

Catalog No.: 20193 / 20199

Reference No.: K061008

Revision Date: February 16, 2010

SECTION 1 – Kit / Preparation and Company Identification

1.1 QUICKVUE RSV TEST

For in-vitro diagnostic use only

1.2 The QuickVue RSV (Respiratory Syncytial Virus) Test is a dipstick immunoassay that allows the capture and visual detection of RSV Antigen (viral fusion protein).

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, 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):

CAS#	EINECS	Chemical Name	Kit Component	% Weight	Classification:			
					US OSHA	WHMIS	EU	Risk Phrases
26628-22-8	247-852-1	Sodium Azide	RSV Extraction Reagent	0.2%	Irritant	N/A	Xn	R25, R32, R52

The RSV Extraction Reagent preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; or the Canadian Hazardous Products Act, R.S. 1985, c. H-3. The classifications listed below are based on the 0.2% sodium azide concentration.

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 Mechanical Impact: Not sensitive under normal conditions.

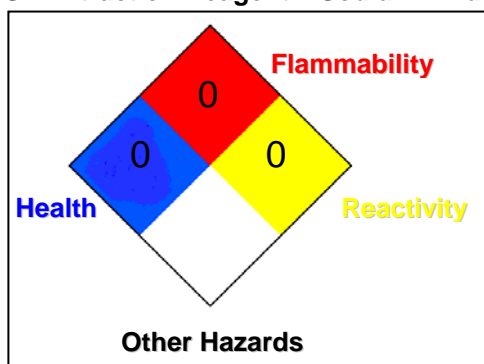
Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

5.5 Additional Considerations (Extraction Reagent):

- 5.5.1 Flash Point Non Combustible
- 5.5.2 Auto-ignition Temperature Not Applicable
- 5.5.3 Upper / Lower Explosion Limit Not Applicable

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

RSV Extraction Reagent – Sodium Azide 0.2%



*** 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:** This kit contains materials of biological origin. Avoid personal contact. Use Universal Precautions during clean-up procedures. Wash hands thoroughly after handling the components within this kit.
- 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 the RSV Extraction Reagent. 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.

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.
- 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 – Not for use by the general public!*

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 the 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.

8.2.3 Wash hands thoroughly after handling components of this kit.

8.2.4 Environmental Controls: No special environmental controls are required.

SECTION 9 – Physical and Chemical Properties

Characteristic	RSV Extraction Reagent (Sodium Azide 0.2%)
Boiling Point (°C)	Not Available
Melting Point (°C)	Not available
Specific Gravity	Approximately 1
Vapor Pressure (mm Hg)	Not available
Vapor Density (AIR = 1)	Not available
Evaporation Rate (Ether = 1)	< 1
pH:	Neutral
Solubility in Water:	Soluble
Appearance and Odor:	Clear, Odorless

SECTION 10 – Stability and Reactivity

Characteristic	RSV Extraction Reagent (Sodium Azide 0.2%)
Stability	Stable
Conditions to Avoid	Incompatible materials
Materials to avoid (Incompatibilities)	None Known
Hazardous Decomposition or Byproducts	Nature of decomposition of products not known
Hazardous Polymerization	Will not occur

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 – Sodium Azide 0.2% (RTECS#: VY8050000)

When used and handled according to specifications, this component 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: Vapors, mists, sprays or dusts from components within this kit may cause irritation to the respiratory tract.

CONTACT WITH SKIN or EYES:

Contact may cause eye or skin irritation.

SKIN ABSORPTION:

General irritation at area of contact may occur.

INGESTION:

Irritation of the mouth, throat and other tissues of the gastrointestinal system may occur if components within this kit are swallowed.

INJECTION:

Accidental injection from components within this kit may cause burning, reddening and swelling in addition to the wound. Injection from any component within this kit is highly unlikely.

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 (Sodium Azide 0.2%) may include general eye, skin, nose, and throat irritation. Symptoms may be delayed for several hours after exposure.

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.

CHEMICAL NAME	ACGIH	IARC	NTP	OSHA
Sodium Azide	No	None	No	No

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 or the individual components at this time.

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.

NOTE: The ecological effects have not been thoroughly investigated for this kit or the individual components.

Label Information:

ANSI Z129.1	RSV Extraction Reagent (Sodium Azide 0.2%)	Kit Package
Labeling:	CAUTION: Harmful if swallowed. Eye and skin irritant.	CAUTION: Kit components may be harmful if swallowed, inhaled, or absorbed through skin. Components may be eye and skin irritants.
Label Precautions:	Do not swallow or take internally. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling.	Do not swallow or take internally. Do not get in eyes, on skin, or on clothing. This kit contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases. Follow package insert instructions for use.

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.

15.2 Canadian Regulations:

CANADIAN DSL/NDL 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):


RSV Extraction Reagent – Sodium Azide 0.2%

Health	1 *
Flammability	0
Physical Hazard	0
Protective Equipment	B

B: Safety glasses and gloves

15.5 EU Labeling Classification:

RSV Extraction Reagent – Sodium Azide 0.2%

<p>Classification:</p> <p>Xn  Harmful</p>	<p>Risk Phrases:</p> <p>R25: Toxic if swallowed R32: Contact with acids liberates very toxic gas R52: Harmful to aquatic organisms</p> <p>Safety Phrases:</p> <p>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.</p>
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***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.

15.6 Japan: Existing and New Chemical Substances (ENCS): Sodium Azide 26628-22-8 1-482

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.

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SUPERCEDES: September 20, 2006

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.

DEFINITIONS OF TERMS

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. **Protective Equipment** – **A:** Safety Glasses. **B:** Safety glasses and gloves. **C:** Safety glasses, gloves and body protection. **D:** Splash goggles with face shield, gloves and body protection. **E:** Eye protection, gloves and dust mask respiratory protection. **F:** Eye protection, gloves, body protection and dust mask respiratory protection. **G:** Eye protection, gloves and air purifying respiratory protection.

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; onetime overexposure can cause permanent injury and can be fatal); **4** (extreme acute exposure hazard; single overexposure can be fatal). * Indicates chronic hazard. Flammability Hazard: **0** (minimal hazard); **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 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 and 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 of material per million parts of 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 **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, **LDo**, **TC**, **TCo**, **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 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/NDL**); 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.