



REVISION: REV

06\_00«REV

»

GM501 GRADIENT 45% / GM501 GRADIENT 90%

VALID FROM: 06/01/2018

SAFETY DATA SHEET GM501 GRADIENT 45% / GM501 GRADIENT 90%

PAGE 1 OF 6

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Product form : Mixture  
Product name : GM501 Gradient 90% / GM501 Gradient 90%  
Product code : 4 GM 501G-90-XX / 4 GM 501G-90-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 45 % and 90 % is a gradient system for semen preparation. GM501 Gradient 45 % and 90 % can be used 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  
Lübecker Straße 9  
D-23738 Lensahn  
Germany  
info@gynemed.de

**1.4 Emergency telephone number**

Emergency number : +49 (0)4363 90 32 90

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC

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	< 60	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) 205-633-7	< 1	Not classified
HEPES	(CAS No) 7365-45-9 (EC No) 230-907-9	<1	Not classified
Sodium Pyruvate	(Cas No) 113-24-6	<1	Not classified



REVISION: REV

06\_00«REV  
»

GM501 GRADIENT 45% / GM501 GRADIENT 90%

VALID FROM: 06/01/2018

SAFETY DATA SHEET GM501 GRADIENT 45% / GM501  
GRADIENT 90%

PAGE 2 OF 6

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
	(EC No) 204-024-4		
Silica Basic Solution	not applicable	45 (Gradient 45 %) 90 (Gradient 90 %)	Not classified
Phenol Red	(Cas No) 1405-41-0	< 1	Skin Irrit. 2, H315 Eye irrit. 2, H319 Stot.se 3, H336
Full text of R- and 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 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.

##### 5.3 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.

###### 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.

##### 6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Collect spillage.

##### 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.

##### 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.



REVISION: REV

06\_00«REV  
»

GM501 GRADIENT 45% / GM501 GRADIENT 90%

VALID FROM: 06/01/2018

SAFETY DATA SHEET GM501 GRADIENT 45% / GM501 GRADIENT 90%

PAGE 3 OF 6

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
------	--------------------	---	---

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. Wear fire/flame resistant/retardant clothing

Personal protective equipment  
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 EU-directive 89/686/EEC and the standard EN374 derived from it.

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

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 : Red solution  
Odour : Odourless  
Odour threshold : No data available  
pH : 7.20 – 7.60 (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 : Gradient 90%: 1.1050-1.1150 g/ml  
Solubility : Highly soluble in water.  
Log Pow : No data available  
Viscosity : Gradient 90%: < 1.65 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



REVISION: REV

06\_00«REV  
»

GM501 GRADIENT 45% / GM501 GRADIENT 90%

VALID FROM: 06/01/2018

SAFETY DATA SHEET GM501 GRADIENT 45% / GM501  
GRADIENT 90%

PAGE 4 OF 6

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
------	--------------------	---	---

#### 10.1 Reactivity

No additional information available.

#### 10.2 Chemical stability

Mixture

#### 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.

### 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 medium meets the requirements of the ISO 10993-5 guidelines.
Skin/eye/mucosa corrosion/irritation	:	Not classified 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 The medium meets the requirements of the ISO 10993-11 and ISO 10993-12 guidelines.
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

No additional information available

#### 12.2 Persistence and degradability

##### GM501 Gradient 90%

Persistence and degradability : Not established

#### 12.3 Bioaccumulative potential

##### GM501 Gradient 90%

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



REVISION: REV  
06\_00«REV  
»

GM501 GRADIENT 45% / GM501 GRADIENT 90%

VALID FROM: 06/01/2018

SAFETY DATA SHEET GM501 GRADIENT 45% / GM501  
GRADIENT 90%

PAGE 5 OF 6

Waste 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 73/78 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

No REACH Annex XVII restrictions.  
Contains no REACH candidate substance.

###### 15.1.2 National regulations

No additional information available.

##### 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 R-, H- and EUH-phrases

Eye Irrit. 2 : Serious eye damage/eye irritation, Category 2  
H319 : Causes serious eye irritation  
Skin Irrit. 2, : Causes skin irritation, Category 2  
H315 : Causes skin irritation  
Stot.se 3 : Specific Target Organ Toxicity Category 3 (transient effects, dizziness, drowsiness)  
H336 : May cause drowsiness or dizziness



REVISION: REV

06\_00«REV

»

GM501 GRADIENT 45% / GM501 GRADIENT 90%

VALID FROM: 06/01/2018

SAFETY DATA SHEET GM501 GRADIENT 45% / GM501  
GRADIENT 90%

PAGE 6 OF 6

---

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.

FORM: SAFETY DATA SHEET

SCOPE: GM501 MEDIALINE - GYNEMED

REVISION: 06\_00      VALID FROM: 2018-06-01

## FORMBLATTFREIGABE

	AUTOR	GEPRÜFT	FREIGEgeben		
NAME:	Dr. Julia Heinzmann	Benthe Brauer	Dr. Fabian Sell	REV.:	Rev 06_00
UNTERSCHRIFT:				ERSETZT:	Rev 05_00
DATUM:	31.05.2018	31.05.2018	31.05.2018	GÜLTIG AB:	2018-06-01

Hinweise an QMB:

Vor Ausdruck in PDF Dokument zur elektronischen Verteilung diese Seite löschen. Bei elektronischer Verteilung ist dieses Blatt der Anweisung nicht vorhanden.

FORM: SAFETY DATA SHEET

SCOPE: GM501 MEDIALINE - GYNEMED

REVISION: 06\_00 VALID FROM: 2018-06-01

## ÄNDERUNGSHISTORIE

REV #	DATUM ÄNDERUNG	ÄNDERUNG	SCHULUNG ERFORDERLICH
05_00	2016-07-20	Update Format	Nein
06_00	2018-06-01	Allgemeines Produktupdate (Abschnitt 3.2, 8.2, 10.2) , Firmenname korrigiert (Gynemed GmbH & Co KG)	Nein