SECTION 1 – Kit / Preparation and Company Identification

1.1 **QUICKVUE RSV 10** *(For In Vitro diagnostic use only)*

1.2 The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection.

1.3 **Manufacturer:** Quidel Corporation – 10165 McKellar Court – San Diego, CA 92121
   **Telephone No.:** 1-858-552-1100 **Toll Free No.:** 1-800-874-1517 **Fax No.:** 1-858-453-4338

1.4 **Emergency No.:** Poison Control @ 1-800-222-1222 (USA only)

SECTION 2 – Composition / Ingredients Information

2.1 **Description of Components:** Test strips, Reagent Solution, Reagent Tubes, Disposable Pipettes, Sterile Nasopharyngeal Swabs, RSV Positive Control Swab and Negative Control Swab.

2.2 **Hazardous Ingredients:** Dangerous solid or liquid substances present in >1% (or as required by applicable U.S., Canadian and E.U. regulations):

<table>
<thead>
<tr>
<th>CAS#</th>
<th>EINECS</th>
<th>Chemical Name</th>
<th>Kit Component</th>
<th>% Weight</th>
<th>Classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>US OSHA</td>
</tr>
</tbody>
</table>

No hazardous substances greater than 1% are contained within this kit.

** See Section 15 and Section 16 – Regulatory Information for additional information on hazard classifications.

SECTION 3 – Hazard Identification

**Emergency Overview:** As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical components within this kit and ensure prompt removal from skin, eyes, and clothing.

3.1 This kit may contain material of human and/or animal origin and should be considered as potentially capable of transmitting infectious diseases.

3.2 All patient samples, contaminated components, and fluids should be handled as potentially infectious. Follow **Universal Precautions** as necessary.

3.3 **Warning Properties:** Not available

SECTION 4 – First Aid Measures

**Special Instructions:**

4.1 **Inhalation** Inhalation of any component in this kit is unlikely.
4.2 **Eye Contact**
If components of this kit enter the eyes and cause discomfort, gently wash eyes under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

4.3 **Skin Contact**
If components of this kit contact the skin and cause discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

4.4 **Ingestion**
If a component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

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**SECTION 5 – Fire Fighting Measures**

5.1 **Extinguishing Media:** For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.

5.2 **Special Fire Fighting Procedures:** This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 **Unusual Fire and Explosion Hazards:** When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide).

   - Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

5.4 **Additional Considerations:**

5.4.1 Flash Point: Non-combustible
5.4.2 Auto-ignition Temperature: Not available
5.4.3 Upper / Lower Explosion Limit: Not available

5.5 **NFPA Ratings (see ‘Definition of Terms’ for explanation of numerical ratings):**

**Only trained and competent personnel shall attempt to extinguish a fire. Contact emergency response personnel as required. Be cautious of surrounding materials that may react with the extinguishing media.**

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**SECTION 6 – Accidental Release Measures**

6.1 **Personal Precautions:** This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures involving patient samples.

6.2 **Environmental Precautions:** No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Contain spill to prevent migration.

6.3 **Spill and Leak Procedures:** Large spills of this kit are unlikely. Utilize safety glasses, nitrile gloves, and lab coat/apron when responding to spills involving the components of this kit.
SECTION 7 – Handling and Storage

7.1 Handling: As with all chemicals, avoid getting 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. This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit. Not for use by the general public.

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

7.3 Specific Use: For in vitro diagnostic use only – Not for use by general public!

SECTION 8 – Exposure Control and Personal Protection

8.1 Exposure Limits: Not available

8.2 Occupational Exposure Controls:

8.2.1 Engineering Controls:
No special engineering controls are required when working with this kit. Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

8.2.2 Personal Protective Equipment (PPE):

Respiratory Protection: None needed under normal conditions of use.

Eye Contact: Safety glasses or face shield are recommended to prevent eye contact.

Hand Contact: Impervious gloves (nitrile or equivalent) should be worn to prevent hand contact.

Skin Contact: Lab Coat or similar garment should be worn.

