

Safety Data Sheet

Document no: SDS-55

Product: VitriFit **Page 1/6****Date first created:** 2019/05/24**Version** 3**Date revised:** 2025/06/01

SECTION 1: Identification of substance/mixture and of the company/undertaking**1.1. Product identifier:**

VitriFit in various colours,
Clear (4278), Blue (4279),
Green (4280), Yellow (4281),
Lime Green (4282),
Purple (4284),
Orange (4285), Pink (4286)

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

VitriFit is an open system vitrification carrier for storage of oocytes, embryos and blastocysts.

1.3. Details of the supplier of the safety data sheet:**EU MDD****Legal Manufacturer:****DK**

ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark

Supplier / Contract manufacturer:**USA:**

CooperSurgical, Inc
95 Corporate Drive
Trumbull
06611 Connecticut
USA

EU MDR**Legal Manufacturer / manufacturer:****USA**

CooperSurgical, Inc.
95 Corporate Drive
Trumbull
06611 Connecticut
USA

EU representative**The Netherlands**

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

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 defined as a non-hazardous article and therefore not covered by the 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.

ORIGIO a/s - CooperSurgicalLautrupvang 2, 1st floor, 2750 Ballerup, DenmarkWeb: www.Coopersurgical.com

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SECTION 3: Composition / information on ingredients**3.2. Mixture:**

VitriFit is a solid form stick made of Polystyrene with small amounts of non-classified pigments (additives):

<u>Component</u>	<u>Approx. %</u>	<u>Classification</u>
(All colours contain):		
Ethylenebis(oxyethylene)bis[3-(5-tert-butyl-4-hydroxy-m-tolyl) propionate]	<0,5	None
(clear, blue, green, purple, orange, pink)		
N-N'-ethane-1-diylbis(hexadecan-1-amide	<0,5	None
N,N'-ethylenedi(stearamide)	<0,5	None
(lime, orange, pink)		
Pigment Yellow 138	<0,5	None
(purple, orange, pink)		
Stearic acid	<0,5	None
(blue, green)		
29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32) copper	<0,5	None
(purple, pink)		
Pigment Violet 19	<0,5	None
(yellow)		
1-methyl-1,3-propanediyl esters	<0,5	None
(lime)		
Polychloro copper phthalocyanine	<0,5	None
(purple)		
Pigment Red 122	<0,5	None
(orange)		
Pigmet Orange 79	<0,5	None
(blue)		
Carbon black	<0,1	None

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SECTION 4: First aid measures**4.1. Description of first aid measures:****Inhalation:** Not relevant**Ingestion:** Not relevant**Skin:** First aid not expected to be necessary.**Eyes:** First aid not expected to be necessary.

If irritation develops, flush with copious amounts of water – if it continues, 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

None

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:

Collect and dispose as medical waste. 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 according to product specifications. After work wash hands with water and mild soap.

7.2. Conditions for safe storage, including any compatibilities:

See product specifications.

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:

Danish TLV list – Carbon Black (dust/respirable) 3,5 mg/m³- note K(carcinogen – in case of dusty form or if product is containing inhalable carbon black) not relevant for VitriFit.

DNEL/PNEC: No CSR.

8.2. Exposure controls:

Appropriate engineering controls: Not relevant

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: Solid stick in various colours.

Odour/odour threshold: Odourless

pH: N/A

Boiling point/boiling point range(°C): N/A

Vapour Pressure: N/A

Specific Gravity: N/A

Vapour Density: N/A

Melting Point: N/A

Solubility H₂O: N/A

Evaporation Rate: N/A

Flash Point: N/A

9.2. Other information

None

SECTION 10: Stability and reactivity**10.1. Reactivity:**

None.

10.2. Chemical stability:

Not relevant.

10.3. Possibility of hazardous reactions:

Not relevant.

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 toxicological effects:**

None known

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

Not relevant.

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. 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-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:**

MDD Directive /MDR regulation, REACH regulation.

Full Quality Assurance No. **CE 733551 (class IIa)**ISO Certificate no. **CE 733550****EU MDR:** TBA**15.2. Chemical safety assessment**

Even though not relevant for this type of product, the product has been classified as non-hazardous according to CLP 1272/2008.

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.

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. ORIGIO a/s shall not be held liable for any damage resulting from handling or from contact with its products.