

Section 1 – Product and Company Identification

1.1 Manufacturer Information

Quidel Corporation	Phone:	1-800-874-1517	Web:	<u>quidel.com</u>
2005 East State Street, Suite 100	Fax:	1-740-592-9820	E-mail:	<u>qehs@quidel.com</u>
Athens, OH 45701	Emergency (24-Hour):	1-866-519-4752		

1.2 Product Information

Product Name: Virus and Chlamydia Control Stocks

Product Name: Virus and Chlamydia Training Panels

Catalog #	Control Stock Product Name	Catalog #	Training Panel Product Name
20-4510130	Echovirus	02-125012	D ³ FastPoint [™] L-DFA [™] Respiratory Virus
20-4420010	Coxsackie virus type B	02-431024	Chlamydia
20-4310010	Chlamydia trachomatis	02-440020	Enterovirus
20-4600010	Varicella-zoster virus	02-461024	Herpes simplex, Varicella-zoster, Cytomegalovirus
20-4700010	Respiratory viruses, seven major*, mixed	02-477020	Respiratory viruses
20-4710010	Influenza A virus	02-478020	Metapneumovirus
20-4720010	Influenza B virus	02-491024	Cytomegalovirus
20-4730010	Respiratory Syncytial virus	02-480024.v2	Herpes simplex
20-4740010	Adenovirus	01-013105.	2000 H1N1 Influenze A Visus Demonstration
20-4750010	Parainfluenza virus type 1	2009H1.P	2009 H1N1 Influenza A Virus Demonstration
20-4760010	Parainfluenza virus type 2		
20-4770010	Parainfluenza virus type 3		
20-4780010	Human Metapneumovirus		
20-4810020	Herpes simplex virus type 1		
20-4820020	Herpes simplex virus type 2		
20-4900010	Cytomegalovirus		

*(influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, parainfluenza virus types 1, 2 and 3)

Intended Use: Frozen viral and chlamydial isolates for use as cell culture controls. For *in vitro* diagnostic use only.

Components: 400 µL vials

Section 2 – Hazard Identification

2.1 Classification of the Substance of Mixture

Not a hazardous substance or mixture. Not a hazardous substance or mixture.

- 2.2 GHS Label Elements, including Precautionary Statements
- 2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS
 - Contains potentially hazardous live viruses and *Chlamydia* from clinical isolates. Product may include one or more of the following: *echovirus, coxsackie virus type B, Chlamydia trachomatis, varicella-zoster virus, influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, parainfluenza virus (types 1, 2, 0r 3), human metapneumovirus, <i>Herpes simplex virus (type 1 or 2), cytomegalovirus.* Follow Universal Precautions when working with these stocks and panels.
 - The Control Stocks and Training Panels contain various antimicrobials including, but not limited to Penicillin G, Streptomycin sulfate, gentamicin, and Amphotericin B. These antimicrobials may exhibit sensitization or toxicity characteristics at low concentrations.
 - Cyclohexamide may cause harm to the unborn child. Possible risk of irreversible effects. Toxic to aquatic organisms.



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

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

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, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising from the Substance or 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

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of the components contained within this kit is unlikely.

6.1	Personal Precautions	Avoid breathing vapors, mist or gas.
6.2	Environmental Precautions	Contain spill to prevent migration to drains, sewers or open water sources.
		Discharge to the environment must be avoided.
6.3	Methods and Materials for Clean-Up	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.
6.4	Recovery and Neutralization	Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.



Section 7 – Handling and Storage

7.1 Specific Use

For professional 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 control stocks ON YOU or IN YOU. Wash exposed areas thoroughly after using the control stocks. Do not eat or drink while using the control stocks. The control stocks should be handled only by qualified clinical or laboratory employees trained on the use of these controls stocks and who are familiar with the potential hazards. **Universal Precautions should be followed when handling and working with these control stocks and training panels.** Keep out of reach of the general public.

7.3 Conditions for Safe Storage (including any incompatibilities)

To maintain efficacy, store according to the package insert instructions.

7.4 Incompatibilities

To maintain efficacy, store according to the package insert instructions.

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits

No data available for the Virus and Chlamydia Control Stocks or Panels.

