safety Data Sheet

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

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|-----------------------------|--------------------------------------|
| Appearance and Odor | Reddish transparent liquid, odorless |
| pH | 7.0 – 7.4 |
| 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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| Stability | Stable. |
| Conditions to Avoid | Direct (sun)light, extremely high or low temperatures. |
| Materials to Avoid | Strong acids and bases. |
| Hazardous Decomposition Products | 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

No known Ecological Damage. No additional data is available for the mobility, bioaccumulative potential, persistence and degradability.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose in a safe manner in accordance to with local and national regulations and 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.

Information shown on the Label ISO 15223-1 & 93/42/EEC

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.