

## Section 1 – Product and Company Identification

### Manufacturer Information

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### Product Information

**Product Name:** Cell Culture Media Products (Catalog #: Various)

**Intended Use:** For use with the Diagnostic Hybrids *FreshCells™* and *FreshCells MixedCells™* (R-Mix™, R-Mix Too™, Super E-Mix™ and H&V Mix™), and *FreshFrozenCells®* cultures. *FreshCells* culture media products are for *in vitro* diagnostic use.

**Components:** Products are available in various volumes, where xxxx is either 0100 = 100 mL, 0500 = 500 mL or 1000 = 1000 mL.

Catalog #	Product Name
10-12xxxx	HBSS (without Ca <sup>2+</sup> or Mg <sup>2+</sup> ; Hanks Balanced Salt Solution)
10-15xxxx	DMEM Planting Medium (10% FBS; Dulbecco's Modified Eagle Medium)
10-20xxxx	Cell Planting Medium
10-200100EU1	Supplement for Cell Planting Medium Base (11 mL)
10-200100EU2	Cell Planting Medium Base (100 mL)
10-210125	MRC-5 Cell Growth Medium
10-22xxxx	ELVIS® Replacement Medium
10-290030	TurboTreat® (A Mink Lung Cell Pretreatment Medium)
10-31xxxx	RM-01 Refeed Medium (Zero-Serum)
10-32xxxx	RM-02 Refeed Medium (2% FBS)
10-33xxxx	RM-03T R-Mix Refeed Medium
10-34xxxx	Chlamydia Isolation Medium
10-35xxxx	RM-05 Refeed Medium (10% FBS)
10-36xxxx	Zero-Serum Refeed Medium – PS
10-38xxxx	Super E-Mix Refeed Medium
10-39xxxx	Zero-Serum Refeed Medium – PSGA
10-95xxxx	EMEM (no L-glutamine; Earle's Minimum Essential Medium)
05-360075 R-Mix	Rinse Buffer, for ReadyCells®
05-370100 R-Mix	Refeed Medium, for ReadyCells

## Section 2 – Hazards Identification

### Emergency Overview

Significant health effects are not anticipated from routine use of these cell culture products when following Universal Precautions and general safety laboratory practices. None of the components listed within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives.

When working with these cultures we always recommend that employees wear appropriate personal protective equipment (PPE), including gloves, a lab coat and eye protection, and follow good laboratory hygiene practices to avoid any and all accidental exposure to workplace materials.

These cultures contain material(s) of human and/or animal origin and should be considered as potentially infectious. Universal Precautions should be followed when working with these cultures.

Various antimicrobials are used within these cell culture media, including Amphotericin B, Gentamicin, Penicillin G and Streptomycin Sulfate. Some or all of these antimicrobials may exhibit sensitization or toxicity (e.g., liver) characteristics at low concentrations.

## Section 2 – Hazards Identification (cont'd)

The U.S.-origin fetal bovine serum (FBS) and bovine serum albumin (BSA) used within these products, and the bovine-derived trypsin used in the preparation of cell cultures, are fully characterized and tested by the supplier(s) to demonstrate normal and specific levels of serum constituents (of the FBS) and to confirm the absence of *Mycoplasma spp.* and other organisms in compliance with US-9CFR113.

### Supplemental Hazard Information (For Reference Only)

Component	Hazard Statements	Precautionary Statements
<b>Cycloheximide (&lt;0.1%)</b> CAS #: 66-81-9 EC #: 200-636-0	H360 May damage fertility of the unborn child.	P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses. P501 Dispose of contents to an approved waste disposal facility.
<b>Gentamicin (&lt;0.1%)</b> CAS #: 1405-41-0 EC #: 215-778-9	H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses. P333+P313: If skin irritation or rash occurs: Get medical attention/advice. P342+P311: If experiencing respiratory symptoms: Call a doctor, physician or a Poison Center.
<b>Streptomycin Sulfate (0.1%)</b> CAS #: 3810-74-0 EC #: 223-286-0	H361 Suspected of damaging fertility or the unborn child.	P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses.
<b>Penicillin G (&lt;0.1%)</b> CAS #: 113-98-4 EC #: 204-038-0	H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses.
<b>Trypsin (&lt;0.1%)</b> CAS #: 9087-70-1 EC #: 232-994-9	H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses. P333+P313: If skin irritation or rash occurs: Get medical attention/advice. P342+P311: If experiencing respiratory symptoms: Call a doctor, physician or a Poison Center.

**NOTE:** Refer to product matrix (Section 15) detailing where each of the above components are present.

### Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Volume
<b>Mixtures</b>					
<ul style="list-style-type: none"> <li>- No ingredients are hazardous according to OSHA criteria.</li> <li>- There are no hazardous chemicals contained within this product at concentrations that are considered hazardous to personal health and/or the environment.</li> </ul>					

### Section 4 – First Aid Measures

#### General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary. Treat symptomatically.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
<i>If swallowed:</i>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

### Section 5 – Fire Fighting Measures

#### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

<i>Extinguishing Media:</i>	For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	Nature of decomposition products not known.
<i>Fire Fighting Equipment:</i>	Firefighters should wear full protective gear when responding to fires.

