

Material Safety Data Sheet (MSDS)

AM-SDG Media

ARTSMedia Sperm Density Gradient Media

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

1.1 Product identifier:

Product form: Mixture

Product name: ARTSMedia Sperm Density Gradient Media (AM-SDG Media)

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: AM-SDG Media are intended for human sperm separation by density gradient centrifugation.

1.2.2. Uses advised against

No additional information available

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

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 mixtures do 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.

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Company details:

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No.) 7732-18-5 (EC No.) 231-791-2	< 55	Not classified
Silica Basic Solution (SIBO)	-	45 (AM-SDG Medium 45 %) 90 (AM-SDG Medium 90 %)	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
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	< 0,1	Not classified
Calcium Chloride Dihydrate	(CAS No.) 10035-04-8	< 0,1	Eye Irrit 2, H319
Sodium Dihydrogen Phosphate Dihydrate	(CAS No.) 13472-35-0	< 0,1	Not classified
Magnesium Sulphate Heptahydrate	(CAS No.) 10034-99-8	< 0,1	Not classified
Sodium Pyruvate	(CAS No.) 113-24-6 (EC No.) 204-024-4	< 0,1	Not classified

Full text of H-statement H319: _H_319_EU: Causes serious eye irritation

Comments: The Media do not contain any raw materials of direct animal-origin or materials that have been produced using TSE relevant 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 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. 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.

4.3. Indication of any immediate medical attention and special treatment needed.

No additional information available.

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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. 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 vapor.

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, in a cool, well-ventilated place away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use it 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. Once opened: 2-8°C

7.3. Specific end use(s)

No additional information available.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

No additional information available

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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	Bluish hazy solution
Odour	Odourless
Odour threshold	No data available
pH	7.2-7.9 (release criteria:7.2-7.6)
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	AM-SDG Medium 45: 1.0500-1.0700 g/ml AM-SDG Medium 90: 1.1050-1.1150 g/ml
Solubility	Soluble in water
Partition coefficient n-octanol/water (Log Kow)	No data available
Viscosity, kinematic	AM-SDG Medium 90: < 1.65 cP
Explosive limits	No data available

9.2. Other information

Information regarding Physical Hazard classes: No additional information available

Other safety characteristics: No additional information available

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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 ($\leq 37^{\circ}\text{C}$).

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. fume.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral /dermal/inhalation): Not classified.

Skin corrosion/irritation: Not classified. Based on available data, the classification criteria are not met

Serious eye damage/irritation: 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 ISO10993-10:2021. This has demonstrated that SIBO and consequently Gradient media are classified as non-sensitizer. Based on available data, the classification criteria are not met.

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 Assay have demonstrated that the media is not toxic.

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:

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.

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): Not classified

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

12.2 Persistence and degradability

Persistence and degradability

Not established.

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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: The mixtures do 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.

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. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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:** Not applicable**Transport by sea:** Not applicable**Air transport** Not applicable**Inland waterway transport** Not applicable**Rail transport:** Not applicable**14.7. Maritime transport in bulk according to IMO instruments:** Not applicable**Company address:**

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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) No 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 (EU) No 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.

15.2. 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: None.

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.

Doc. ID: 11453, Version 2.0, 2024OCT23.

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