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: AmpliVue Bordetella Assay (Catalog #: M209)
Intended Use: The AmpliVue Bordetella Assay is a qualitative in vitro diagnostic test for the detection and identification of *Bordetella pertussis* and *Bordetella parapertussis* from nasopharyngeal swabs.
Components: Kit is composed of individually pouched Detection Cassettes (1185001), Process Buffer (M5087), Reaction Tubes (M5107), Amplicon Cartridge (1215400)

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 Process Buffer (<0.1%).

3.1 Mixtures
Not a hazardous mixture according to Regulation (EC) No. 1272/2008.
Reaction Tube: 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.

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 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 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.

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 components within this kit.

8.2 Exposure Controls
Engineering Measures
Use with adequate ventilation.

Personal Protective Equipment
Respiratory 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.

Skin Protection
Section 8 – Exposure Controls and Personal Protection (cont’d)

**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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Process Buffer</th>
<th>Reaction Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.0-7.6</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear liquid, mild odor</td>
<td>White pellet, odorless</td>
</tr>
</tbody>
</table>

Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Process Buffer</th>
<th>Reaction Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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
Section 11 – Toxicological Properties (cont’d)

Specified Target Organ Toxicity

Single Exposure: No data available  Repeated Exposure: No data available

Aspiration Hazard: No data available

Potential Health Effects

Inhalation: May cause respiratory tract irritation.
Ingestion: May be harmful if swallowed.

Skin: May cause skin irritation upon contact.
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

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 311/312 Hazards: Sodium Azide  CAS #: 26628-22-8  Acute Health Hazard, Chronic Health Hazard.
## Section 15 – Regulatory Information (cont’d)

### 15.2 State Regulations

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**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 Ingredient Disclosure List

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

### 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 this kit.*

## 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:** April 7, 2014

**REVISIONS:** Change to format of SDS.

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