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www.sigmaaldrich.nt-rt.ru || scx@nt-rt.ru

# Технические характеристики на материалы для биопереработки и сырье для рецептур, для биообработки клеточной культуры, химикаты для последующих процессов и рецептур компании Sigma-Aldrich

Виды товаров: среды для культивирования клеток и буферы для биообработки, химикаты для последующих процессов и рецептур, рекомбинантные факторы роста и транспортные белки, добавки, технологические ферменты, материалы для биопереработки рекомбинантных добавок и др.

# **Downstream Process & Formulation Chemicals**



Chemicals used in the downstream processing and purification of biologics often have multiple functions that vary by application, complicating selection for manufacturers with specific quality or cost expectations. Our broad portfolio of downstream chemicals streamlines raw material specification with optimized quality attributes for the full range of downstream needs – then goes a step further by seamlessly integrating supply transparency, documentation, good manufacturing practice (GMP), and change control, all tailored to your risk assessments.

```
G4376
L-Glutathione oxidized
≥98% (HPLC)
```

Expand

480708
 a2-3,6-Neuraminidase, Clostridium perfringens, Recombinant, E. coli

# **Bioprocessing Liquid Cell Culture Media & Buffers**

Our global sterile filtered liquid capabilities are designed to enhance and streamline your process, from clinical-phase trials all the way through to commercial production:

- Cell culture media standard or custom formulation
- Downstream buffers
- Cleaning-in-place (CIP)

As a trusted partner, we bring together products and services from across our company to offer the industry's highest quality sterile filtered liquid capabilities for the biopharmaceutical industry. All manufacturing locations operate according to

ISO 9001:2015 and GMP principles, so we can address your global needs and provide faster turnaround for your order.

## **READY-TO-USE SOLUTIONS THAT OPTIMIZE PRODUCTION**

Process steps such as media and buffer preparation or hydration of bulk powders can consume precious time, labor, and manufacturing floor space. Our ready-to-use sterile filtered liquid solutions eliminate the extra tasks, workforce and space associated with hydrating bulk powders, such as tubing and refilling, sample taking, and additional quality control testing streamline your processes while providing advantages such as:

- Fewer operational and contamination risks
- Reduced process footprint, freeing more floor space
- Elimination of tasks associated with hydrating bulk powders, including extra filtration steps, tubing and refilling, sample taking, and additional quality control testing
- More resources available for value-added tasks and core activities
- Right-sized buffer delivery, reducing chemical waste and WFI use for improved sustainability

Your sterile filtered liquid arrives ready-to-use in the quantities you need, with no waste and no excess to inventory. Our manufacturing facilities are specifically designed to provide sterile filtered products in a wide range of final vessel formats, from standard PET bottles to standard or custom bags, as well as custom volumes and formats. Our products are sterile filtered liquids which are supporting your research and further manufacturing processes. To ensure safe delivery of your sterile filtered liquids, our packaging and transport options include:

- Mobius® or equivalent standard single-use bags, as well as the Mobius® MyWay
  Portfolio of customizable single-use packaging solutions ranging from one-way
  shipping drums to recyclable and reusable bulk liquid containers with individual bar
  coding and tracking for complete control
- Mobius® or equivalent 3D large liquid transportation systems for shipment of bulk sterile filtered liquid product (media, buffers, in-process intermediates, and final bulk drug product) in working volumes of 100, 200, 500, or 1,000 liters, with a user-friendly design and your choice of sterile or non-aseptic connectors for reliable fluid management and secure, sterile disconnection
- Mobius® MyWay or equivalent Portfolio of single-use assembly options, ranging from one-way shipping drums to recyclable and reusable bulk liquid containers that meet your sustainability requirements – all individually bar coded and tracked for complete flexibility and control

## QUALITY INGREDIENTS AND TRANSPARENT SUPPLY

Water for injection is the key starting ingredient for all our liquid products. We ensure consistency, security, and EP and USP compliance by establishing redundant water for injection (WFI) supplies at all our facilities. This bulk-packaged water is suitable for the preparation of both upstream and downstream process solutions in industrial and regulated bioprocessing applications.

