SECTION 1 – Kit / Preparation and Company Identification

1.1 **QUICKVUE RSV TEST**  
For in-vitro diagnostic use only

1.2 The QuickVue RSV test is intended for use as an aid in the rapid diagnosis of acute respiratory syncytial viral infections.

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 @ 1-800-876-4766 (United States only)

SECTION 2 – Composition / Ingredients Information

2.1 **Description of Components:** Test strips, Extraction Reagent with detergents, Extraction Tubes, Disposable Droppers, Nasopharyngeal Swabs, Positive RSV 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): The classifications listed below are based on the 0.2% sodium azide concentration.

<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>26628-22-8</td>
<td>247-852-1</td>
<td>Sodium Azide</td>
<td>RSV Extraction Reagent</td>
<td>0.2%</td>
<td>Irritant</td>
</tr>
</tbody>
</table>


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 Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the Package Insert provided with the kit.

3.2 Contact with the RSV Extraction Reagent to the eyes and/or skin may cause slight irritation upon prolonged exposure. Avoid prolonged contact with any chemical component within this kit.

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

3.4 All patient samples should be handled as potentially infectious. Follow **Universal Precautions** as necessary.

3.5 **Warning Properties:** None
SECTION 4 – First Aid Measures

Special Instructions: No special measures are required.

4.1 **Inhalation**

Inhalation of any component in this kit is unlikely.

4.2 **Eye Contact**

Extraction Reagent may cause slight irritation upon contact. In case of contact with eyes, immediately wash eyes under potable running water for at least 15 minutes, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

4.3 **Skin Contact**

RSV Extraction Reagent may cause slight irritation upon contact. Remove any contaminated clothing and wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

4.4 **Ingestion**

If RSV Extraction Reagent is swallowed, wash mouth out with water provided person is conscious. If irritation or discomfort occurs, obtain medical attention.

SECTION 5 – Fire Fighting Measures

5.1 **Flammable Properties:** RSV Extraction Reagent is non-flammable.

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

5.3 **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.

5.4 **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.

5.5 **Additional Considerations (Extraction Reagent):**

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash Point</td>
<td>Non Combustible</td>
</tr>
<tr>
<td>Auto-ignition Temperature</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper / Lower Explosion Limit</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

5.6 **NFPA Ratings (see Section 16 for definitions of numerical ratings):**

RSV Extraction Reagent

**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.**
SECTION 6 – Accidental Release Measures

6.1 Personal Precautions: Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with the RSV Extraction Reagent. Wash hands thoroughly after handling the components within this kit or patient samples. This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions when performing the test and during the clean-up process.

6.2 Environmental Precautions: This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters the drain, flush with a large volume of water to prevent azide build-up. Contain spills to prevent migration to industrial or sanitary sewer drains.

6.3 Spill and Leak Procedures: Large spills of this kit are unlikely. Personnel who have received basic chemical safety training can generally handle small-scale releases, such as 1 container of this kit. Utilize safety glasses, nitrile gloves, and lab coat/apron when responding to spills involving the components of this kit. Absorb liquid and place in container suitable for disposal. Dispose of in accordance with applicable U.S. Federal, State, or local procedures or appropriate standards of Canada or the EU (see Section 13, Disposal Considerations).

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: Keep away from incompatible materials (Section 10). To maintain efficacy, store according to the package insert instructions.

7.3 Specific Use: For in-vitro diagnostic use only

SECTION 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits: There are no ACGIH, NIOSH, OSHA or country specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

8.2 Occupational Exposure Controls:

8.2.1 Engineering Controls: The RSV Extraction Reagent is aqueous and non-volatile and is not expected to necessitate special ventilation measures. Facilities storing or utilizing this reagent should be equipped with an eyewash fountain and a safety shower.

