

## Data Sheet: CellGro® / CellGenix™ Serum-free ACTIVE Medium

Order No.: 24804-0500

Euro 250,00<sub>+iva</sub> conf. da 500ml

<b>Main components</b>	Salts, Sugars, Amino Acids, Vitamins, Buffers Contains phenol red (pH indicator) Contains L-glutamine
<b>Human proteins</b>	Albumin (human plasma-derived, licensed medicinal product for human use) Insulin (human recombinant, yeast-derived)
<b>Applications</b>	Serum-free expansion and differentiation of chondrocytes
<b>Release specifications:</b>	
<b>Osmolality</b>	290 – 350 (mOsm/kg H <sub>2</sub> O)
<b>pH</b>	7.2 – 7.5
<b>Endotoxin</b>	≤ 0.5 EU/ml
<b>Sterility</b>	Sterility test of the final product
<b>Functionality assay</b>	Median expansion rate of chondrocytes per day
<b>Mycoplasma</b>	Mycoplasma PCR-test of Vero cells
<b>Appearance</b>	Clear, red liquid
<b>Transport</b>	Ambient temperature
<b>Storage at</b>	+2°C to +8°C. Light protection recommended
<b>Intended use</b>	<b>For preclinical ex vivo use. Not intended for therapeutic use.</b>
<b>Quality and raw material statement</b>	Apart from one exception, the formulation does not contain animal-derived components. (A synthetic lipid contains chicken egg-derived lecithin. This lipid is a licensed medicinal product for human use.)  Human proteins have been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).

### Manufacturer

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In the U.S.A. products are distributed under the name of CellGenix™.

## Data Sheet: CellGro® / CellGenix™ GMP Serum-free Dendritic Cell Medium (DC)

Order No.: 20801-0500 **Euro 250,00<sub>+iva</sub> conf. da 500ml**

<b>Main components</b>	Salts, Sugars, Amino Acids, Vitamins, Buffers Contains phenol-red (pH-indicator) Contains L-glutamine
<b>Human <u>proteins</u></b>	Transferrin (human plasma-derived) Albumin (human-plasma-derived, licensed medicinal product for human use, Ph. Eur.) Insulin (human recombinant, yeast-derived, Ph.Eur., USP)
<b>Applications</b>	<ul style="list-style-type: none"><li>• Generation of dendritic cells</li><li>• Expansion of T-cells</li></ul>
<b>Release specifications:</b>	
<b>Osmolality</b>	260 – 320 (mOsm/kg H <sub>2</sub> O), determined according to Ph.Eur.
<b>pH</b>	7.2 – 7.5, determined according to Ph.Eur.
<b>Endotoxin</b>	≤ 1 EU/ml, determined according to Ph.Eur.
<b>Sterility</b>	Sterility test of the final product determined according to Ph.Eur.
<b>Functionality assay</b>	Generation of human dendritic cells from CD14 <sup>+</sup> monocytes
<b>Mycoplasma</b>	Mycoplasma PCR-test of Vero cells, according to Ph.Eur.
<b>Appearance</b>	Clear, red liquid
<b>Transport</b>	Ambient temperature
<b>Storage at</b>	+2°C to +8°C. Light protection recommended
<b>Shelf life</b>	2 years from date of production Minimum 6 months from date of shipping
<b>Intended use</b>	<b>For clinical ex vivo use. Not intended for human in vivo application.</b>
<b>Quality and raw material statement</b>	<p>This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. USP chapter &lt;1043&gt; “ancillary materials for cell, gene, and tissue-engineered products” has been considered in the design of this product. Apart from one exception, the formulation does not contain animal derived components. (A synthetic lipid contains chicken egg-derived lecithin. This lipid is a licensed medicinal product for human use.)</p> <p>Human proteins have been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).</p>

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## Data Sheet: CellGro® / CellGenix™ GMP Serum-free Stem Cell Growth Medium (SCGM)

### Xeno-free

Order No.: 20802-0500 **Euro 250,00<sub>+iva</sub> conf. da 500ml**

<b>Main components</b>	Salts, Sugars, Amino Acids, Vitamins, Buffers Contains phenol-red (pH-indicator) Contains L-glutamine, β-Mercaptoethanol
<b>Human proteins</b>	Albumin (human-plasma-derived, licensed medicinal product for human use, Ph. Eur.) Insulin (human recombinant, yeast-derived, Ph.Eur., USP)
<b>Applications</b>	<ul style="list-style-type: none"><li>• Cultivation of hematopoietic stem and progenitor cells</li><li>• Expansion of NK-cells</li></ul>
<b>Release specifications:</b>	
<b>Osmolality</b>	290 – 350 (mOsm/kg H <sub>2</sub> O), determined according to Ph.Eur.
<b>pH</b>	7.2 – 7.5, determined according to Ph.Eur.
<b>Endotoxin</b>	≤ 1 EU/ml, determined according to Ph.Eur.
<b>Sterility</b>	Sterility test of the final product determined according to Ph.Eur.
<b>Functionality assay</b>	Expansion of human CD34 <sup>+</sup> cells
<b>Mycoplasma</b>	Mycoplasma PCR-test of Vero cells, according to Ph.Eur.
<b>Appearance</b>	Clear, red liquid
<b>Transport</b>	Ambient temperature
<b>Storage at</b>	+2°C to +8°C. Light protection recommended
<b>Shelf life</b>	2 years from date of production Minimum 6 months from date of shipping
<b>Intended use</b>	<b>For clinical ex vivo use. Not intended for human in vivo application.</b>
<b>Quality and raw material statement</b>	<p>This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. USP chapter &lt;1043&gt; "ancillary materials for cell, gene, and tissue-engineered products" has been considered in the design of this product. The formulation does not contain animal derived components (xeno-free).</p> <p>Human proteins have been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).</p>

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**Data Sheet: CellGro® / CellGenix™****Serum-free Multipotent Mesenchymal Stromal Cell (MSC) Medium<sup>1</sup>**

Order No.: 24803-0500

Euro 250,00<sub>+iva</sub> conf. 500ml

**Main components** Salts, Sugars, Amino Acids, Vitamins, Buffers  
Contains phenol red (pH indicator)  
Contains L-glutamine

**Human proteins** Albumin (human-plasma-derived, licensed medicinal product for human use)  
Insulin (human recombinant, yeast-derived)

**Applications** Serum-free expansion of MSC from umbilical cord matrix and blood

**Release specifications:**

**Osmolality** 290 – 350 (mOsm/kg H<sub>2</sub>O)

**pH** 7.2 – 7.5

**Endotoxin** ≤ 0.5 EU/ml

**Sterility** Sterility test of the final product

**Functionality assay** Expansion capacity of human umbilical cord derived MSC (hUC-MSC)

**Mycoplasma** Mycoplasma PCR-test of Vero cells

**Appearance** Clear, red liquid

**Transport** Ambient temperature

**Storage at** +2°C to +8°C. Light protection recommended

**Intended use** **For preclinical ex vivo use. Not intended for therapeutic use.**

**Quality and raw material statement** Apart from one exception, the formulation does not contain animal derived components. (A synthetic lipid contains chicken egg-derived lecithin. This lipid is a licensed medicinal product for human use.)

Human proteins have been collected from healthy donors at the time of collection, and samples of their donations were tested individually and found negative for viral diseases by approved methods (HIV1/HIV2, HBV, HCV, Parvovirus B19).

<sup>1</sup>Horwitz et al (2005). Clarification of the nomenclature for MSC: The International Society for Cellular Therapy position statement. *Cytotherapy* Vol. 7, No.5, 393-395

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