• Upstream applications: cell culture media, cell suspension and wash solutions, and reconstitution of products

• Downstream applications: process and biological buffers, cleaning and rinsing agents, diafiltration and purification buffers

All our liquid media facilities worldwide are part of our comprehensive Global Quality Management System, assuring the highest product consistency, reproducibility, performance, and expertise. We are committed to meeting or exceeding all relevant international guidelines and regulations, and we maintain quality certification programs at all facilities with on-site quality control testing. Our Global Quality Management System is certified as ISO 9001:2015, and all sites voluntarily comply with the Joint IPEC-PQG Guide on Good Manufacturing Practices (GMP) for Excipients and applicable sections of Annex 1 of the EU Guidelines to Good Manufacturing Practice for Medicinal Products.

To provide a consistent supply of material for your business continuity, our Global Raw Material Management Program is robust, controlled, and coordinated to ensure that our incoming supply is safe and secure. We also:

- Qualify, monitor materials and audit manufacturers and suppliers constantly for quality, qualification, and management
- Reduce variability by identifying and mitigating risks in the supply chain
- Work with subject matter experts to establish appropriate release criteria and specifications
- Maintain comprehensive change control and change notification procedures from our suppliers through to our customers

## STREAMLINING YOUR QUALIFICATION AND DRUG FILING

To help you stay on top of regulatory changes and simplify your processes, our manufacturing sites have 100% access to our industry-leading **Emprove® Program**. This powerful, always up-to-date repository of current and anticipated regulatory data supports our high-quality pharmaceutical and biopharmaceutical raw materials and consumables, providing you with comprehensive documentation that can:

- Speed approval preparation and extend compliance
- Facilitate the qualification process
- Support risk assessment
- Increase supply chain transparency

#### E7510

### Earle's Balanced Salt Solution 10x

Without sodium bicarbonate, 10 ×, liquid, sterile-filtered, suitable for cell culture

### $\Box$

15408

#### EX-CELL® TiterHigh™ Medium

Animal-component free, liquid, sterile-filtered, suitable for insect cell culture

### $\Box$

H1641

### Hanks' Balanced Salt Solution 10x

Without sodium bicarbonate, 10 ×, liquid, sterile-filtered, suitable for cell culture

 $\Box$ 

#### Hanks' Balanced Salt Solution 10x

Without calcium chloride, magnesium sulfate and sodium bicarbonate, 10 ×, liquid, sterile-filtered, suitable for cell culture

#### 

M6774

#### McCown's Woody Plant Basal Salt Mixture

powder, suitable for plant cell culture

 $\Box$ 

M6895

#### MEM Vitamin Solution (100×)

sterile-filtered, BioReagent, suitable for cell culture

 $\Box$ 

M9274

#### Murashige and Skoog Basal Medium

suitable for plant cell culture, with sucrose and agar

 $\square$ 

M0404

#### Murashige and Skoog Basal Medium

powder, suitable for plant cell culture, with Gamborg's vitamins

 $\Box$ 

M6899

## Murashige and Skoog Basal Salts with minimal organics

powder, suitable for plant cell culture

 $\Box$ 

M2909

#### Murashige and Skoog Modified Basal Salt Mixture

powder, suitable for plant cell culture

 $\Box$ 

M7024

#### Murashige and Skoog Shoot Multiplication Medium A

powder, suitable for plant cell culture

 $\Box$ 

P6668

#### Phytamax™ Orchid Maintenance Medium

powder, suitable for plant cell culture

 $\square$ 

P0931

Phytamax<sup>™</sup> Orchid Maintenance Medium without Charcoal powder, suitable for plant cell culture

 $\Box$ 

P1056 Phytamax™ Orchid Medium with Charcoal and Banana Powder

#### 

#### P6793

#### Phytamax<sup>™</sup> Orchid Multiplication Medium

powder, suitable for plant cell culture

#### $\Box$

S6765

#### Schenk and Hildebrandt Basal Salt Mixture

fine powder, suitable for plant cell culture

#### $\Box$

T2610

#### StableCell<sup>™</sup> Trypsin Solution

10X, sterile-filtered, BioReagent, suitable for cell culture, 5.0 g porcine trypsin and 2 g EDTA, 4Na per liter of 0.9% sodium chloride