8.2.2 Personal Protective Equipment (PPE):

   - **Respiratory:** 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 long sleeved garment should be worn to prevent exposure to skin and contamination of clothing.
SECTION 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RSV Extraction Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>Not Available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Approximately 1</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Density (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>pH:</td>
<td>Neutral</td>
</tr>
<tr>
<td>Solubility in Water:</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor:</td>
<td>Clear, Odorless</td>
</tr>
</tbody>
</table>

SECTION 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RSV Extraction Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Incompatible materials</td>
</tr>
<tr>
<td>Materials to avoid (Incompatibilities)</td>
<td>None Known</td>
</tr>
<tr>
<td>Hazardous Decomposition or Byproducts</td>
<td>Nature of decomposition of products not known</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur</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 of this kit; the following toxicology information is available for raw materials present in greater than 1% concentration.

**RSV Extraction Reagent:**

When used and handled according to specifications, this product does not have any harmful effects according to our experience. The substance is not subject to classification.

11.2 **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 mucous membranes and inhalation of aerosolized material.

11.3 **Potential Effects of Acute Overexposure, By Route Of Exposure:**

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

**INHALATION:** No irritating effect known

**CONTACT WITH SKIN or EYES:** No irritating effect known

**SKIN ABSORPTION:** No irritating effect known

**INGESTION:** No irritating effect known

**INJECTION:** No irritating effect known
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:**
Symptoms of overexposure to the RSV Extraction Reagent may include general eye, skin, nose, and throat irritation.

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

11.7 **Carcinogenicity:** None of the components present in the RSV Extraction Reagent preparation at concentrations equal to or greater than 0.1% are listed by IARC, ACGIH, NTP, OSHA or California Prop 65.

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### SECTION 12 – Ecological Information

12.1 **Ecotoxicity – Not Available**
No adverse effects on the environment are expected from the components of this kit.

12.2 **Mobility, Persistence and Degradability**
Mobility, persistence and degradation data are not available for the components of this kit.

12.3 **Bioaccumulative Potential**
There is limited potential for the components within this kit to accumulate in plant or animal systems. The ecological effects have not been thoroughly investigated, but currently none have been identified.

### SECTION 13 – Disposal Considerations

Dispose of waste materials, unused components and contaminated packaging in compliance with country (i.e., Canada, EU) federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information. This product is not considered a RCRA hazardous waste.

**RCRA P-Series:** P105, Sodium Azide
**RCRA U-Series:** None listed

### SECTION 14 – Transport Information

14.1 **U.S. Transportation**
This product is regulated per 49 CFR 172.101, the U.S. department of transportation:

- Proper Shipping Name: None
- Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

14.2 **Canadian Transportation**
The above-listed DOT basic description applies to this product under the regulations of Transport Canada.
14.3 International Air Transportation

This product is regulated per International Air Transportation Association (IATA) Dangerous Goods Regulations:

<table>
<thead>
<tr>
<th>Proper Shipping Name:</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hazardous for Transport:</td>
<td>This substance is considered to be non-hazardous for air transport.</td>
</tr>
</tbody>
</table>

SECTION 15 – Regulatory Information

15.1 U.S. Federal and State Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

<table>
<thead>
<tr>
<th>Regulatory Reference</th>
<th>RSV Extraction Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 CFR 355.30/355.40 - SECTION 302</td>
<td>Not applicable</td>
</tr>
<tr>
<td>40 CFR 302.4 – SECTION 304</td>
<td>Not applicable</td>
</tr>
<tr>
<td>40 CFR 372.65 – SECTION 313</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

U.S. SARA SECTION 311/312 FOR KIT: Acute health effects; chronic health effects.

