Safety Data Sheet

Document no: SDS-47

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

1. 1. Product identifier:

BlastGen™
1205

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

For in-vitro culture of human embryos from cell stage 4-8 to blastocyst stage. BlastGenTM can also be used for blastocyst transfer.

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

Manufacturer: ORIGIO a/s
Knardrupvej 2
2760 Måløv
Denmark
+45 46 79 02 00

1.4. Emergency telephone:

(UK)	**(DK)**
NHS (England or Wales): 0845 46 47	Poison line +45 82 12 12 12
NHS 24 (Scotland): 08454 24 24 24	

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.

SECTION 3: Composition / information on ingredients

3.2. Mixture :

Component	CAS / EC no.	Approx. %	Classification
Water		>90	
Sodium chloride	7647-14-5	<1	
Human serum albumin		<1	
Potassium dihydrogen sulfate	7778-80-5	<0.01	
Sodium dihydrogen phosphate	13472-35-0	<0.01	
Magnesium sulfate pentahydrate	10034-99-8	<0.01	
Trisodium citrate dihydrate	6132-04-3	<0.01	
Sodium bicarbonate	144-55-8	<0.1	
Glucose	50-99-7	<0.01	
Calcium lactate pentahydrate	5743-47-5	<0.01	
Pyruvic acid, sodium salt	113-24-6	<0.01	
Amino acids		<0.01	
SSR® (Synthetic Serum Replacement)*		<0.01	
Vitamins		<0.01	
Gentamicin sulphate	1405-41-0	<0.01	Skin Sens. 1; H317 Resp. Sens. 1; H334
Sodium hyaluronate	9067-32-7	<0.01	
EDTA	6381-92-6	<0.01	
Sodium hydroxide	1310-73-2/ 215-185-5	<0.01	Skin Corr.1A;H314
Hydrogen chloride	7647-01-0	<0.01	
GM-CSF (Sagramostim)	123774-72-1	0.000002	

*Contains recombinant human insulin.

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

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:
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 2-8ºC, 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/odour threshold:	Odourless
pH:	7.2-7.4
Boiling point/boiling point range(ºC):	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 toxicological effects:
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.

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 .. ..

SECTION 14: Transportation information

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

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:
To be determined.
USA:
United States Food and Drug Administration (FDA): 510(k) (example - **K002836)**
Full Quality Assurance No. (example - **CE 82107)**

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

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:

(EKS.) SAGE In Vitro Fertilization, a CooperSurgical Company, 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.

SAGE In Vitro Fertilization 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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