 $\Box$ 

T2601

#### StableCell<sup>™</sup> Trypsin Solution

1X, sterile-filtered, BioReagent, suitable for cell culture, 0.5 g porcine trypsin and 0.2 g EDTA, 4Na per liter of Hanks' Balanced Salt Solution with phenol red

 $\Box$ 

T2605

#### StableCell<sup>™</sup> Trypsin Solution

5X, sterile-filtered, BioReagent, suitable for cell culture, 2.5 g porcine trypsin and 0.2 g EDTA, 4Na per liter of Hanks' Balanced Salt Solution with phenol red

 $\Box$ 

T4424

#### Trypsin solution from porcine pancreas

1 ×, sterile-filtered, BioReagent, suitable for cell culture, 2.5 g porcine trypsin per liter in Hanks' Balanced Salt Solution with phenol red

#### T4049

#### **Trypsin-EDTA solution**

0.25%, sterile-filtered, BioReagent, suitable for cell culture, 2.5 g porcine trypsin and 0.2 g EDTA, 4Na per liter of Hanks' Balanced Salt Solution with phenol red

W3500

Water

sterile-filtered, BioReagent, suitable for cell culture

 $\square$ 

W3513

Water

**BioPerformance** Certified

 $\square$ 

W0876 White's Basal Salt Mixture powder, suitable for plant cell cultur

# **Bioprocessing Recombinant Supplements**



Our wide range of cell culture supplements is designed with one goal in mind: to help grow your success. All over the world, biopharmaceutical companies rely on our products to satisfy the fundamental nutrition needs of cell culture processes, knowing from experience that our quality products and expertise can help them improve productivity and stability, while mitigating risk.

## **RECOMBINANT GROWTH FACTORS AND TRANSPORT PROTEINS**

All our recombinant, non-animal origin (NAO) supplements are specifically formulated for cell culture applications. Recombinant manufacturing in state-of-the-art, cGMP production facilities ensures reliable and consistent supply, while also supporting simplified regulatory processes. You will find an industry-leading selection of recombinant supplements and process enzymes for your specific application, including:

### **SUPPLEMENTS**

- CellPrime® rAlbumin ideally suited for media development, optimization or supplementation, it is used as an animal-free substitute for human/bovine serum albumin, removing the variability introduced by blood-derived proteins and safeguarding against adventitious virus or prion contaminations.
- CellPrime® rTransferrin often used to replace serum transferrin in combination with recombinant albumin and recombinant insulin as a supplement mix in cell culture media formulations, CellPrime® rTransferrin removes the variability introduced by blood-derived proteins and safeguards against adventitious virus or prion contaminations.
- CellPrime® rInsulin extending the long-term viability of various cell lines while enhancing cell growth and protein production, this NAO supplement is often used in upstream processes for monoclonal antibodies (mAbs), viral vaccines, and stem cell expansion.

## **PROCESS ENZYMES**

- CellPrime® rTrypsin used to dissociate and resuspend adherent cells during harvest in vaccine production, it can also be utilized for stem cell cultures, dislodging adherent cells grown on carriers while preserving the structural and functional integrity of cell surface markers. Other applications include recombinant insulin manufacturing and general life science cell culturing.
- CellPrime® rTrypsin STD a companion product to CellPrime® rTrypsin, it is released against the criteria set forth in the USP monograph for crystallized trypsin (USP 43, 2013).

Specific activity is determined using BAEE as the substrate, with less stringent requirements for distribution between the alpha and beta isoforms of the enzyme.

• CellPrime® rLysozome – more potent than animal-derived enzymes, CellPrime® rLysozome can be used to lyse bacterial cells more conveniently and gently at a comparable cost, while offering a non-animal derived safety profile.

## **OTHER SUPPLEMENTS**

As part of our comprehensive portfolio, we also offer animal-derived cell culture supplements used globally in diagnostics and numerous commercial biopharmaceutical products. While mammalian cells can be challenging to work with from a bioprocessing perspective, our experience and stringent product quality help you tackle complex processing and scale-up parameters with confidence.

In addition, we produce a variety of complementary products for specific cell culture and *in vitro* diagnostics (IVD) applications. Products such as bovine transferrin, EX-CYTE®, and bovine gamma globulin, for example, are specifically designed and produced to meet the quality and documentation needs of customers operating in a regulated environment.