8.2.3 Environmental Controls: No special environmental controls are required.

SECTION 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control Swabs (+/-)</th>
<th>Reagent Tube</th>
<th>Reagent Solution (Saline Solution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Density (AIR = 1)</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>pH:</td>
<td>Not available</td>
<td>Not available</td>
<td>Neutral</td>
</tr>
</tbody>
</table>
QUICKVUE® RSV 10 TEST

Solubility in Water:  
Soluble  
Soluble  
Soluble

Appearance and Odor:  
Small white swabs; odorless  
White lyophilized pellet buffer with detergents; odorless  
Clear, Odorless

SECTION 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control Swabs (+/-)</th>
<th>Reagent Tube</th>
<th>Reagent Solution (Saline Solution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Incompatible materials</td>
<td>Incompatible materials</td>
<td>Incompatible materials</td>
</tr>
<tr>
<td>Materials to avoid (Incompatibilities)</td>
<td>None known</td>
<td>None known</td>
<td>None known</td>
</tr>
<tr>
<td>Hazardous Decomposition or Byproducts</td>
<td>Thermal decomposition may release toxic fumes of CO and CO₂</td>
<td>Thermal decomposition may release toxic fumes of CO and CO₂</td>
<td>Thermal decomposition may release toxic fumes of CO and CO₂</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Has not been reported</td>
<td>Has not been reported</td>
<td>Has not been reported</td>
</tr>
</tbody>
</table>

SECTION 11 – Toxicological Information

11.1 Toxicity Data for Hazardous Ingredients:
There are currently no toxicity data available for the components contained within this kit.

11.2 Primary Routes of Exposure:
Overexposures to components within this kit are not expected. Common routes of exposure may include ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with eyes, contact with mucous membranes and inhalation of aerosolized material.

11.3 Potential Effects of Acute Overexposure, By Route Of Exposure:
This kit contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

INHALATION:  Vapors, mists, sprays, or dusts of this kit may cause irritation to the respiratory tract.

CONTACT WITH SKIN or EYES:  Contact may cause eye or skin irritation.

SKIN ABSORPTION:  Skin absorption unlikely for intact skin.

INGESTION:  If components of this kit are swallowed, irritation of the mouth, throat, and other tissues of the gastro-intestinal system may occur.

INJECTION:  Accidental injection with components of this kit is highly unlikely. In the rare event an injection occurs, the puncture point may experience burning, reddening, and swelling.
11.4 Potential Effects of Chronic Exposure:
Long-term skin or eye contact may result in dermatitis or eye irritation.

11.5 Symptoms of Overexposure:
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for this kit.

11.6 Medical Exposure Aggravated by Exposure:
Persons with pre-existing skin disorders; eye problems or impaired respiratory system function can be more susceptible to health effects associated with overexposures to components within this kit.

11.7 Carcinogenicity:
To the best of our knowledge, this kit does not contain any substances that are listed by ACGIH, IARC, NTP or California Prop 65.

SECTION 12 – Ecological Information

12.1 Ecotoxicity – Not Available
No adverse effects on the environment are expected from the components of this kit. There is no aquatic toxicity data for this kit at this time.

12.2 Mobility
Mobility data are not available for the components of this kit.

12.3 Persistence and Degradability
There is no persistence or degradation data for any component of this kit at this time.

12.4 Bioaccumulative Potential
There is limited potential for the components within this kit to accumulate in plant or animal systems.

SECTION 13 – Disposal Considerations
Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU, etc.), federal

SECTION 14 – Transport Information

14.1 U.S. Transportation, Canadian Transportation, and International Air Transportation
This kit is not regulated for transport.

SECTION 15 – Regulatory Information

15.1 U.S. Federal and State Regulations

<table>
<thead>
<tr>
<th>Code</th>
<th>QuickVue RSV 10 Test Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 CFR 355.30/355.40 - SECTION 302</td>
<td>Not Listed</td>
</tr>
<tr>
<td>40 CFR 302.4 – SECTION 304</td>
<td>Not Listed</td>
</tr>
<tr>
<td>40 CFR 372.65 – SECTION 313</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>
QUICKVUE® RSV 10 TEST

U.S. SARA SECTION 311/312 FOR KIT: Not applicable
U.S. TSCA INVENTORY STATUS: Not applicable
OTHER U.S. FEDERAL REGULATIONS: Not applicable
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROP 65): None
CALIFORNIA - 8 CCR SECTION 339 – DIRECTOR’S LIST OF HAZARDOUS SUBSTANCES: None

15.2 Label Information – ANSI Z129.1: Not applicable

ENVIRONMENTAL HAZARDS:
Do not discharge effluent containing components of this kit into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. For guidance, contact your State Water Board or Regional Office of the EPA.

15.3 Canadian Regulations:

CANADIAN DSL/NDSL INVENTORY STATUS:
The components of this kit are not listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS:
Not applicable

15.4 HMIS Ratings (See ‘Definition of Terms' for explanation of numerical ratings):

QuickVue RSV 10 Test Kit

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Health</td>
<td>0</td>
</tr>
<tr>
<td>Flammability</td>
<td>0</td>
</tr>
<tr>
<td>Physical Hazard</td>
<td>0</td>
</tr>
<tr>
<td>Protective Equipment</td>
<td>B</td>
</tr>
</tbody>
</table>

15.5 EU Labeling Classification:
Not applicable

15.6 Japan – Existing and New Chemical Substances (ENCS): None

SECTION 16 – Other Information

This MSDS has been prepared in accordance with ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US 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.