### Section 6 – Accidental Release Measures

#### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials and Methods for Clean-Up:</i>	Soak up with inert absorbent material (e.g. paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

## Section 7 – Handling and Storage

**Specific Use:** For *in vitro* diagnostic use only. Not for use by the general public.

### Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

**Conditions for Safe Storage:** To maintain efficacy, store according to the kit specific Package Insert instructions.

**Incompatibilities** To maintain efficacy, store according to the kit specific Package Insert instructions.

**Additional Reference:** Follow standard handling guidelines as detailed in CDC-NIH Manual, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, latest edition.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** No data available for the specific components within these products.

### Exposure Controls:

**Engineering Measures** Use with adequate ventilation.

#### Personal Protective Equipment

*Respiratory Protection:* None needed under normal conditions of use. Avoid generation of dusts, mists or other airborne forms when working with these products.

*Hand Protection:* Handle with appropriately rated chemical resistant gloves (nitrile or equivalent). Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling these cultures.

*Eye Protection:* Wear safety glasses with side shields or goggles to prevent eye contact.

*Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.

*Hygiene Measures:* Wash hands before and after use and at the end of the workday.

#### Environmental Exposure Controls

No special environmental controls are required.

## Section 9 – Physical and Chemical Properties

Characteristic	Cell Culture Media
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available

### Section 9 – Physical and Chemical Properties (cont'd)

Characteristic	Cell Culture Media
pH	No data available
Solubility in Water	No data available
Appearance and Odor	Clear, aqueous liquid; cherry-peach to light red in color; odorless with no signs of turbidity. Exceptions include: <i>TurboTreat</i> (10-290030) or <i>Supplement for Cell Planting Medium Base</i> (10-200100EU1), which are clear to light straw/yellow in color; odorless with no signs of turbidity.

### Section 10 – Stability and Reactivity

Characteristic	Cell Culture Media
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	No data available

### Section 11 – Toxicological Information

**Acute Toxicity** No data available for the specific Cell Culture Media products for inhalation or dermal exposure

**Potential Health Effects:**

<i>Skin Corrosion/ Irritation:</i>	No data available	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i>	May cause eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

**Carcinogenicity** No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the IARC, ACGIH, NTP or OSHA.

**Reproductive Toxicity** No Data available

**Teratogenicity** No data available

**Specified Target Organ General Toxicity (GHS)**

<i>Single Exposure (GHS):</i>	No data available
<i>Repeated Exposure (GHS):</i>	No data available

## Section 11 – Toxicological Information (cont'd)

### Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

**Synergistic Effects**                      No data available

### Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

Liver – Irregularities – Based on Human Evidence (Cycloheximide, Gentamicin, Amphotericin B, Streptomycin sulfate)

## Section 12 – Ecological Information

**Ecotoxicity**                                      No data available                      **Mobility in Soil**                      No data available

**Persistence / Degradability**              No data available                      **PBT and vPvB Assessment**      No data available

**Bioaccumulation**                              No data available

**Other Adverse Effects**                      An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

## Section 13 – Disposal Considerations

### Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this product. Do not discharge any of the solutions, reagents, controls or cultures into drains, water courses or onto the ground.

### Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country (e.g. Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

## Section 14 – Transportation Information

**U.S. Department of Transportation (DOT)**                      This kit is not regulated for transport.

**International Air Transportation (IATA)**                      This kit is not regulated for transport.

**International Maritime Dangerous Goods (IMDG)**              This kit is not regulated for transport.

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

**OSHA Hazards** Non-hazardous

**SARA 302** The following chemicals are subject to reporting levels established by SARA Title III, Section 302:  
Cycloheximide CAS #: 66-81-9 Revision Date: 2007-07-01

**SARA 313** The following chemicals are subject to reporting levels established by SARA Title III, Section 313:  
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.

**SARA 311/312** No SARA hazards.

#### State Regulations

##### California Prop 65:

**WARNING** – Various cultures contain a chemical known to the State of California to cause birth defects or other reproductive harm (see component/product chart below).

Cyclohexidine CAS #: 66-81-9 Revision Date: 2007-09-28

Streptomycin Sulphate CAS #: 3810-74-0 Revision Date: 2007-09-28

Components Products	10-12xxxx	10-15xxxx	10-20xxxx	10-210125	10-22xxxx	10-290030	10-31xxxx	10-32xxxx	10-33xxxx	10-34xxxx	10-35xxxx	10-36xxxx	10-38xxxx	10-39xxxx	10-95xxxx	05-360075	05-370100
Bovine Serum		X	X	X	X	X		X		X	X		X				
Amphotericin B					X			X		X	X			X			
Cyclohexamide										X							
Gentamicin		X	X	X		X		X		X	X			X			
Penicillin G					X			X	X		X	X	X	X		X	X
Streptomycin Sulfate					X			X	X	X	X	X	X	X		X	X
L-Glutamine		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
HEPES		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Phenol Red	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Trypsin									X								X

#### Additional Regulatory Information

##### Safety, Health and Environmental regulations/legislation specific for the mixture:

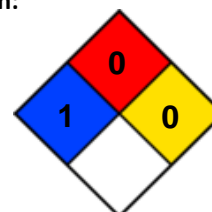
Not completed for the components contained within this kit.

**Chemical Safety Assessment:** Not completed for the components contained within this kit.

##### HMIS Kit Classification:



##### NFPA Kit Classification:



**Section 16 – Other Information**

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**SUPERCEDES:** April 15, 2010

**REVISIONS:** GHS update.

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