a CooperSurgical Company

Safety Data Sheet

Document no: SDS-47

Date first created: 2014/07/17 **Version 5** **Date revised: 2026/03/24**

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

1. 1. Product identifier:

BlastGen®
1205 (also part of the 1206 Kit)

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

BlastGen™ is for embryo culture from Day 3 through to the blastocyst stage.
Should also be used for embryo transfer.

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

Legal Manufacturer:	**EU representative**	**Supplier / Contract manufacturer:**
With MDD		
Origio A/S Knardrupvej 2 DK-2760 Måløv Denmark +45 46 79 02 00	NA	**Costa Rica:** CooperMedical, SRL Edificio Nº 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 Nº 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

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.

SECTION 3: Composition / information on ingredients

3.2. Mixtures :

Component	CAS / EC no.	Approx. %	Classification
Magnesium sulphate	10034-99-8/600-073-4	<0.01	Acute Tox. 4, H302/H312/H332
Potassium Chloride	7447-40-7/231-211-8	<0.01	Not classified
Potassium Phosphate, monobasic	7778-77-0/231-913-4	<0.01	Not classified
Sodium Bicarbonate	144-55-8/205-633-8	<0.1	Not classified
Sodium Chloride	7647-14-5/ 231-598-3	<1.0	Eye Irrit. 2, H319
Sodium dihydrogen phosphate	13472-35-0/603-853-2	<0.01	Not classified
Sodium citrate	6132-04-3/612-118-5	<0.01	Not classified
Synthetic Serum replacement (SSR®)*		<0.01	-
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<
GM-CSF (Sagramostim)	123774-72-1	0.000002	-
Amino Acids incl.:		<0.01	
Glycine	56-40-6/200-272-2		Not classified
L-Isoleucine	73-32-5/200-798-2		Not classified
L-Leucine	61-90-5/200-522-0		Not classified
L-Lysine.	657-27-2/211-519-9		Not classified
L-Valine	72-18-4/200-773-6		Not classified
Vitamins incl.		<0.01	
Calcium pantothenate	137-08-6/205-278-9		Not classified
Folic Acid	59-30-3/200-419-0		Skin Irrit. 2, H315 Eye Irrit. 2, H319
Calcium Lactate	5743-47-5/611-530-2	<0.01	Not classified
Glucose	50-99-7/200-075-1	<0.01	Not classified
Sodium Pyruvate	113-24-6/204-024-4	<0.01	Not classified
Human Serum Albumin		<1.0	-
Sodium Hyaluronate	9067-32-7/618-620-0	<0.01	Not classified
Water		>90	Not classified

* Contains recombinant human insulin

Contains Sodium hydroxide and Hydrogen chloride for PH adjustment	<0.001	

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:
Not considered to be a fire hazard.

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:
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:
Avoid any unnecessary contact with skin and eyes. Do not mouth pipette. After work wash hands thoroughly with water and mild soap.

7.2. Conditions for safe storage, including any compatibilities:
Use care in handling/storage. Store in original container at 2-8ºC, 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

SECTION 9: Physiological and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	A clear, colourless 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_2O:	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. (LD_{50} 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), Cytotoxicity (V79 Chinese hamster cells), Sensitization (Local Lymph Node Assay) and Irritation (vaginal irritation).
The last 3 according to EN/ISO 10993. There was no evidence of cytotoxicity, sensitisation or irritation.

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).

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 733561	

EU MDR:

ISO13485	BSI CE 72267
EC Full Quality Assurance System	BSI MDR 768070
EC-Design-Examination Certificate	BSI MDR 768176

USA:
United States Food and Drug Administration (FDA): 510(k)
K152932
(+K140317 for the 1206 kit)

The product has been evaluated in accordance with CLP Regulation (EC) No 1272/2008.
The product is not considered to be hazardous.

15.2. Chemical safety assessment:
N/A

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, 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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