8.2	Exposure Controls
	Engineering Measures

	Engineering Measures	Use with adequate ventilation.
	Personal Protective Equipment	
	Respiratory Protection	None needed under normal conditions of use.
	Skin Protection	Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.
	Eye Protection	Wear safety glasses with side shields or goggles to prevent eye contact.
	Body Protection	Use body protection appropriate for the task. A laboratory coat is recommended.
	Hygiene Measures	Wash hands before use, 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	Virus and Chlamydia Control Stocks	Virus and Chlamydia Training Panels
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ 0 = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
рН	Neutral Neutral	
Solubility in Water	Soluble suspension	Soluble suspension
Appearance and Odor	Clear, aqueous liquid; cherry-peach to red- orange in color; odorless	Clear, aqueous liquid; cherry-peach to red-orange in color; odorless



Section 10 – Stability and Reactivity

Characteristic	Virus and Chlamydia Control Stocks	Virus and Chlamydia Training Panels
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	No data available	No data available
Materials to Avoid	No data available	No data available
Hazardous Decomposition Products	No data available	No data available

Section 11 – Toxicological Properties

11.1 Information on Toxico	ological Effects				
Acute Toxicity		No data a	vailable		
Skin Corrosion / Irritat	tion	No data a	vailable		
Respiratory or Skin Se	ensitization	No data a	vailable		
Generative Cell Mutag	genicity	No data a	vailable		
Carcinogenicity			as probable, poss		t levels greater than or equal to 0.1% is onfirmed human carcinogen by the ACGIH,
Reproductive Toxicity		No data a	vailable		
Teratogenicity		No data a	vailable		
Specified Target Organ	n Toxicity				
Single Exposure:	No data available	Rep	peated Exposure:	No data a	available
Aspiration Hazard	No data available				
Potential Health Effect	ts				
Inhalation:	May cause respira	tory tract i	irritation.	Skin:	May cause skin irritation upon contact.
Ingestion:	May be harmful if	swallowed	ł.	Eyes:	May cause eye irritation.

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 the components within this kit.

11.3 Additional Information

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

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 kit. Do not discharge any of the control stocks 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.

Cultures or other materials exposed to the control stocks should be autoclaved at 121°C for 20 minutes prior to disposal.

Section 14 – Transporation Information

14.1 U.S Department of Transportation (DOT)

UN3373, Biological Substance Category B, 6.2, PG III (49 CFR 173.199)

14.2 International Air Transportation Association (IATA)

UN3373, Biological Substance Category B, 6.2, PG III (49 CFR 173.199)

14.3 Canada

Requires "Permit to import human pathogen(s)"; both PHA (Public Health Agency) and CIFA (Canadian Food Inspection Agency) import permits are required for each shipment; and appropriate UN numbers as referenced in above DOT detail.

14.4 ROW (other Regions of the World)

An importation and/or exportation permit may be required. Due diligence of local regulations and permits must be confirmed; and appropriate UN shipping requirements met where necessary.

**This material typically shipped on dry ice. Adhere to applicable regulatory requirements.

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards	None
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.
SARA311/312 Hazards	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
	-	-	-	-	-	-	-

<u>California Prop 65</u>: **WARNING!** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Cycloheximide (<0.1%)	CAS #: 66-81-9	Revision Date: 2007-09-28
Streptomycin Sulfate (<0.1%)	CAS #: 3810-74-0	Revision Date: 2007-09-28

15.3 Canadian – WHMIS Ingredient Disclosure List

Chemical Name	CAS #	Minimum Concentration	





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 comp	Not completed for the components contained				
HMIS Kit Classification:		NFPA Kit Classification:					
Health Hazard:	1	Health Hazard (blue):	1				
Chronic Health Hazard: *		Fire Hazard (red):	0				
Flammability:	0	Reactivity (yellow):	0				
Physical Hazard:	0	Special Hazards (white):	None				

*Use additional care when handling these control stocks.

Section 16 – Other Information

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

PREPARED BY: Quidel Corporation 12544 High Bluff Drive, Suite 200 San Diego, CA 92130 SUPERSEDES: v2014JUN04

REVISIONS: Change to format of SDS.

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