R7131

# RPMI 1640 Amino Acids Solution (50×)

Without L-glutamine, sterile-filtered, BioReagent, suitable for cell culture

Ы

## PROPERTIES

400 sterile-filtered BioReagent liquid cell culture | mammalian: suitable endotoxin, tested ambient 2-8°C

14008C

# Serum Plus<sup>™</sup> Medium Supplement

# made with gamma irradiated FBS **PROPERTIES**

500

γ-irradiated by SER-TAIN™ process (FBS) sterile; sterile-filtered

solution dry ice -20°C

M0446

# StableCell<sup>™</sup> MEM

With Earle's salts, stable glutamine, and sodium bicarbonate, liquid, sterile-filtered, suitable for cell culture **PROPERTIES** 

400

sterile-filtered liquid cell culture | mammalian: suitable endotoxin, tested sodium pyruvate: no HEPES: no Hanks' salts (2% CO<sub>2</sub>): no NaHCO<sub>3</sub>: yes Earle's salts (5% CO<sub>2</sub>): no stable glutamine: yes phenol red: yes L-glutamine: no glucose: yes ambient 2-8°C

# StableCell<sup>M</sup> MEM, Alpha Modification

With stable glutamine and sodium bicarbonate, with ribonucleosides and deoxyribonucleosides, liquid, sterile-filtered, suitable for cell culture **PROPERTIES** 

#### 400

sterile-filtered liquid cell culture | mammalian: suitable Hanks' salts (2% CO<sub>2</sub>): no Earle's salts (5% CO<sub>2</sub>): yes phenol red: yes glucose: yes HEPES: no sodium pyruvate: no stable glutamine: yes NaHCO<sub>3</sub>: yes L-glutamine

M6199

# StableCell<sup>™</sup> MEM, Alpha Modification

With stable glutamine and sodium bicarbonate, without ribonucleosides and deoxyribonucleosides, liquid, sterilefiltered, suitable for cell culture

## PROPERTIES

**400** 

sterile-filtered liquid cell culture | mammalian: suitable Endotoxin, tested Earle's salts (5% CO<sub>2</sub>): yes NaHCO<sub>3</sub>: yes stable glutamine: yes phenol red: yes L-glutamine: no glucose: yes HEPES: no Hanks' salts (2% CO<sub>2</sub>): no sodium pyruvate: yes ambient T3449

# TrypZean® Solution, 1×

recombinant, expressed in corn, sterile-filtered

Sign Into View Organizational & Contract Pricing

## PROPERTIES

expressed in corn **300** sterile-filtered aqueous solution 1 × cell culture | mammalian: suitable 7.70-8.30 dry ice -20°C

C6295

# Cell Freezing Medium-DMSO Serum free 1x

sterile-filtered, suitable for cell culture **PROPERTIES** 

sterile-filtered 200 liquid cell culture | mammalian: suitable cryopreservation: suitable

endotoxin, tested dry ice -20°C

# **Demecolcine solution**

# 10 µg/mL in HBSS, ACF Qualified, BioXtra **PROPERTIES**

sterile-filtered BioXtra liquid 10 µg/mL in HBSS cell culture | mammalian: suitable 2-8°C CN[C@H]1CCc2cc(OC)c(OC)c(OC)c2C3=CC=C(OC)C(=O)C=C13 1S/C21H25NO5/c1-22-15-8-6-12-10-18(25-3)20(26-4)21(27-5)19(12)13-7-9-17(24-2)16(23)11-14(13)15/h7,9-11,15,22H,6,8H2,1-5H3/t15-/m0/s1 NNJPGOLRFBJNIW-HNNXBMFYSA-N

# Dimethyl sulfoxide

## PROPERTIES

Hybri-Max<sup>™</sup> **400** 2.7 (vs air) 0.42 mmHg ( 20 °C) sterile-filtered BioReagent ≥99.7% liquid 573 °F 42 %, 63 °F

# E6267 Earle's Balanced Salts

With sodium bicarbonate, without calcium chloride and magnesium sulfate, liquid, sterile-filtered, suitable for cell culture