U.S. TSCA INVENTORY STATUS: The components of this kit are listed on the TSCA Inventory.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No

15.2 Label Information

ANSI 129.1 CAUTION: Harmful if swallowed, eye and skin irritant. Do not swallow or take internally. Do not get into eyes, on skin, or on clothing.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing 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. Do not discharge effluent containing this kit to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

15.3 Canadian Regulations:

CANADIAN DSL/NDSL INVENTORY STATUS: Sodium Azide is listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS: None Required

15.4 HMIS Ratings (See Page 8 for Definition of Ratings):

<table>
<thead>
<tr>
<th>RSV Extraction Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
</tr>
<tr>
<td>Flammability</td>
</tr>
<tr>
<td>Physical Hazard</td>
</tr>
<tr>
<td>Protective Equipment</td>
</tr>
</tbody>
</table>

B: Safety glasses and gloves

Reference Only
### 15.5 EU Labeling Classification:

**RSV Extraction Reagent (0.2% Sodium Azide)**

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Risk Phrases:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xn Harmful</td>
<td>R25: Toxic if swallowed</td>
</tr>
<tr>
<td></td>
<td>R32: Contact with acids liberates very toxic gas</td>
</tr>
<tr>
<td></td>
<td>R52: Harmful to aquatic organisms</td>
</tr>
</tbody>
</table>

**Safety Phrases:**

- S23: Do not breathe vapor
- S24/25: Avoid contact with skin and eyes.
- S29/35: Do not empty into drains; dispose of this material and its container in a safe way.

***EU Classification, Risk Phrases and Safety Phrases are based on the chemical characteristics for Sodium Azide. The RSV Extraction Reagent is not classified as a hazardous material.***

### SECTION 16 – Other Information

**PREPARED BY:** Quidel Corporation  
10165 McKellar Court  
San Diego, CA 92121  
1-800-874-1517

**DATE OF PRINTING** September 21, 2006

Quidel Corporation provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this kit by a properly trained person using this kit. Quidel Corporation shall not be held liable for any damage resulting from handling or use.
A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

**CAS #:** This is the Chemical Abstract Service Number that uniquely identifies each compound.

**ACGIH** - American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits.

**TLV** - Threshold Limit Value - an airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers can be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour Time Weighted Average (TWA), the 15-minute Short Term Exposure Limit, and the instantaneous Ceiling Level (C). Skin absorption effects must also be considered.

**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.

**Hazard Ratings:**

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM:** Health Hazard: 0 (minimal acute or chronic exposure hazard); 1 (slight acute or chronic exposure hazard); 2 (moderate acute or significant chronic exposure hazard); 3 (severe acute exposure hazard; onet ime overexposure can cause permanent injury and can be fatal); 4 (extreme acute exposure hazard; onetime overexposure can be fatal). * Indicates chronic hazard. Flammability Hazard: 0 (minimal); 1 (materials that require substantial pre-heating before burning); 2 (combustible liquid or solids; liquids with a flash point of 38-93°C [100-200°F]); 3 (Class IB and IC flammable liquids with flash points below 38°C [100°F]); 4 (Class IA flammable liquids with flash points below 23°C [73°F] and boiling points below 38°C[100°F]). Reactivity (Phyiscal) Hazard: 0 (normally stable); 1 (material that can become unstable at elevated temperatures or which can react slightly with water); 2 (materials that are unstable but do not detonate or which can react violently with water); 3 (materials that can detonate when initiated or which can react explosively with water); 4 (materials that can detonate at normal temperatures or pressures).

**National Fire Protection Association:** Health Hazard: 0 (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); 1 (materials that on exposure under fire conditions could cause irritation or minor residual injury); 2 (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); 3 (materials that can on short exposure could cause serious temporary or residual injury); 4 (materials that under very short exposure could cause death or major residual injury). Flammability Hazard: 0 (nonflammable); 1 (flammable); 2 (combustible); 3 (inflammable); 4 (ignitable). Reactivity Hazard: Refer to definitions for "Hazardous Materials Identification System".

**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 air with no 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: LD₅₀ - 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 per million of parts per air or water; mg/m³ concentration expressed in weight of substance per volume of air; mg/kg quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include TL, the lowest dose to cause a symptom and TCL, the lowest concentration to cause a symptom; TDo, LD₅₀, LD₀, TC, TC₅₀, LC₅₀, and LC₀, 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. **RTCECS** - 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 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 Hazardous 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.