

**Section 1 – Product and Company Identification**
**1.1 Manufacturer Information**

Quidel Corporation	Phone:	1.800.874.1517	Web:	<a href="http://quidel.com">quidel.com</a>
2005 East State Street, Suite 100	Fax:	1.740.592.9820	E-mail:	<a href="mailto:gehs@quidel.com">gehs@quidel.com</a>
Athens, OH 45701	Emergency (24-Hour):	1.866.519.4752		

**1.2 Product Information**

Product Name: Molecular Controls

Quidel Molecular Product	Catalog No.	Control Components	Volume (mL)
Influenza A+B Controls	M106	Influenza A+B Positive Control (M5029) Negative Control (M5031)	2.0 2.0
RSV + hMPV Controls	M107	RSV + hMPV Positive Control (M5030) Negative Control (M5031)	2.0 2.0
Clostridium difficile Controls	M108	Clostridium difficile Positive Control (M5040) Negative Control (M5031)	2.0 2.0
HSV 1+2 Controls	M109	HSV-1 Positive Control (M5108) HSV-2 Positive Control (M5109) Negative Control (M5110)	1.0 1.0 1.0
Adenovirus Controls	M110	Adenovirus Positive Control (M5059) Negative Control (M5031)	2.0 2.0
Strep A+G Controls	M111	Group A+G Streptococcus Positive Control (M5062) Negative Control (M5086)	0.5 0.5
Parainfluenza Virus Controls	M115	Parainfluenza Positive Control (M5069) Negative Control (M5031)	2.0 2.0
GBS Controls	M116	Group B Streptococcus Positive Control (M5081) Negative Controls (M5236)	1.0 2.0
Bordetella Controls	M117	Bordetella Positive Control (M5100) Negative Control (M5183)	2.0 2.0
Solana HSV 1+2 / VZV Controls	M118	HSV 1+2 / VZV Positive Control (M5202) Negative Control (M5203)	1.0 1.0
Trichomonas Controls	M119	Trichomonas vaginalis Positive Controls (M5138) Negative Control (M5031)	2.0 2.0
HSV 1+2 / VZV Controls	M121	HSV 1+2 / VZV Positive Control (M5047) Negative Control (M5135)	1.0 1.0
Solana Influenza A+B Controls	M122	Influenza A+B Positive Control (M5126) Negative Control (M5203)	1.0 1.0
Solana RSV + hMPV Controls	M123	RSV + hMPV Positive Control (M5131) Negative Control (M5203)	1.0 1.0

Intended Use: Molecular control sets are intended to be used as full process controls in molecular testing.

**Section 2 – Hazard Identification**

- 2.1 Classification of the Substance of Mixture** Not a hazardous substance or mixture.
- 2.2 GHS Label Elements, including Precautionary Statements** Not a hazardous substance or mixture.
- 2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS**
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Sodium azide used as a preservative in the positive and negative controls (<0.1%).

**Section 3 – Composition / Information on Ingredients**

- 3.1 Mixtures**
- Positive Control 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.
- Negative Control 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 (do not swallow). 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.

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| <b>6.1 Personal Precautions</b>               | Avoid breathing vapors, mist or gas.   |
| <b>6.2 Environmental Precautions</b>          | Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.                        |
| <b>6.3 Methods and Materials for Clean-Up</b> | 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. |
| <b>6.4 Recovery and Neutralization</b>        | 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

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| <b>7.1 Specific Use</b>  | Refer to product specific package insert. Not for use by the general public.   |
| <b>7.2 Precautions for Safe Handling</b>                                 | 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. Keep out of reach of the general public.  |
| <b>7.3 Universal Precautions</b>   | No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in the 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. |
| <b>7.4 Conditions for Safe Storage (including any incompatibilities)</b> | To maintain efficacy, store according to the package insert instructions.  |
| <b>7.5 Incompatibilities</b>   | To maintain efficacy, store according to the package insert instructions.  |

### Section 8 – Exposure Controls and Personal Protection

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| <b>8.1 Exposure Limits</b>                 | No data available for the components within this kit.   |
| <b>8.2 Exposure Controls</b>               |   |
| Engineering Measures                       | Use with adequate ventilation.  |
| Personal Protective Equipment              |   |
| <i>Respiratory Protection</i>              | None needed under normal conditions of use.   |
| <i>Skin Protection</i>                     | 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. |
| <i>Eye Protection</i>                      | Wear safety glasses with side shields or goggles to prevent eye contact.  |
| <i>Body Protection</i>                     | Use body protection appropriate for the task. A laboratory coat is recommended.   |
| <i>Hygiene Measures</i>                    | Wash hands before use, after use and at the end of the workday.   |
| <b>8.3 Environmental Exposure Controls</b> | No special environmental controls are required.   |
| <b>8.4 Special Notes</b>                   | No data available.  |

**Section 9 – Physical and Chemical Properties**

Characteristic	Positive Controls	Negative Controls
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H <sub>2</sub> O = 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
pH	Neutral	Neutral
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Clear liquid, mild odor

**Section 10 – Stability and Reactivity**

Characteristic	Positive Controls	Negative Controls
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 Toxicological Effects**

Acute Toxicity	No data available	
Skin Corrosion / Irritation	No data available	
Respiratory or Skin Sensitization	No data available	
Generative Cell Mutagenicity	No data available	
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 ACGIH, IARC, NTP or OSHA.	
Reproductive Toxicity	No data available	
Teratogenicity	No data available	
Specified Target Organ Toxicity		
<u>Single Exposure:</u>	No data available	<u>Repeated Exposure:</u> No data available
Aspiration Hazard	No data available	
Potential Health Effects		
<i>Inhalation:</i>	May cause respiratory tract irritation.	<i>Skin:</i> May cause skin irritation upon contact.
<i>Ingestion:</i>	May be harmful if swallowed.	<i>Eyes:</i> May cause eye irritation.

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

**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**

Liver – Irregularities – Based on human evidence (sodium azide)

### 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.

### 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 solutions, reagents or controls 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 Association (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

None

SARA 302

The following chemicals are subject to reporting levels established by Sara Title III, Section 302:

Sodium Azide

CAS #: 26628-22-8

Revision Date: 2007-07-01

SARA 313

The following chemicals are subject to reporting levels established by SARA Title III, Section 313:

Sodium Azide

CAS #: 26628-22-8

Revision Date: 2007-07-01

SARA311/312 Hazards

Sodium Azide

CAS #: 26628-22-8

Acute Health Hazard, Chronic Health Hazard

**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
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes	Yes

**Section 15 – Regulatory Information (cont'd)**

California Prop 65: This kit does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**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**

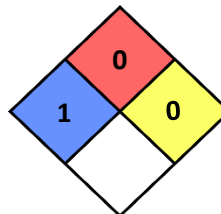
European Union – Regulation (EC) 1907/2006.

**Chemical Safety Assessment**

Not completed for the components contained within this kit.

**NFPA Kit Classification:**

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


**Section 16 – Other Information**

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**SUPERSEDES:** July 27, 2017

**REVISIONS:** Section 1.2, updated GBS Controls number for the Negative Control; Section 7, added Universal Precautions statement; Section 15, updated to WHMIS Classification reference, removed HMIS Classification, added NFPA 704 Placard; Section 16, removed general statement; general text and format changes throughout.

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SD1005002EN00 (10/18)