



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

1.1 Product identifier

Product name **VGRAD 100 %, 80 %, 40 %, KIT**
Product form Mixture

1.2 Relevant identified uses of the substance or mixture and uses advised against

Industrial/Professional use spec For professional use only.
Use of the substance/mixture Gradient system for semen preparation
Uses advised against No additional information available.

1.3 Details of the supplier of the safety data sheet

Manufacturer VITROMED GmbH
Hans-Knöll-Str. 6
07745 Jena
Germany
support@vitromed.com

1.4 Emergency telephone number

Emergency number +49 3641 5 39 19 76

SECTION 2 – HAZARDS IDENTIFICATION

2.1 Emergency telephone number

Classification (EC) No 1272/2008 Not classified.
Adverse physicochemical, human health and environmental effect No additional information available.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 No labelling applicable.

2.3 Other hazards

No additional information available.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Not applicable.

3.2 Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008
Calcium chloride dihydrate	CAS-No. 10035-04-8	< 1%	Eye Irrit. 2, H319
If applicable Gentamicin sulfate	CAS-No. 1405-41-0	< 1%	Resp. Sens. 1, H334; Skin Sens. 1, H317; Repr. 1A, H360
If applicable Phenol red sodium salt	CAS-No. 34487-61-1	< 1%	Skin Irrit. 2, H315; Eye Irrit. 2, H319, STOT SE 3, H335

Full text of H-phrases: 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

4.1 Description of first aid measures

First-aid measures general Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation Allow affected person to breathe fresh air. Allow the victim to rest.
First-aid measures after skin contact Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available.

SECTION 5 – FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

No additional information available.

5.2 Advice for firefighters

Firefighting instructions Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Emergency procedures Evacuate unnecessary personnel.
Protective equipment Equip cleanup crew with proper protection.
Emergency procedures Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up Collect spillage. Store away from other materials.

6.3 Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe 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.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions Do not use after expiry date. The content cannot be re-sterilized after opening. Keep only in the original container away from direct (sun)light. Keep container closed when not in use. Do not freeze before use. The product can be used for at least 1 month after opening the container when sterile conditions are maintained, and the products are stored at room temperature. Do not expose product to sources of irradiation.

Incompatible products Strong bases. Strong acids.

Incompatible materials Sources of ignition. Direct (sun)light.

Storage temperature 2 – 8 °C

7.3 Specific end uses(s)

See instructions for use delivered with the product.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

No additional information available.

8.2 Exposure controls

Appropriate engineering controls	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).
Other information	Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Transparent liquid
Colour	Bluish hazy solution. When product contains phenol red: reddish hazy solution.
Odour	odourless.
Odour threshold	No data available
pH	7.2 – 7.9 (release criteria: 7.2 – 7.6)
Relative evaporation rate (butylacetate=1)	No data available
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Flammability (solid, gas)	Non flammable.
Vapour pressure	No data available
Relative vapour density at 20°C	No data available
Relative density	< 1.13 g/mL
Solubility	Highly soluble in water
Log Pow	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	< 2 cP at 25°C
Explosive properties	No data available
Oxidising properties	No data available
Explosive limits	No data available

9.2 Other information

Other properties No additional information available.

SECTION 10 – STABILITY AND REACTIVITY

10.1 Reactivity

No additional information available.

10.2 Chemical stability

Stable after transport (max. 5 days) at elevated temperature ($\leq 37^{\circ}\text{C}$). Stable for 18 months after date of manufacture.

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Direct (sun)light. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity (oral, dermal, inhalation)	Not classified. Extensive data from Sperm Survival tests have demonstrated that the medium is not toxic. The product has been evaluated for its toxicity by an independent test laboratory using the AGAR diffusion test. The medium meets the requirements of the ISO 10993-5 guidelines.
Skin corrosion/irritation Additional information	Not classified. Based on available data, the classification criteria are not met. The product has been evaluated for its irritating potential by an independent test laboratory using the primary vaginal test-repeated exposure. The medium meets the requirements of the ISO 10993-10 guidelines.
Serious eye damage/irritation Additional information	Not classified. Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Additional information	Not classified. Based on available data, the classification criteria are not met. The product has been evaluated for its sensitizing potential by an independent test laboratory using the Kligman maximization test. The medium meets the requirements of the ISO 10993 guidelines.
Germ cell mutagenicity Additional information	Not classified. Based on available data, the classification criteria are not met.
Carcinogenicity Additional information	Not classified. Based on available data, the classification criteria are not met.
Reproductive toxicity Additional information	Not classified. Based on available data, the classification criteria are not met.
STOT-single exposure Additional information	Not classified. The product has been evaluated for its biological reaction by an independent test laboratory using the systemic injection test (single dose). The medium meets the requirements of the ISO 10993 guidelines.
STOT-repeated exposure Additional information	Not classified. Based on available data, the classification criteria are not met.
Aspiration hazard Additional information	Not classified. 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.

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: under normal conditions there is no exposure to the product.

SECTION 12 – ECOLOGICAL INFORMATION**12.1 Toxicology**

Hazardous to the aquatic environment, short-term (acute) Not classified.

Hazardous to the aquatic environment, long-term (chronic) Not classified.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

No additional information available.

12.6 Other adverse effects

Avoid release to the environment.

SECTION 13 – DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Product / packaging disposal recommendations Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials Avoid release to the environment.

SECTION 14 – TRANSPORT INFORMATION

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

14.1 UN number

Not regulated for transport.

14.2 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.

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) Not applicable.

Transport hazard class(es) (IMDG) Not applicable.

Transport hazard class(es) (IATA) Not applicable.

Transport hazard class(es) (ADN) Not applicable.

Transport hazard class(es) (RID) Not applicable.

14.4 Packing group

Packing group (ADR) Not applicable.

Packing group (IMDG) Not applicable.

Packing group (IATA) Not applicable.

Packing group (ADN) Not applicable.

Packing group (RID) Not applicable.

14.5 Environmental hazards

Dangerous for the environment No

Marine pollutant No

Other information No supplementary information available.

14.6 Special precautions for user

Overland transport No data available.

Transport by sea	No data available.
Air transport	No data available.
Inland waterway transport	No data available.
Rail transport	No data available.

14.7 Transport in bulk according to Annex II and the IBC Code

Not applicable.

SECTION 15 – REGULATORY INFORMATION

15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture

EU-Regulations	<p>Contains no REACH substances with Annex XVII restrictions.</p> <p>Contains no substance on the REACH candidate list.</p> <p>Contains no REACH Annex XIV substances.</p> <p>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.</p> <p>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.</p>
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National regulations

Germany

Water hazard class (WGK)	WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1)
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Hazardous Incident Ordinance (12. BImSchV)	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)
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15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

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.
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Other information	<p>Eye Irrit. 2: Serious eye damage/eye irritation, Category 2</p> <p>Repr. 1A: Reproductive toxicity, Category 1A</p> <p>Resp. Sens. 1: Respiratory sensitisation, Category 1</p> <p>Skin Irrit. 2: Skin corrosion/irritation, Category 2</p> <p>Skin Sens. 1: Skin sensitisation, Category 1</p> <p>STOT SE 3: Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation</p> <p>H315: _H_315_EU : Causes skin irritation</p> <p>H317: _H_317_EU : May cause an allergic skin reaction</p> <p>H319: _H_319_EU : Causes serious eye irritation</p> <p>H334: _H_334_EU : May cause allergy or asthma symptoms or breathing difficulties if inhaled</p> <p>H335: _H_335_EU : May cause respiratory irritation</p> <p>H360: _H_360_EU : May damage fertility or the unborn child</p>
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