The hazard ratings on this MSDS are for appropriately trained workers using the Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 Program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks (Refer to Definitions of Terms at the end of this MSDS). Chronic (long-term) health effects are indicated in the HMIS by an asterisk (*). HMIS is a registered trade and service mark of the NPCA. For details on HMIS ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.
PREPARED BY:  Quidel Corporation  
10165 McKellar Court  
San Diego, CA 92121  
1-800-874-1517  

SUPERCEDES:  September 20, 2010  

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.
HAZARD RATINGS:

POSITIVE HAZARDS:

Chemical/Physical Hazards:

S

Safety and Health, which is the research arm of the U.S.

OSHA - U.S. Occupational Safety and Health Administration

PEL - Permissible Exposure Limit - This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, “Vacated 1989 PEL,” is placed next to the PEL that was vacated by Court Order.

IDLH - Immediately Dangerous to Life and Health - This level represents a concentration from which one can escape within 30 minutes without suffering escape-preventing or permanent injury. The DFG - MAK is the Republic of Germany’s Maximum Exposure Level, similar to the U.S. PEL. NIOSH is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). NIOSH issues exposure guidelines called Recommended Exposure Levels (RELs). When no exposure guidelines are established, an entry of NE is made for reference. Protective Equipment – A: Safety Glasses. B: Safety glasses and gloves. C: Safety glasses, gloves and body protection. D: Splash goggles with face shield, goggles and body protection. E: Eye protection, goggles and dust mask respiratory protection. F: Eye protection, goggles, body protection and dust mask respiratory protection. G: Eye protection, gloves and air purifying respiratory protection.

FLAMMABILITY LIMITS IN AIR: Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). Flash Point - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in the absence of any other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: LCLo - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; LC50 - Lethal Concentration (gases) which kills 50% of the exposed animals; ppm concentration expressed in parts of material per million parts of air or water; mg/kg quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include TDL0, the lowest dose to cause a symptom; and TCL0 the lowest concentration to cause a symptom; TDo, LDLo, LDo, TC, TC0, LCLo, and LCo, the lowest dose (or concentration) to cause lethal or toxic effects. BEI - Biological Exposure Indices, represent the levels of determinants that are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV. Ecological Information: EC is the effect concentration in water.

Data from several sources are used to evaluate the cancer-causing potential of the material. The sources and ratings are: IARC - the International Agency for Research on Cancer; 1 = Carcinogenic to humans, 2A, 2B = Probably carcinogenic to humans, 3 = Unclassifiable as to carcinogenicity in humans, and 4 = Probably not carcinogenic to humans. NTP - the National Toxicology Program; K =Known to be a human carcinogen, and R = Reasonably anticipated to be a human carcinogen. RTECS - the Registry of Toxic Effects of Chemical Substances. OSHA - Occupational Safety and Health Administration and CAL/OSHA - California’s subunit of the Occupational Safety and Health Administration; Ca = Carcinogen defined with no further categorization. ACGIH – American Conference of Governmental Industrial Hygienists; A1 = Confirmed human carcinogen, A2 = Suspected human carcinogen, A3 = Confirmed animal carcinogen with unknown relevance to humans, A4 = Not classifiable as a human carcinogen, and A5 = Not suspected as a human carcinogen. NIOSH – U.S. National Institute for Occupational Safety and Health; Ca = Potential occupational carcinogen, with no further categorization. EPA – U.S. Environmental Protection Agency; A = Human carcinogen, B = Probable human carcinogen, C = Possible human carcinogen, D = Not classifiable as to human carcinogenicity, E = Evidence of Non-carcinogenicity for humans, K = Known human carcinogen, L = Likely to produce cancer in humans, CBD = Cannot be determined, NL = Not likely to be carcinogenic in humans, and I = Data are inadequate for an assessment of human carcinogenic potential.

REGULATORY INFORMATION:

This section explains the impact of various laws and regulations on the material. EPA is the U.S. Environmental Protection Agency. WHMIS is the Canadian Workplace Hazards Materials Information System. DOT and TC are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Non-Domestic Substances List (DSL/NDSSL); the U.S. Toxic Substance Control Act (TSCA); Marine Pollutant status according to the DOT; the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations. This section also includes information on the precautionary warnings that appear on a material’s industrial package label.