

## Safety Data Sheet

Document no: SDS-52

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**Product:** SAGE 1-Step GM-CSF with HSA Page 1/6

**Date first created:** 2017/08/18

**Version** 4

**Date revised:** 2025/06/01

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

#### 1.1. Product identifier:

SAGE 1-Step GM-CSF  
With HSA  
7701

#### 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 embryos following fertilization 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:**

**USA**

CooperSurgical, Inc.  
95 Corporate Drive  
Trumbull  
06611 Connecticut  
USA  
Phone no. (+45) 46 79 02 00

**EU representative**

**The Netherlands**

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

**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

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

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### 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**

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### SECTION 3: Composition / information on ingredients

#### 3.2. Mixtures :

Component	CAS / EC no.	Approx. %	Classification / tba
GM-CSF	123774-72-1	<0.001	-
Magnesium sulfate heptahydrate	10034-99-8/600-073-4		
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.

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### 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.

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### 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.

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### 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 <sub>2</sub> O:	Soluble
Evaporation Rate:	N/A
Flash Point:	None

#### 9.2. Other information

None

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### 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.

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### SECTION 11: Toxicological information

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

No available information. (LD<sub>50</sub> 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.

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### 11.2 Information on other hazards

The product has been tested in biocompatibility tests, Mouse Embryo Assay (MEA) (or Sperm Survival Test (SST)), Delayed Contact Hypersensitivity test or Local Lymph Node Assay (LLNA) and/or Vaginal Irritation test. There was no evidence of MEA (or SST) toxicity, delayed contact hypersensitivity (or local lymph node sensitivity) and the irritation test classified the product as a non-irritant.

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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.

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## 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 ...

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## 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.

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### 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).

##### EU MDR:

ISO13485:2016	FM 72267
EC Quality Management System Certificate	BSI MDR 768070
EC Technical Documentation Assessment Certificate	BSI MDR 768183

##### USA:

United States Food and Drug Administration (FDA): 510(k) K172197

#### 15.2. Chemical safety assessment: N/A

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### SECTION 16: Other Information

#### Abbreviations:

CSR = Chemical Safety Report  
DNEL = Derived No-Effect Level  
LD<sub>50</sub> = 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.

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.

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