

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

1.1 Product identifier

Product form : Mixture
Product name : GM501 Hyaluronidase
Product code : 4 HY 0010
4 HY 0001-5

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 : Medium used in the oocyte denudation process in preparation of ICSI or other ART procedures.

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
certificates-gynemed@nexpringhealth.com

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

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]
Hyaluronidase (from bovine source)	(CAS No) 37326-33-3 (EC No) 253-464-3	80 IU/ml	Not classified
Ultrapure water	(CAS No) 7732-18-5 (EC No) 231-791-2	≥ 99	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC No) 231-598-3	< 1	Not classified
HEPES	(CAS No) 7365-45-9 (EC No) 230-907-9	< 1	Not classified
Human Serum Albumin	(CAS No) 70024-90-7	< 1	Not classified
Sodium lactate	(CAS No) 867-56-1 (EC No) 212-762-3	< 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
Potassium Chloride	(CAS No) 7447-40-7 (EC No) 231-211-8	< 1	Not classified
Calcium	(CAS No) 10035-04-8	< 1	Eye Irrit. 2, H319

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
chloride dihydrate			
Sodium Dihydrogen Phosphate Dihydrate	(CAS No) 13472-35-0	< 1	Not classified
Magnesium Sulphate Heptahydrate	(CAS No) 10034-99-8	< 1	Not classified
Sodium Pyruvate	(CAS-No.) 113-24-6 (EC-No.) 204-024-4	< 1	Not classified
Full text of H-statements: see section 16			
Comments	:	The hyaluronidase used in this product is derived from bovine testis is certified with a TSE risk evaluation Certificate of Suitability (CEP).	

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.
- 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 : 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 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.

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 : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

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, well ventilated place away from direct (sun)light.

Keep container closed when not in use.
 Do not freeze.
 Do not use after the expiry date.
 After opening the container, the product can be used up to 7 days if 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 sunlight.
 Storage temperature : 2-8°C

7.3 Specific end use(s)

See instructions 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 : Wear fire/flare resistant/retardant clothing.
 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 : White/Yellow transparent liquid.

Odour	: Odourless.
Odour threshold	: No data available
pH	: 7.3 – 7.9
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	: Non flammable.
Vapour pressure	: No data available
Vapour pressure at 50°C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20°C	: No data available
Solubility	: Highly soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive limits	: No data available
Lower explosion limit	: No data available
Upper explosion limit	: No data 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 ($\leq 37^{\circ}\text{C}$). Stable for 12 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
Acute toxicity (inhalation)	: In addition, the product has been evaluated for its cytotoxicity potential by an independent test laboratory using a XTT cytotoxicity test according to the ISO 10993-5 guidelines. The medium was considered non-cytotoxic.
Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
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.
Specific target organ toxicity (single exposure)	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure)	: Not classified

Additional information : Based on available data, the classification criteria are not met.
 Aspiration hazard : Not classified
 Additional information : Based on available data, the classification criteria are not met.

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available

11.2.2. Other information

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.

Hyaluronidase: The hyaluronidase used in this product is extracted and purified from bovine testes. The testes were collected from animals which were found healthy by pre- and postmortem inspection and which were exempt from Bovine Spongiform Encephalopathy (BSE).

Route of exposure: Under normal conditions there is no exposure to the product.

SECTION 12: Ecological information

12.1 Toxicity

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

12.2 Persistence and degradability

GM501 Hyaluronidase
 Persistence and degradability : Not established
Sodium Chloride (7647-14-5)
 Persistence and degradability : Not established

12.3 Bioaccumulative potential

GM501 Hyaluronidase
 Bioaccumulative potential : Not established
Sodium Chloride (7647-14-5)
 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 Endocrine disrupting properties

No additional information available

12.7 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

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

Packing group (ADR/IMDG/IATA/AND/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 market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2 National regulations

France

Code	Description
RG 67	Nasal septum lesions caused by potassium chloride dust in potash mines and their dependencies

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

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

Full text of H- and EUH-statements:

Eye Irrit. 2 : Serious eye damage/eye irritation, Category 2
 H319 : _H_319_EU: 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.