



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

Product Formal Name	V^VGRAD 100 %, 80 %, 40 %, KIT
Product Form	Mixture
Product Use	For professional use only; Gradient system for semen preparation
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% Calcium chloride dihydrate, CAS-No. 10035-04-8, Eye Irrit. 2, H319 If applicable < 1% Gentamicin sulfate, CAS-No. 1405-41-0, Resp. Sens. 1, H334; Skin Sens. 1, H317; Repr. 1A, H360 If applicable < 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

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

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 reesterilized 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

VGRAD - Colorless hazy liquid, odorless

VGRAD with phenol red - Reddish hazy liquid, odorless

VGRAD with gentamicin - Colorless hazy liquid, odorless

VGRAD with phenol red & gentamicin - Reddish hazy liquid, odorless

VGRAD

Safety Data Sheet

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	< 1.13 g/mL
Solubility	Highly soluble in water
Solubility in Water	complete
Viscosity	< 2 cP at 25°C
Evaporation Rate	Not available

SECTION 10 – STABILITY AND REACTIVITY

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

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Extensive data on Sperm Survival tests have demonstrated that the medium is not toxic.
Acute toxicity (inhalation)	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	Not classified
Additional information	Based on available data, the classification criteria are not met. The product has been evaluated for its irritating potential by and 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	Not classified
Additional information	Based on available data, the classification criteria are not met
Respiratory or skin sensitization	Not classified
Additional information	Based on available data, the classification criteria are not met. The product has been evaluated for its sensitizing potential by and independent test laboratory using the Kligman maximization test. The medium meets the requirements of the ISO 10993 guidelines
Germ cell mutagenicity	Not classified
Additional information	Based on available data, the classification criteria are not met
Carcinogenicity	Not classified
Additional information	Based on available data, the classification criteria are not met
Reproductive toxicity	Not classified
Additional information	Based on available data, the classification criteria are not met
STOT-single exposure	Not classified
Additional information	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	Not classified
Additional information	Based on available data, the classification criteria are not met

VGRAD

Safety Data Sheet

Aspiration hazard	Not classified
Additional information	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: under normal conditions there is no exposure to the product.

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

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

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