

Safety Data Sheet

Document no: SDS-45

Product: SAGE 1-Step™ with HSA Page 1/6

Date first created: 2014/01/12 **Version** 6 **Date revised:** 2025/06/01

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

1.1. Product identifier:

SAGE 1-Step™
With HSA
6701

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

This product is intended for the *in vitro* culture of human gametes and embryos from fertilisation until Day 5/6 of development. The medium can also be used for embryo transfer.

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

Legal Manufacturer:

With MDD

Origio A/S
Knardrupvej 2
DK-2760 Måløv
Denmark
+45 46 79 02 00

EU representative

NA

Supplier / Contract manufacturer:

Costa Rica:

CooperMedical, SRL
Edificio N° B-49, 51 Ave 0
Parque Industrial Zona Franca Coyol
La Garita, Alejuela COSTA RICA 20113

With MDR

USA

CooperSurgical, Inc.
95 Corporate Drive
Trumbull
06611 Connecticut
USA

The Netherlands

CooperSurgical Distribution B.V
Celsiusweg 35
5928 PR Venlo
The Netherlands

Costa Rica:

CooperMedical, SRL
Edificio N° B-49, 51 Ave 0
Parque Industrial Zona Franca Coyol
La Garita, Alejuela COSTA RICA 20113

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

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 identification

2.1. Classification of the substance or mixture:

The product is classified as non-hazardous according to CLP Regulation (EC) No 1272/2008 with later amendments.

2.2. Label elements:

None.

2.3. Other hazards: None known.

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

CooperSurgical - ORIGIO a/s

Lautrupvang 2, 1st floor, 2750 Ballerup, Denmark

Web: www.Coopersurgical.com

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SECTION 3: Composition / information on ingredients

3.2. Mixtures :

Component	CAS / EC no.	Approx. %	Classification / tba
Magnesium sulfate heptahydrate	10034-99-8/600-073-4	<0.1	-
Potassium Chloride (KCl)	7447-40-7/231-211-8	<0.1	-
Potassium Phosphate, monobasic	7778-77-0/231-913-4	<0.1	-
Sodium bicarbonate	144-55-8/205-633-8	<1	-
Sodium Chloride (NaCl)	7647-14-5/231-598-3	<1	Eye Irrit. 2, H319
EDTA-Na2 Dihydrate	6381-92-6/613-386-6	<0.01	Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Acute Tox. 4, H332 Aquatic chronic 3, H412
Gentamicin Sulfate salt	1405-41-0/215-778-9	<0.01	Skin Sens.1, H317 Resp. Sens. 1, H334
Amino Acids		<0.01	-
Calcium lactate pentahydrate	5743-47-5/611-530-2	<0.1	-
Glucose	50-99-7/200-075-1	<0.1	-
Sodium Pyruvate	113-24-6/204-024-4	<0.1	-
Human Serum Albumin (HSA)		<1	-
Phenol Red Sodium salt	34487-61-1/252-057-8	<0.01	Skin Irrit. 2 H315 Eye Irrit. 2, H319 STOT SE 3 H335
Sodium Hyaluronate	9067-32-7/618-620-0	<0.1	-
Hydrochloric acid 2N	7647-01-0	<0.01	-
Water		>90	

SECTION 4: First aid measures

4.1. Description of first aid measures:

Inhalation: Not a likely source of exposure.

Ingestion: Wash out mouth with water. If swallowed consult a physician.

Skin: Wash with soap and water after each contact.

Eyes: Flush with copious amounts of water. Assure adequate flushing by separating the eyelids with fingers. If irritation develops, consult 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

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SECTION 5: Firefighting measures

- 5.1. Extinguishing media:**
Dry chemical, foam, carbon dioxide or water spray.
- 5.2. Special hazards arising from the substance or mixture:**
None.
- 5.3. Advice for firefighters**
Not considered to be a fire hazard.

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:**
Absorb on suitable absorbent, such as paper tissue. 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 and eyes. Wash thoroughly after handling. Do not mouth pipette. After work wash hands with water and mild soap.
- 7.2. Conditions for safe storage, including any compatibilities:**
Store in original container at 2-8°C, protected from light. Do not freeze.
- 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 equipment:	None required
Skin protection:	Disposable medical gloves, such as disposable nitrile gloves.
Eye protection:	None required
Other protective equipment:	Work clothes, including standard precautions for healthcare workers

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SECTION 9: Physiological and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	A clear, red liquid.
Odour:	Odourless
Boiling point:	N/A
Vapour Pressure:	N/A
Specific Gravity:	N/A
Vapour Density:	N/A
Melting Point:	N/A
Solubility H ₂ O:	Soluble
Evaporation Rate:	N/A
Flash Point:	None

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:

Hazardous polymerisation is not expected to occur.

10.4. Conditions to avoid:

None known.

10.5. Incompatible materials:

Unknown.

10.6. Hazardous decomposition products:

None known.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) no 1272/2008:

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:	None known.

11.2. Information on other hazards

The product has been tested in biocompatibility tests, Mouse Embryo Assay (MEA) and Sperm Survival Test (SST). There was no evidence of cytotoxicity.

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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:

Dispose of as medical waste.

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: Transportation information

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

14.1. UN number or ID number: 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. Maritime transport in bulk according to IMO instruments: Not relevant.

SECTION 15: Regulatory Information

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

The product has been evaluated in accordance with CLP Regulation (EC) No 1272/2008.

The product has been classified as non-hazardous.

This product is covered by Medical device regulations.

Contains a medicinal substance (Gentamicin).

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EU MDD:

ISO13485:2016

BSI CE 733550 MDSAP Certificate 738514

EC Full Quality Assurance System

BSI CE 733551

EC-Design-Examination Certificate

BSI CE 733555

EU MDR: TBA

USA:

United States Food and Drug Administration (FDA): 510(k) K133707

15.2. Chemical safety assessment: N/A

SECTION 16: Other Information

Abbreviations:

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

LD₅₀ = 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, ORIGIO a/s 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, ORIGIO a/s 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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