Safety Data Sheet

Document no: SDS-SAGE-04-EN

Section 1 – PRODUCT AND COMPANY IDENTIFICATION

1.1. Product identifier:

Product Name: **Quinn's Advantage® Cleavage Medium**
Catalog Number: **ART-1026, ART-1027**

1.2. Relevant identified uses of the substance or mixture and uses advised against:

For culture through to cleavage stage. Can also be used for embryo transfer.

1.3. Details of the supplier of the safety data sheet:

Responsible person for the safety data sheet (e-mail): ra@coopersurgical.com

Legal Manufacturer:
CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611
USA

Contract manufacturers:
COOPER MEDICAL SRL
Edificio N B49, 51 Ave 0
Parque Industrial Zona Franca Coyol
La Garita, Alajuela COSTA RICA 20113
+45 46 79 02 00 (RA – DK)

1.4. Emergency telephone:

(UK)
NHS (England or Wales): 0845 46 47
NHS 24 (Scotland): 08454 24 24 24

(DK)
Poison line +45 82 12 12 12

Section 2 – HAZARD(S) IDENTIFICATION

2.1. Classification of the substance or mixture:

The product is a medical device (IVF) and therefore not covered by the CLP Regulation (EC) No. 1272/2008.

2.2. Label elements:

None.

2.3. Other hazards:

PBT/vPvB: the product contains no substance which is considered PBT/vPvB according to criteria in Annex XIII.

Product contains the aminoglycoside, gentamicin sulfate.
This broad-spectrum antibiotic has been associated with nephrotoxicity and/or ototoxicity when administered i.v. and serum concentrations are maintained at static levels above 10 mcg/mL for extended periods.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

3.2. Mixtures:

An aqueous, isotonic, complex mixture of organic and inorganic salts and simple carbohydrates, at neutral pH intended for in vitro mammalian cell culture. Contains 0.010 mg/mL gentamicin and 0.003 mg/mL phenol red as a pH indicator.

Component	CAS / EC no.	Approx. %	Classification
Physiological salts including:		< 1	
Magnesium Sulfate, Heptahydrate	10034-99-8		Not classified
Potassium Chloride	7447-40-7		Not classified
Sodium citrate, dihydrate	7558-79-4		Not classified
Sodium Chloride (USP)	7647-14-5		Eye Irrit. 2
Sodium Bicarbonate	144-55-8	< 1	Not classified
Gentamicin Sulfate (EP)	1405-41-0	10 µg/ml	Skin Sens.1, H317 Resp. Sens. 1, H334
Amino Acids including:		< 1	
Glycine	58-40-6		Not classified
Taurine,	107-35-7		Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE H335 (not specified)
Energy substrates:		< 1	
D-(+)-Glucose (Dextrose)	50-99-7		Not classified
Sodium Puruvate	113-24-6/ 204-024-4		Skin Sens.1, H317
Others:			
EDTA Tetrasodium salt	10378-23-1	< 0,01	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE H335 (resp.tract)
Phenol Red Sodium salt	34487-61-1	< 0,01	Skin Irrit. 2 H315 Eye Irrit. 2, H319 STOT SE 3 H335
Milli RX Water		> 90	Not classified

Section 4 – FIRST-AID MEASURES

4.1. Description of first aid measures:

Inhalation: Not relevant.
Skin contact: In case of skin contact, wash immediately and thoroughly with soap and water.
Eye contact: In case of eye contact, flush with copious quantities of water. Remove contact lenses, if any; In case of serious hypersensitivity reaction, rush for immediate medical attention.
Ingestion: If swallowed, wash out mouth with water provided the person is conscious. Call a physician.

4.2. Most important symptoms and effects, both acute and delayed:

None known.

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

None known.

Section 5 – FIRE FIGHTING MEASURES

5.1. Extinguishing media:

Use water, CO_2 or any other media suitable for extinguishing fire.

5.2. Special hazards arising from the substance or mixture:

Non-flammable.

5.3. Advice for firefighters:

None known.

Section 6 – ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

None required.

6.2. Environmental precautions:

None required.

6.3. Methods and material for containment and cleaning up:

Use absorbent material to mop up spill. Wash area with water.
Further handling of spillage/waste - see section 13.

6.4. Reference to other sections:

See above.

Section 7 – HANDLING AND STORAGE

7.1. Precautions for safe handling:

Use care in handling/storage. Avoid any unnecessary contact with skin, eyes or mucus membranes. Use aseptic working techniques at all times. Do not mouth pipette. After work wash hands with water and mild soap. Individuals with previous history of allergy to antibiotics and/or asthma, should avoid potential exposure.

7.2. Conditions for safe storage, including any incompatibilities:

Store the product at 2°- 8°C upon receipt. Unused product may be kept refrigerated at 2°- 8°C until the expiration date indicated on the label. Close container tightly after use.
In addition see manufacturer's specifications.

