Safety Data Sheet

Document no: SDS-SAGE-33

Product:	**Vitrification Warming Kit XL** **1.0M Sucrose Warming Solution – Part A** **0.5M Sucrose Warming Solution – Part B** **MOPS Solution – Part C**	**Page 1/4**
Date first created: 2017	**Version 4**	**Date revised: 2023.Aug.01**

Section 1 – PRODUCT AND COMPANY IDENTIFICATION

1.1. Product identifier:

Product Name: **Vitrification Warming Kit / Vitrification Warming Kit XL**
1.0M Sucrose Warming Solution, Part A
0.5M Sucrose Warming Solution, Part B
MOPS Solution, Part C

Catalog Number: **ART-8030 / ART-8031 / ART-8034**

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

These products are intended for the recovery of human embryos (pronuclear zygotes through day 3, cleavage stage embryos and blastocyst stage embryos) that have been vitrified using the SAGE Vitrification Kit (ART-8025/ART-8026) This kit is designed to be used in conjunction with the SAGE Vitrification Kit (ART-8025/ART-8026) for ultra-rapid freezing of specimens.

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.

Contains 12 mg/mL human serum albumin, a derivative of human blood and a potentially biohazardous material.

All donors used in its manufacture were individually tested and found to be non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods.

Donors of the source material have been screened for Creutzfeldt-Jakob disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of CJD is also considered extremely remote.
No cases of transmission of viral disease or CJD have ever been identified for plasma protein fraction.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

3.2. Mixtures:
Part A/B/C

Component	CAS / EC no.	Approx. %	Classification
Physiological salts incl. Magnesium Chloride, Potassium Chloride		< 1	
Sodium Chloride (USP)	7647-14-5	< 1	Eye Irrit. 2
Sodium Bicarbonate	144-55-8	< 0,1	Not classified
EDTA tetrasodium salt	10378-23-1	< 0,01	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 (Respiratory Tract) Acute Tox . 4, H302 Eye Dam. 1, H318
Gentamicin Sulfate (EP)	1405-41-0	10 µg/ml	Skin Sens.1, H317 Resp. Sens. 1, H334
Amino Acids incl. Glycine, L-Arginine monohydrochloride, L-Cystine 2HCl, L-Phenylalanine, Taurine	58-40-6	< 1	
Energy substrates incl. D-(+)-Glucose (Dextrose)		< 1	

Sucrose	57-50-1	10 - 30	Not classified
Albumin, human 25% alburx (human origin)		< 1	
Hydrochloric acid, 37% 10N	7647-01-0	< 0,5	Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3; H335: C ≥ 10 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 %
MOPS, biological buffer	1132-61-2	< 1	Not classified
Phenol Red Sodium salt	34487-61-1	< 0,01	Skin Irrit. 2 H315 Eye Irrit. 2, H319 STOT SE 3 H335
Sodium Hydroxide 10N	1310-73-2	< 0,01	Eye Irrit. 2; H319: 0,5% ≤ C<2% Skin Corr. 1A; H314: C ≥ 5% Skin Corr. 1B; H314: 2% ≤C< 5% Skin Irrit. 2; H315: 0,5 % ≤ C < 2%
Milli RX Water		> 70	

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:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

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

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) - **EH40/2005 Workplace exposure limits**:

	Long-term exposure limit (8-hr TWA ref. period) ppm / mg.m-3	**Short-term exposure limit** (15-minute ref. period) ppm / mg.m-3
Hydrochloric Acid:	1 / 2	5 / 8
Sodium Hydroxide :	- / -	- / 2

EU Exp. Limit 5 ppm / 7 mg/m3 Ceiling limit.

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 (ºC):	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

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.

Toxicity data for human serum albumin have not been thoroughly investigated. This material should be treated as a potentially biohazardous product.

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:

Full Quality Assurance No. **CE 82107**

EC Design-Examination Cert. **CE 551319**

USA:

United States Food and Drug Administration (FDA): 510(k) **K073522/ K173731**

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.

Safety Data Sheet

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Product:	**Vitrification Warming Kit** **1.0M Sucrose Warming Solution – Part A** **0.5M Sucrose Warming Solution – Part B** **MOPS Solution – Part C**	

Date first created: 2017 **Version 4** **Date revised: 2023.Aug.01**

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.

The information contained herein is furnished without warranty of any kind. Users should consider these data only as a supplement to other information gathered by them and must take independent determinations of the suitability and completeness of information from all other sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

(Effective date: 2017 Sep 12)

DOCUMENT HISTORY REVISION

CR / ECN Number	Revision Number	Effective Date	Nature of Revision
N/A	04	2023 Aug 01	New layout to match EU REACH regulation + addition XL product code ART-8034
N/A	03	2017 Sep 12	ART-8031 added to sections 1 and 3.
N/A	02	2016 Feb 15	Updated document to SDS format.
012-007	01	15 Feb 12	Updated document to new MSDS format.
08-022	New	10 Apr 08	1. New Document