

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: Fresh Cells and Mixed Cells (Catalog #: Various)

Intended Use: FreshCells and MixedCells cultures are intended for virus and/or Chlamydia isolation and to aid in the diagnosis of diseases associated with infectious agents. FreshCells and Mixed Cells culture media products are for *in vitro* diagnostic use.

Components: Refer to Section 16 for detailed list of product codes, product names and product (cell line) source descriptions.

Section 2 – Hazards Identification

Emergency Overview

Significant health effects are not anticipated from routine use of these Fresh Cell or Mixed Cell 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 cells 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 cells 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 cells.

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

WARNING:

Primary monkey cell lines may harbor endogenous viruses such as simian viruses, foamy viruses, adenoviruses, Herpes B virus, etc. which may be hazardous to humans. The most common endogenous viruses are SV5 and SV40. Some of these viruses may be expressed only after the cells have been “stressed” by, e.g., environmental factors, age of the culture, or inoculation with a specimen or fresh medium. Consequently, all results obtained using this product should be reviewed by appropriately trained laboratory personnel, aware of the possibility that observed CPE may be caused by an endogenous virus as well a virus in the specimen.

The U.S. origin fetal bovine serum (FBS) used within these cells 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.

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 large spill or release 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 FreshCell or MixedCell 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.

Section 6 – Accidental Release Measures (cont'd)

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 FreshCells or MixedCells ON YOU or IN YOU. Wash exposed areas thoroughly after using. Do not eat or drink while working with the FreshCells or MixedCells. FreshCells or MixedCells 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 FreshCells or MixedCells. 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	FreshCells and MixedCells
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.

Section 10 – Stability and Reactivity

Characteristic	FreshCells and MixedCells
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 inhalation or dermal exposure when working with the FreshCells or MixedCells.

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.

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

Single Exposure (GHS): No data available

Repeated Exposure (GHS): 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 (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.

Note: CITES [Diagnostic Hybrids (Quidel) complies with all regulations promulgated by the Convention on International Trade in Endangered Species (CITES). Accordingly, special permits and arrangements must be made to ship all primate products internationally.]

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:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302
- 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
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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).

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

15.3 Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
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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 FixedCells and MixedCells, as they may contain potentially infectious materials.

Section 16 – Other Information

16.1 Product Information

Product Code	Product name	Product (cell line) source description
<u>FreshCells™ Singles Prefixes</u> [Products of human origin are indicated with asterisks (*) in table below.]		
42-	NHFL*	human neonatal lung
43-	HEL*	human embryonic lung
44-	MRHF*	human foreskin fibroblast
46-	pAGMK	primary African green monkey kidney
47-	pCMK	primary Cynomolgus monkey kidney
48-	pRK	primary rabbit kidney, New Zeal White
49-	pRhMK	primary Rhesus monkey kidney
51-	MRC-5*	human embryonic lung fibroblast
52-	CV-1	African green monkey kidney
53-	BGMK	Buffalo green monkey kidney
54-	McCoy	mouse fibroblast
55-	ELVIS® BHK	baby hamster kidney, genetically modified
56-	A549*	human lung carcinoma
57-	Hep-2*	human epidermoid carcinoma
58-	Mv1Lu	mink lung
59-	NCI-H292	human pulmonary muco-epidemoid carcinoma
62-	MNA	mouse neuroblastoma
67-	Vero 76	African green monkey kidney
72-	HeLa*	human cervix adenocarcinoma
74-	293*	human kidney epithelial
75-	HeLa 229*	human cervix adenocarcinoma
76-	RD*	human rhabdomyosarcoma
77-	Caco-2*	human colon adenocarcinoma
78-	L-929	mouse subq connective
81-	CHO-K1	Chinese hamster ovary
83-	MDCK	Madin-Darby canine kidney
84-	Vero	African green monkey kidney
85-	WI-38*	human embryonic lung fibroblasts
86-	LLC-MK2	Rhesus monkey kidney
87-	Hs27 (HFF)*	human foreskin fibroblast
89-	BHK-21	baby hamster kidney, genetically modified
<u>MixedCells™ Prefixes</u>		
92- [Super E-Mix™]	A549* and BGMK-hDAF	human lung carcinoma and Buffalo green monkey kidney
96- [R-Mix™]	A549* and Mv1Lu	human lung carcinoma and mink lung
97- [R-Mix Too™]	A549* and MDCK	human lung carcinoma and Madin-Darby canine kidney
98- [H&V-Mix™]	MRC-5* and CV-1	human embryonic lung fibroblast and African green monkey kidney
<u>Product Code Suffixes</u>		
___-0101	Shell-vial	___-24xx Multi-well plate, 24-well size, ("xx" denotes number of wells filled)
___-0102	Shell-vial with coverslip	___-48xx Multi-well plate, 48-well size, ("xx" denotes number of wells filled)
___-0620EU	Tube, 13 mm diameter	___-96xx Multi-well plate, 96-well size, ("xx" denotes number of wells filled)
___-0600	Tube, 16 mm diameter	___-384xxx Multi-well plate, 384-well size, ("xxx" denotes wells filled)
___-Txxx	Flask, ("xxx" denotes number of cm ²)	

C prefix = CITES; A suffix = SV5 and SV40 antisera or REF No. xx-309, where xx=format (14=tube, 15=shell-vial, 16=flask, 18=MWP)

Section 16 – Other Information (cont'd)

16.1 Product Information (cont'd)

CellPro Product Name	CellPro Product Description	CellPro Product Code
RK	Primary Rabbit Kidney (New Zeal White)	101
RMK	Primary Rhesus Monkey Kidney	102
RMKa	Primary Rhesus Monkey Kidney w/ SV5 & SV40	103
A549	Human Lung Carcinoma	201
BGMK	Buffalo Green Monkey Kidney	202
HEp-2	Human Cervix Carcinoma	203
McCoy	Mouse Fibroblast	204
McCoy Lights	Mouse Fibroblast	205
MRC-5	Human Lung Fibroblast	206
HFF	Human Foreskin Fibroblast	207
Vero	African Green Monkey Kidney	208
WI-38	Human Lung Fibroblast	209
MDCK	Madin-Darby Canine Kidney	210
RD	Rhabdomyosarcoma, Embryonal, Human	211
Mv.1.LU	Mink Lung	212
HeLa	Human Epithelioid Cervical Carcinoma	213
CRFK	Cat Kidney, <i>Felis catus</i>	214

16.2 SDS Preparation

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SUPERCEDES: September 9, 2015

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

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