

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product form : Mixture
Product name : GM501 Gradient 100%
Product code : 4 GM 501G-100-XX

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

1.2.1 Relevant identified uses

Industrial/Professional use spec : For professional use only.
Use of the substance/mixture : GM501 Gradient 100 % can be used for semen preparation in combination with IUI, IVF and ICSI.

1.2.2. Uses advised against

No additional information available.

1.3 Details of the supplier of the material safety data sheet

Gynemed GmbH & Co. KG
Wagrienring 24b
D-23730 Sierksdorf
Germany
info@gynemed.de

1.4 Emergency telephone number

Emergency number : +49 (0)4561 51325 00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

Adverse physicochemical, human health and environmental effects
No additional information available.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
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 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC No) 231-791-2	< 20	Not classified
Calcium chloride dihydrate	(CAS No) 10035-04-8	< 1	Eye Irrit. 2, H319
Potassium Chloride	(CAS No) 7447-40-7 (EC No) 231-211-8	< 1	Not classified
Magnesium Sulphate Heptahydrate	(CAS No) 10034-99-8	< 1	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC No) 231-598-3	< 1	Not classified
Sodium Dihydrogen Phosphate Dihydrate	(CAS No) 13472-35-0	< 1	Not classified
Glucose monohydrate	(CAS No) 14431-43-7	< 1	Not classified
Sodium Hydrogen Carbonate	(CAS No) 144-55-8 (EC No) 205-633-8	< 1	Not classified
HEPES	(CAS No) 7365-45-9 (EC No) 230-907-9	< 1	Not classified
Sodium Pyruvate	(Cas No) 113-24-6 (EC No) 204-024-4	<1	Not classified
Silica Basic Solution	not applicable	90-99	Not classified

Full text of H-phrases: see section 16

Comments : The media do 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	:	Assure fresh air breathing. 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 for at least 15 minutes. Obtain medical attention if pain, blinking or redness persists.
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.
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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.

5.3 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

6.1.1 For non-emergency personnel

Emergency procedures	:	Evacuate unnecessary personnel.
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6.1.2 For emergency responders

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.
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6.4 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.
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7.2 Conditions for safe storage, including any incompatibilities

Storage conditions	:	Keep only in the original container in a cool ventilated place away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use after expiry date. The product can be safely used up to 7 days after opening the container when sterile conditions are maintained and the products are stored at 2-8°C. Content cannot be resterilized after opening.
Incompatible products	:	Strong bases. Strong acids.
Incompatible materials	:	Sources of ignition. Direct (sun)light.
Storage temperature	:	2-8°C

7.3 Specific end use(s)

See instruction for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Obtain medical attention if any discomfort should occur.

8.2 Exposure controls

Appropriate engineering controls	:	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
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Personal protective equipment	:	Wear fire/flamm 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 the 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
Colour	:	Bluish hazy solution.
Odour	:	Odourless
Odour threshold	:	No data available
pH	:	7.20 – 7.90 (release criteria: 7.20-7.60)
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	:	1.1150-1.1250 g/ml
Solubility	:	Soluble in water.
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Viscosity	:	< 1.75 cP
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2 Other information

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 (≤ 37 °C). Stable for 18 months from 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

Fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity	:	Not classified. Extensive data on Sperm Survival Test 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.
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Skin/eye/mucosa corrosion/irritation	:	Not classified. 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.
Respiratory or skin sensitization	:	Not classified. 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	:	Not classified.
Carcinogenicity	:	Not classified.
Reproductive toxicity	:	Not classified.
Specific target organ toxicity (single exposure)	:	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.
Specific target organ toxicity (repeated exposure)	:	Not classified.
Aspiration hazard	:	Not classified.
Potential adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

Not classified.

12.2 Persistence and degradability

GM501 Gradient 100%

Persistence and degradability : Not established

12.3 Bioaccumulative potential

GM501 Gradient 100%

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 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 / ADN

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

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1 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 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 June 2019 on persistent organic pollutants.

15.1.2 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)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed
 SZW-list of mutagenic substances : None of the components are listed
 NON-exhaustive list of reproductive toxins - Breastfeeding : None of the components are listed
 NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed
 NON-exhaustive list of reproductive toxins - Development : None of the components are listed

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, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None

Full text of H- and EUH-phrases

Eye Irrit. 2 : Serious eye damage/eye irritation, Category 2
 H319 : Causes serious eye irritation

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.