

Section 1 – Product and Company Identification

1.1 Manufacturer Information

Quidel Corporation	Phone:	1.800.874.1517	Web: quidel.com
2005 East State Street, Suite 100	Fax:	1.740.592.9820	E-mail: gehs@quidel.com
Athens, OH 45701	Emergency (24-Hour):	1.866.519.4752	

1.2 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; MEM-# and CIM-10, xxx is either -05 = 50 mL, -100 = 100 mL and 500 = 500 mL.

DHI/Quidel Catalog #	CellPro Catalog #	Product Name
10-12xxxx	N/A	HBSS (without Ca2+ or Mg2+; Hanks Balanced Salt Solution)
N/A	406-xxx	HBSS (with Ca2+ or Mg2+; Hanks Balanced Salt Solution)
10-15xxxx	N/A	DMEM Planting Medium (10% FBS; Dulbecco's Modified Eagle Medium)
10-20xxxx	N/A	Cell Planting Medium
10-200100EU1	N/A	Supplement for Cell Planting Medium Base (11 mL)
10-200100EU2	N/A	Cell Planting Medium Base (100 mL)
10-210125	N/A	MRC-5 Cell Growth Medium
10-22xxxx	N/A	ELVIS® Replacement Medium
10-290030	N/A	TurboTreat® (A Mink Lung Cell Pretreatment Medium)
10-31xxxx	N/A	RM-01 Refeed Medium (Zero-Serum)
10-32xxxx	402-xxx	RM-02 Refeed Medium (2% FBS)
10-33xxxx	N/A	RM-03T R-Mix Refeed Medium
10-34xxxx	405-xxx	Chlamydia Isolation Medium
10-35xxxx	404-xxx	RM-05 Refeed Medium (10% FBS)
10-36xxxx	N/A	Zero-Serum Refeed Medium – PS
10-38xxxx	N/A	Super E-Mix Refeed Medium
10-39xxxx	N/A	Zero-Serum Refeed Medium – PSGA
10-95xxxx	N/A	EMEM (no L-glutamine; Earle's Minimum Essential Medium)
05-360075	N/A	Rinse Buffer, for ReadyCells®
05-370100	N/A	Refeed Medium, for ReadyCells
N/A	401-xxx	MEM-0 Minimum Essential Medium 0% FBS
N/A	403-xxx	MEM-5 Minimum Essential Medium 5% FBS

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.

Section 2 – Hazards Identification (cont'd)

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.

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.

2.1 Supplemental Hazard Information (For Reference Only) – Not a hazardous substance or mixture.

Component	Hazard Statements	Precautionary Statements
Cycloheximide (<0.1%) 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.
Gentamicin (<0.1%) 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.
Streptomycin Sulfate (0.1%) 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.
Penicillin G (<0.1%) 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.
Trypsin (<0.1%) 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 16) detailing where each of the above components are present.

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200).

Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

3.2 No chemicals need to be disclosed according to the applicable regulations for the components in this kit.

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.

4.1 Description of First Aid Measures

If inhaled: Move the person to fresh air and support breathing as required.

In case of skin contact: Wash affected area with soap and water. Seek medical advice if irritation develops.

In case of eye contact: 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.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified.

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.

5.1 Suitable Extinguishing Media

For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising from the Substance of Mixture

Nature of decomposition products not known.

5.3 General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

5.4 Fire Fighting Equipment

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. A spill or releases of any of the components listed in this SDS is unlikely.

6.1 Personal Precautions

Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the Cell Culture Media products. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.

6.2 Methods and Materials for Clean-Up

Wipe 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.

6.3 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.

6.4 Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

7.1 Specific Use

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

7.2 Precautions for Safe Handling

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

7.3 Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

7.4 Conditions for Safe Storage

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

7.5 Incompatibilities

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

7.6 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

- 8.1 Exposure Limits:** No data available for the specific components within these products.
- 8.2 Exposure Controls:**
- Engineering Measures** Use with adequate ventilation.
- Personal Protective Equipment**
- Respiratory Protection:* None needed under normal conditions of use.
- 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.
- 8.3 Environmental Exposure Controls** No special environmental controls are required.
- 8.4 Special Notes** No data available.

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 ₂ 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
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. <i>Exceptions include:</i> TurboTreat (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

11.1 Information on Toxicological Effects Acute Toxicity

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

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Synergistic Effects No data available

11.2 Signs and Symptoms of Exposure

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

11.3 Additional Information

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

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

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 PBT and vPvB Assessment No data available

12.6 Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid disposal to the environment.

Section 13 – Disposal Considerations

13.1 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.

13.2 Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, 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

- | | |
|---|--|
| 14.1 U.S. Department of Transportation (DOT) | This kit is not regulated for transport. |
| 14.2 International Air Transportation (IATA) | This kit is not regulated for transport. |
| 14.3 International Maritime Dangerous Goods (IMDG) | This kit is not regulated for transport. |

Section 15 – Regulatory Information

15.1 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.

15.2 State Regulations

The following chemicals appear on one or more of the following state hazardous substance lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
--	-	-	-	-	-	-	-

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

15.3 Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
--	--	--

Section 15 – Regulatory Information (cont'd)

15.4 Additional Regulatory Information

Safety, Health and Environmental regulations/legislation specific for the mixture No data available

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

HMIS Kit Classification:

Health Hazard: 1
 Chronic Health Hazard: *
 Flammability: 0
 Physical Hazard: 0

NFPA Kit Classification:

Health Hazard (blue): 1
 Fire Hazard (red): 0
 Reactivity (yellow): 0
 Special Hazards (white): None

**Use additional care when handling the Cell Culture Media as they may contain potentially infectious materials.*

Section 16 – Other Information

16.1 Product Matrix

Components Products	10-12xxxx & 406-xxx	10-15xxxx	10-20xxxx	10-210125	10-22xxxx	10-290030	10-31xxxx	10-32xxxx & 402-xxx	10-33xxxx	10-34xxxx & 405-xxx	10-35xxxx & 404-xxx	10-36xxxx	10-38xxxx	10-39xxxx	10-95xxxx	05-360075	05-370100	401-xxx	403-xxx
Bovine Serum		X	X	X	X	X		X		X	X		X						X
Amphotericin B					X			X		X	X			X				X	X
Cyclohexamide										X									
Gentamicin		X	X	X		X		X		X	X			X				X	X
Penicillin G					X			X	X		X	X	X	X		X	X	X	X
Streptomycin Sulfate					X			X	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	X	X
HEPES		X	X	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	X	X
Trypsin									X								X		

16.2 SDS Preparation

PREPARED BY: Quidel Corporation
 12544 High Bluff Drive, Suite 200
 San Diego, CA 92130

SUPERCEDES: April 30, 2015

REVISIONS: General format update. Added new information for CellPro products.

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.