

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

### 1.1 Product identifier

Product form : Mixture  
 Product name : GM501 10% HSA  
 Product code : 4 HSA 0005

### 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 HSA (10 % human serum albumin) is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of GM501 HSA solution as a supplement for culture medium.

#### 1.2.2 Uses advised against

No additional information available.

### 1.3 Details of the supplier of the material safety data sheet

Gynemed Medizintechnik 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 Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Human Serum Albumin	(CAS No) 70024-90-7	10	Not classified	Not classified
Saline Buffer	-	90	Not classified	Not classified

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.
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## 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.  
 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 reesterilized 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

No additional information available.

#### 8.2 Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.  
 Hand protection : Wear protective gloves.  
 Eye protection : Chemical goggles or safety glasses.  
 Respiratory protection : Wear appropriate mask.  
 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 : yellow transparant liquid  
 Odour : Odourless  
 Odour threshold : No data available  
 pH : 7.20 – 7.40

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
Relativ density	: No data available
Solubility	: Highly soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
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

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	: Extensive data on Mouse Embryo Assay have demonstrated that the medium is not toxic.
Skin corrosion/irritation	: Not classified

The medium meets the requirements of the

ISO 10993-10 guidelines.

Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified

The medium has been evaluated for its sensitizing potential by an independent test laboratory using the direct intracutaneous injection test. The medium meets the requirements of the ISO10993-10 guidelines.

Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
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.
Other information	: Human Serum Albumin: 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: With embryo transfer and intrauterine insemination, the medium comes into contact with the uterus mucosal membranes.

## SECTION 12: Ecological information

**12.1 Toxicity**

No known ecological damage caused by this product.

**12.2 Persistence and degradability**

**GM501 10% HSA**

Persistence and degradability : Not established

**12.3 Bioaccumulative potential**

**GM501 10% HSA**

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**

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

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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.