

Safety Data Sheet

Document no: SDS-54

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Date first created: 2018/10/09 **Version** 3 **Date revised:** 2025/06/01

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

1.1. Product identifier:

ORIGIO® Handling with and
without Phenol red
8310 / 8311

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

ORIGIO® Handling™ is intended for ART procedures involving handling and micromanipulation of gametes and embryos outside CO2 incubator. Indication includes oocyte retrieval (incl. follicle flushing), gamete (oocyte/sperm) and embryo washing, and micromanipulation procedures including ICSI, assisted hatching, polar body and trophectoderm biopsy.

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 Coyoil
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 Coyoil
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

2.2. Label elements:

None.

2.3. Other hazards: None known.

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

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SECTION 3: Composition / information on ingredients
3.2. Mixtures

Component	CAS / EC no.	Approx. %	Classification
Water		>90	Not classified
Sodium Chloride (NaCl)	7647-14-5/231-598-3	<1	Eye Irrit. 2, H319
L-Asparagine H ₂ O	5794-13-8/611-593-6	<0.01	Not classified
L-Aspartic Acid	56-84-8/200-291-6	<0.01	Not classified
L-Glutamic Acid	56-86-0/200-293-7	<0.01	Not classified
L-Alanine	56-41-7/200-273-8	<0.001	Not classified
L-Proline	147-85-3/205-702-2	<0.01	Not classified
L-Serine	56-45-1/200-274-3	<0.01	Not classified
Glycine	56-40-6/200-272-2	<0.1	Not classified
Taurine	107-35-7/203-483-8	<0.01	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE H335 (not specified)
Calcium chloride dihydrate	10035-04-8/600-075-5	<0.1	Acute Tox. 4, H302 Eye Irrit. 2, H319
Calcium L-lactate pentahydrate	5743-47-5	<0.1	
Magnesium sulfate heptahydrate	10034-99-8/600-073-4	<0.1	Acute Tox. 4, H302/H312/H332
Potassium Chloride (KCl)	7447-40-7/231-211-8	<0.1	Not classified
Tri Sodiumcitrate Dihydrate	6132-04-3	<0.001	Not classified
D-(+)-Glucose	50-99-7/200-075-1	<0.01	Not classified
Sodium Bicarbonate	144-55-8/205-633-8	<0.1	Not classified
Sodium Dihydrogen Phosphate Dihydrate	13472-35-0/603-853-2	<0.01	Not classified
Pyruvic Acid Sodium Salt	113-24-6/204-024-4	<0.01	Not classified
L-Alanyl-L-Glutamine	39537-23-0/609-717-9	<1	Not classified
Gentamicin Sulfate	1405-41-0/215-778-9	<0.01	Skin Sens.1, H317 Resp. Sens. 1, H334
Human Serum Albumin		<1	Not classified
HEPES sodium salt	75277-39-3/278-169-7	<1	Not classified
Calcium pantothenate	137-08-6/205-278-9	<0.01	Not classified
Folic Acid	59-30-3/200-419-0	<0.01	Skin Irrit. 2, H315 Eye Irrit. 2, H319
MOPS Free Acid	1132-61-2/214-478-5	<1	Not classified
Phenol Red Sodium salt (8311)	34487-61-1/252-057-8	<0.01	Skin Irrit. 2 H315 Eye Irrit. 2, H319 STOT SE 3 H335

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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

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.

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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

SECTION 9: Physiological and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	A clear, colourless liquid (8310)/ A clear red liquid (8311).
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.

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SECTION 11: Toxicological information

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

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), Direct cytotoxicity, Local Lymph Node Assay (LLNA) and Vaginal Irritation test.

There was no evidence of MEA/SST toxicity, cytotoxicity, local lymph node sensitivity nor irritation classifying the product as non-toxic, non-sensitization and non-irritant.

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 ...

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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.

SECTION 15: Regulatory Information

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

EU MDD:

ISO13485	BSI CE 733550	MDSAP Certificate 738514
EC Full Quality Assurance System	BSI CE 733551	
EC-Design-Examination Certificate	BSI CE 744875	

EU MDR: TBA

USA:

United States Food and Drug Administration (FDA): 510(k) **K173624**

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

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.

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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.