## PROPERTIES

**400** sterile-filtered liquid cell culture | mammalian: suitable endotoxin, tested NaHCO3: 2.2 g/L phenol red: 0.011 g/L glucose: 1.0 g/L (Dextro) ambient

E6267

# **Earle's Balanced Salts**

With sodium bicarbonate, without calcium chloride and magnesium sulfate, liquid, sterile-filtered, suitable for cell culture

# PROPERTIES

400 sterile-filtered liquid cell culture | mammalian: suitable endotoxin, tested NaHCO3: 2.2 g/L phenol red: 0.011 g/L glucose: 1.0 g/L (Dextro) ambient

E2888

# **Earle's Balanced Salts**

With sodium bicarbonate, liquid, sterile-filtered, suitable for cell culture

# PROPERTIES

400 sterile-filtered liquid cell culture | mammalian: suitable endotoxin, tested phenol red: 0.011 g/L glucose: 1.0 g/L (Dextro) NaHCO3: 2.2 g/L ambient

## G9785 GSEM Supplement

# 50 ×, liquid, sterile-filtered, suitable for cell culture **PROPERTIES**

sterile-filtered **200** liquid 50 × cell culture | mammalian: suitable endotoxin, tested dry ice -20°C

# HOBB7 HEPES solution

4.0 out of 5 stars, average rating value. Read a Review. Same page link.

4.0

Essential+ Grade

# 1 M, pH 7.0-7.6, sterile-filtered, BioReagent, suitable for cell culture

# PROPERTIES

sterile-filtered **300** BioReagent BioXtra

liquid (Tightly closed. Dry) 1 M cell culture | mammalian: suitable endotoxin, tested 7.0-7.6 6.8-8.2

# K3129 Kao and Michayluk Vitamin Solution

100 ×, liquid, suitable for plant cell culture

## PROPERTIES

sterile-filtered **500** liquid 100 × cell culture | plant: suitable yellow 4.0-6.5 agriculture dry ice -20°C

# M5550 MEM Amino Acids (50x) solution

Without L-glutamine, liquid, sterile-filtered, BioReagent, suitable for cell culture

# PROPERTIES

200 sterile-filtered BioReagent liquid cell culture | mammalian: suitable endotoxin, tested 2-8°C

# **Downstream Process & Formulation Chemicals**

Chemicals used in the downstream processing and purification of biologics often have multiple functions that vary by application, complicating selection for manufacturers with specific quality or cost expectations. Our broad portfolio of downstream chemicals streamlines raw material specification with optimized quality attributes for the full range of downstream needs – then goes a step further by seamlessly integrating supply transparency, documentation, good manufacturing practice (GMP), and change control, all tailored to your risk assessments.

Raw materials within our industry-leading **Emprove® chemicals portfolio** are supported with comprehensive, up-to-date documentation to help you navigate regulatory challenges, manage risks, and improve processes. The portfolio is divided into categories that reflect the specific application needs of drug manufacturers.

G4376 L-глутатион окисленный ≥98% (ВЭЖХ) □ 480708 a2-3,6-нейраминидаза, Clostridium perfringens, рекомбинантная, E. coli Алматы (7273)495-231 Ангарск (3955)60-70-56 Архангельск (8182)63-90-72 Астрахань (8512)99-46-04 Барнаул (3852)73-04-60 Белгород (4722)40-23-64 Благовещенск (4162)22-76-07 Брянск (4832)59-03-52 Владивосток (423)249-28-31 Владикавказ (8672)28-90-48 Владимир (4922)49-43-18 Волагоград (844)278-03-48 Вологоград (844)278-03-48 Воролеж (473)204-51-73 Екатеринбург (343)384-55-89 Иваново (4932)77-34-06 Ижевск (3412)26-03-58 Иркутск (395)279-98-46 Казань (843)206-01-48 Калининград (4012)72-03-81 Калуга (4842)92-23-67 Кемерово (3842)65-04-62 Киров (8332)68-02-04 Коломна (4966)23-41-49 Кострома (4942)77-07-48 Краснодар (861)203-40-90 Краснодар (861)203-40-90 Красноярск (391)204-63-61 Курск (4712)77-13-04 Курган (3522)50-90-47 Липецк (4742)52-20-81

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Киргизия +996(312)96-26-47

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