7.3. Specific end use(s):

See section 1.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters:

Occupational exposure limits (Manufacturer recommended OEL) : none

DNEL/PNEC: No CSR.

8.2. Exposure controls:

Appropriate engineering controls:	Local exhaust is adequate; mechanical (general) ventilation is recommended.
Environmental exposure controls:	None known.

Personal protective equipment:

Respiratory protection:	None Required
Skin protection:	Disposable medical gloves, such as disposable nitrile gloves.
Eye protection:	Use Safety glasses.
Other Protective Equipment:	Work clothes, including standard precautions for healthcare workers

Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Appearance:	Particle-free, Pink-rose color, clear liquid
Odour/ Odour threshold:	Not available/ Not determined
pH:	Not available/ Not determined
Melting point/freezing point (°C):	Not available/ Not determined
Initial boiling point and boiling range (°C):	Not available/ Not determined
Flash point (°C):	Not available/ Not determined
Evaporation rate:	Not available/ Not determined
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits (vol-%):	Not relevant
Vapour pressure:	Not available/ Not determined
Specific gravity:	~1.0
Solubility:	Not available/ Not determined
Partition coefficient: n-octanol/water:	Not available/ Not determined
Auto-ignition temperature (°C):	Not relevant
Decomposition temperature (°C):	Not available/ Not determined
Viscosity:	Not available/ Not determined
Explosive properties:	Not relevant

9.2. Other information:
None.

Section 10 – STABILITY AND REACTIVITY

10.1. Reactivity:
None.

10.2. Chemical stability:
Stable.

10.3. Possibility of hazardous reactions:
Will not occur.

10.4. Conditions to avoid:
Do not expose product to elevated temperatures (above 40 °C) for extended periods of time. Store product at 2–8 °C when not being used.
Deterioration of the liquid medium may be recognized by any or all of the following: pH change, precipitate or particulates, cloudy appearance, color change.

10.5. Incompatible materials:
None

10.6. Hazardous decomposition products:
Thermal decomposition of the product will not occur.

Section 11 – TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects:
No available information. (LD50 not established for the individual components).
Information on likely routes of exposure: Not expected for this product.

Inhalation:	No effects expected.
Skin:	No effects expected.
Eyes:	No effects expected.
Ingestion:	No effects expected.
Chronic effects:	Individuals with previous history of allergy to antibiotics and/or asthma, should avoid potential exposure.

11.2. Information on other hazards

Product contains the aminoglycoside, gentamicin sulfate.
This broad-spectrum antibiotic has been associated with nephrotoxicity and/or ototoxicity when administered i.v. and serum concentrations are maintained at static levels above 10 mcg/mL for extended periods.

Section 12 – ECOLOGICAL INFORMATION

12.1. Toxicity:
No data available.

12.2. Persistence and degradability:
No data available.

12.3. Bioaccumulative potential:
No data available.

12.4. Mobility in soil:
No data available.

12.5. Results of PBT and vPvB assessment:
The substances are not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Endocrine disrupting properties
No data available.

12.7. Other adverse effects:
No ecological information available.

Section 13 – DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods:
Disposal should be in accordance with existing disposal practices employed at your institution for infectious waste. Observe all federal, state, and local environmental regulations for waste disposal.

Disposed of in an approved land fill or incinerate providing local environmental regulations permit.

EWC-code: 18 .. ..

Section 14 – TRANSPORT INFORMATION

Not classified as dangerous goods for transportation (ADR/RID/IMDG/IATA).

14.1. UN-no.: None.
14.2. UN proper shipping name: None.
14.3. Transport hazard class(es): None.
14.4. Packing group: None.
14.5. Environmental hazards: None.
14.6. Special precautions for user: None.
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
Not relevant.

Section 15 – REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

EU MDD:
Full Quality Assurance No. **CE 82107**
EC Design-Examination Cert. **CE 551319**
Product ART-1026 is remediated and approved under EU MDR: **MDR 768173**

USA:
United States Food and Drug Administration (FDA): 510(k) **K002836**

The product has been evaluated in accordance with CLP Regulation (EC) No 1272/2008 (classification).
The product has been classified as non-hazardous.

15.2. Chemical safety assessment:

Not relevant.

Section 16 – OTHER INFORMATION

Abbreviations:

CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
LD_{50} = Lethal Dosis 50 %
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative

Training advice:

No special training is required. However, the user should be well instructed according to specific IFU and be familiar with this Safety Data Sheet.

Additional information:

Coopersurgical warrants that its products conform to the information designated herein. The information, data, and recommendations contained herein are believed to be accurate and reported in good faith. The information may not be all inclusive and is to be used only as a guide with caution.
Coopersurgical shall not be held liable for any damage resulting from handling, or from contact with the product. We reserve the right to revise this SDS periodically as new information becomes available.

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