

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-XXX

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
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

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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	< 10	Not classified
Calcium chloride dihydrate	(CAS No) 10035-04-8	< 0.1	Eye Irrit. 2, H319
Potassium Chloride	(CAS No) 7447-40-7 (EC No) 231-211-8	< 0.1	Not classified
Magnesium Sulphate Heptahydrate	(CAS No) 10034-99-8	< 0.1	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	< 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	< 0.1	Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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	:	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. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	:	Rinse immediately with plenty of water. 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/effects	:	May cause an allergic skin reaction.
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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 the 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.
Hygiene measures	:	Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions	:	Keep only in the original container away from direct (sun)light, in a cool and well-ventilated place. 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.
Incompatible products	:	Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.
Storage temperature : 2-25°C unopened. 2-8°C after opening.

7.3 Specific end use(s)

See instruction for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available.

8.1.2 Recommended monitoring procedures

No additional information available.

8.1.3 Air contaminants formed

No additional information available.

8.1.4 DNEL and PNEC

No additional information available.

8.1.5 Control banding

No additional information available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2 Personal protection equipment

Personal protective equipment : Avoid all unnecessary exposure.

Personal protective equipment symbol(s) :



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).

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.

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).

Thermal hazards : No additional information available.

8.2.3 Environmental exposure controls

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 : Not available
Melting point : Not available
Freezing point : Not available

Boiling point	:	Not available
Flammability	:	Non flammable
Explosive limits	:	Not available
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	7.2 - 7.9 (release criteria: 7.2 - 7.6)
Viscosity, dynamic	:	< 1.75 cP
Solubility	:	Soluble in water
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50 °C	:	Not available
Density	:	Not available
Relative density	:	1.1150 - 1.1250 g/ml
Relative vapour density at 20 °C	:	Not available
Particle characteristics	:	Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

No additional information available.

9.2.2 Other safety characteristics

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 sunlight. 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 (oral/dermal/inhalation)	:	Not classified (Based on available data, the classification criteria are not met.)
Skin corrosion/irritation	:	Not classified (Based on available data, the classification criteria are not met.)
Serious eye damage/irritation	:	Not classified (Based on available data, the classification criteria are not met.)
Respiratory or skin sensitization	:	Due to the potentially skin sensitizing nature of SIBO, this raw material was tested using an in vitro skin sensitization test in line with ISO 10993-10:2021. This has demonstrated that SIBO and consequently GM501 Gradient 100% are classified as non-sensitizer.
Germ cell mutagenicity	:	Not classified (Based on available data, the classification criteria are not met.)
Carcinogenicity	:	Not classified (Based on available data, the classification criteria are not met.)
Reproductive toxicity	:	Not classified (Extensive data on Human Sperm Survival Assays have demonstrated that the medium is not toxic.)
Specific target organ toxicity - single exposure	:	Not classified (Based on available data, the classification criteria are not met.)
STOT - repeated exposure	:	Not classified (Based on available data, the classification criteria are not met.)
Aspiration hazard	:	Not classified (Based on available data, the classification criteria are not met.)

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

11.2.2 Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

Hazardous to the aquatic environment, short-term (acute) or long-term (chronic) : Not classified.

12.2 Persistence and degradability

Persistence and degradability : Not established

12.3 Bioaccumulative potential

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 / ADN

14.1 UN number

UN-No. (ADR) / (IMDG) / (IATA) / (ADN) / (RID) : Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) / (IMDG) / (IATA) / (ADN) / (RID) : Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) / (IMDG) / (IATA) / (ADN) / (RID) : Not applicable

14.4 Packing group

Packing group (ADR) / (IMDG) / (IATA) / (ADN) / (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 / Transport by sea / Air transport / Inland waterway transport / Rail transport

No data available

14.7 Maritime transport in bulk according to IMO instruments

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 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.

Contains no substance subject to Regulation (EU) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

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)

France

Occupational diseases

Code	Description
RG 31	Occupational diseases caused by aminoglycosides, including streptomycin, neomycin and their salts
RG 65	Eczematiform lesions of allergic mechanism
RG 66	Occupational rhinitis and asthma
RG 67	Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies
RG 78	Diseases caused by sodium chloride in salt mines and their dependencies

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

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product.
 Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

Switzerland

Storage class (LK) : LK 10/12 - Liquids

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-statements:

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.