Material Safety Data Sheet (MSDS)

AM EmbryoGrip

ARTSMedia Hyaluronan Embryo Transfer Medium

Product No.: 510010/511010

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

1.1 Product identifier:
Product form: Mixture
Product name: ARTSMedia Hyaluronan Embryo Transfer Medium (AM EmbryoGrip)

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 substance/mixture: ARTSMedia Hyaluronan Embryo Transfer Medium (AM EmbryoGrip) is a transfer medium intended for embryo transfer.

1.2.2. Uses advised against
ARTSMedia Hyaluronan Embryo Transfer Medium (AM EmbryoGrip) contains gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic (allergic reaction).

1.3. Details of the supplier of the safety data sheet
ARTSMedia Denmark ApS
Kongevejen 149,
2830 Virum
Denmark
info@artsmedia.dk
Customer service: +45 53504530

1.4. Emergency telephone number

Emergency number: +45 82121212

SECTION 2: Hazards identifications

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 ≥0.1% in accordance with REACH Annex XIII.

The mixture does not contain substances 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. Substances
Not applicable
3.2. Mixtures

Component	CAS No.	%
Potassium chloride	7447-40-7	<0,1
Magnesium sulfate, 7 H2O	10034-99-8	<0,1
Potassium phosphate monobasic, anhydrous	7778-77-0	<0,1
Magnesium chloride 6H2O	7791-18-6	<0,1
Sodium chloride	7647-14-5	0,1-1
Calcium chloride dihydrate	10035-04-8	<0,1
Sodium bicarbonate	144-55-8	0,1-1
Insulin	11061-68-0	<0,1
Human Transferrin, recombinant	11096-37-0	<0,1
Sodium selenite	10102-18-8	<0,1
Ethanolamin	141-43-5	<0,1
EDTA	60-00-4	<0,1
EDTA FE3+ iron (III) sodium salt	15708-41-5	<0,1
Tri sodium citrate dihydrate	6132-04-3	<0,1
Zink sulfate heptahydrate	7446-20-0	<0,1
Gentamicin sulphate salt	1405-41-0	<0,1
Glycine	56-40-6	<0,1
L-aspartic acid	56-84-8	<0,1
BME amino acid solution 50x	N/A	0,1-1
MEM amino acid solution 100x	N/A	0,1-1
Alanyl-L- glutamine	39537-23-0	<0,1
BME vitamin solution 100x	N/A	0,1-1
Myo Inositol	87-89-8	<0,1
Calcium-L-lactate hydrat	41372-22-9	<0,1
D-(+)-Glucose anhydrat	50-99-7	<0,1
Sodium pyruvate	113-24-6	<0,1
Albumin (Human, HSA), USP	70024-90-7	0,1-1
Hyaluronic acid	9067-32-7	<0,1
Phenol Red sodium salt (only 510010)	34487-61-1	<0,1
Ultrapure water	7732-18-5	>90

Comments: Components have not been in contact with material of animal-origin except for fish peptone used in the manufacture of gentamicin sulfate. TSE declaration for gentamicin sulfate issued by the active substance manufacturer is presented stating that the peptone is derived from non-TSE relevant fish.

SECTION 4: First aid measures

4.1. Description of first aid measures

First aid measures in 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 breath fresh air. Allow the victim to rest.
First aid measures after skin contact: Remove affected clothing and wash all exposed skin areas 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 firefighting water from entering the environment.
Protection during firefighting: Do not enter the 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: 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 vapor.

7.2. Conditions for safe storage, including any incompatibilities.
Storage conditions: Keep refrigerated in the original container. Keep away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use it after expiry date. Cannot be re-sterilized after opening. Do not expose product to sources of irradiation.
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 product.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters
No additional information available

8.2. Exposure controls
Appropriate engineering control: Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

Personal protective equipment: Wear fire/flame 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 must meet 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 an 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	Transparant liquid
Odour	Odourless
Odour threshold	No data available
pH	7.2 – 7.45
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	No data available
Solubility	Highly soluble in water
Partition coefficient n-octanol/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

Stable after transport (max. 14 days) at elevated temperature (≤ 37°C).

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid.

Direct (sun)light. Extremely high or low temperatures. Do not expose products to sources of irradiation.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Fume.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

MEA-Test: Passed

Following tests are passed:
Cytotoxicity (ISO 10993-5:2009)
Vaginal irritation (ISO 10993-10:2010)
Skin sensitization (ISO 10993-10:2010)

Other information:

Human Serum Albumin: The plasma which is the source of the human serum albumin was tested and found negative for HBsAg, Anti-HIV-1/-HIV2, HCV, HCV-RNA, and HIV-RNA. Furthermore, source material has been tested for parvovirus B19 and found to be non-elevated. The albumin agrees with all the requirements set forth by the European and United States health authority regarding safety.

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. Based on available data, the classification criteria are not met

STOT-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:

Endocrine disrupting Properties: Based on available data, the classification criteria are not met

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

Additional information: 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): Not classified
Hazardous to the aquatic environment, 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 Endocrine disrupting Properties
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 of it 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: No data available
Transport by sea: No data available
Air transport: No data available
Inland waterway transport: No data available
Rail transport: No data available

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 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

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, labelling 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: No other information.
ARTSMedia Denmark ApS is not liable for any damage resulting from handling or contact with this product.

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