

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: ReadyCells Frozen Cell Monolayers in Shell-Vials, Singles and Mixed

Catalog Number	Product Name / Synonyms: Frozen Cell Monolayers
F-54-0102-24	McCoy (singles: mouse)
F-87-0102-24	Hs27 (singles: human foreskin fibroblasts)
F-92-0102-24	Super E-Mix (mixed cells: A549 and BGMK with hDAF)
F-96-0102-24	R-Mix (mixed cells: A549 and Mv1Lu)
F-97-0102-24	R-Mix Too (mixed cells: A549 and MDCK)

Intended Use: ReadyCells® are frozen cultured cell monolayers intended for virus and/or Chlamydia isolation and to aid in the diagnosis of diseases associated with infectious agents. ReadyCells culture media products are for *in vitro* diagnostic use.

Components: Frozen Shell-Vials (<1 mL each)

Section 2 – Hazards Identification

Emergency Overview

Significant health effects are not anticipated from routine use of these ReadyCells, 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.

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

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
ReadyCells	Dimethyl Sulfoxide	67-68-5	200-664-3	7.5	<1 mL

Mixtures

- No ingredients are hazardous according to OSHA criteria.
- There are no hazardous chemicals contained within this product at concentrations that are considered hazardous to personal health and/or the environment.

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.). Decontaminate with suitable disinfectants, such as household chlorine bleach (dilution 1:10) or 70% ethyl or isopropyl alcohol.
<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 cells.

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	ReadyCells
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

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

Characteristic	ReadyCells
pH	No data available
Solubility in Water	No data available
Appearance and Odor	Clear, aqueous liquid; odorless

Section 10 – Stability and Reactivity

Characteristic	ReadyCells
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 inhalation or dermal exposure data available for the ReadyCells components.

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.

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.

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

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:
 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.

State Regulations

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Dimethyl Sulfoxide	67-68-5	No	Yes	No	Yes	No	No

California Prop 65:

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Canadian Regulations

Chemical Name	CAS #	Minimum Concentration
Dimethyl Sulfoxide	67-68-5	1%

Additional Regulatory Information

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

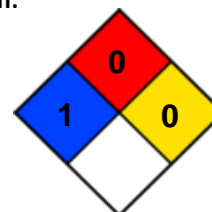
Not completed for the components contained within this kit.

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

HMIS Kit Classification:



NFPA Kit Classification:



Section 16 – Other Information

PREPARED BY: Quidel Corporation
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SUPERCEDES: July 13, 2010

REVISIONS: GHS update and rebranding.

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.