

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: QuickVue+® Strep A Test (Catalog #: 20122)

 Intended Use: The QuickVue+ Strep A test is intended for the rapid detection of Group A Streptococcal antigen from throat swabs or beta-hemolytic colonies recovered from culture. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection. This kit is for *in vitro* diagnostic use only.

Components: Kit is composed of individually pouched test cassettes, Extraction Reagent A (Sodium Nitrite), Extraction Reagent B (Acetic Acid), sterile rayon-tipped throat swabs, plastic tubes and tips, positive control (heat inactivated Group A Streptococcus) and negative control (heat inactivated Group C Streptococcus).

Section 2 – Hazards Identification

 The hazards associated with this kit are related to the **Extraction Reagent A** that contains 4M Sodium Nitrite (27.6%) and **Extraction Reagent B** that contains 0.2M Acetic Acid (1.2%).

Emergency Overview

Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this SDS and the kit specific Package Insert. The Extraction Reagents within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008/EC.

OSHA Hazards	Target Organs	GHS Classification
Oxidizer, Target Organ Effect, Toxic by Ingestion, Irritant	Blood, cardiovascular system, smooth muscle	Oxidizing liquids (Category 3) Acute Toxicity, Oral (Category 4) Eye Irritation (Category 2A) Acute Aquatic Toxicity (Category 2)

GHS Label Elements & Precautionary Statements

Component	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Extraction Reagent A		Warning	H302 Harmful if swallowed. H319 Causes serious eye irritation. H401 Toxic to aquatic life.	P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements			Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Extraction Reagents

Component	Chemical Name	CAS #	EINECS #	Index #	Concentration (%)	Component Volume (mL)
Extraction Reagent A	Sodium Nitrite	7632-00-0	231-555-9	007-010-00-4	27.6	15
Extraction Reagent B	Acetic Acid	64-19-7	200-580-7	607-002-00-6	1.2	15

Section 4 – First Aid Measures

General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance.

- 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:* Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice.

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.

Indication of any immediate medical attention and special treatment needed

No data available

Section 5 – Fire Fighting Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

- Suitable Extinguishing Media:* For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available.
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the Extraction Reagents contained within this kit are unlikely.

- Personal Precautions (e.g., PPE):* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the Extraction Reagents. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from spill area.
- Recovery and Neutralization:* Collect spilled material and place in a sealed container for disposal.
- Materials and Methods for Clean-Up:* Thoroughly wash the area with soap and water after a spill or release clean-up.
- Environmental Precautions:* Contain spill to prevent migration to public industrial / sanitary sewers or open water sources.

Section 7 – Handling and Storage

Specific Use: For *in vitro* diagnostic use only – Not for use by general public.

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 using this kit.

Conditions for Safe Storage: To maintain efficacy, store according to the package insert instructions. Keep out of reach of the general public.

Incompatibilities None.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits:

Chemical Name	CAS #	Exposure Limits (US)	Exposure Limits (EU)	Exposure Limits (EU)
Acetic Acid	64-19-7	ACGIH: 10 ppm TWA 15 ppm STEL	Austria: 10 ppm STEL 5 ppm MAK	Ireland: 10 PPM STEL 5 ppm TWA
		OSHA: 10 ppm TWA	Belgium: 10 ppm STEL 5 ppm TWA	Italy: 5 ppm TWA
		NIOSH: 10 ppm TWA 15 ppm STEL	Denmark: 5 ppm Ceiling Finland: 5 ppm STEL France: 5 ppm VLCT Germany: 2 ppm TWA 2 ppm MAK 4 ppm Peak	Netherlands: 15 mg/m ³ STEL 8 mg/m ³ TWA
			Spain: 10 ppm VLA-EC 5 ppm VLA-EC	
				Sweden: 5 ppm CLV
				Greece: 5 ppm STEL/TWA
				Exposure Limits (Japan)
				JSOH: 10 ppm OEL
Sodium Nitrite	7632-00-0	None Established	None Established	None Established

**** Refer to OSHA IMIS Code Number S236 for general information on the monitoring methods used by OSHA for Sodium Nitrite.**

**** When mixing Extraction Reagent A and Extraction Reagent B, the initial chemical reaction will create Nitrogen Dioxide and Nitric Oxide as reaction products.**

Exposure Controls

Engineering Measures

Use with adequate ventilation to maintain worker exposure below limits listed above.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Section 8 – Exposure Controls and Personal Protection (continued)

- Hand 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.
- Eye Protection:** Wear safety glasses with side shields or goggles to prevent eye contact.
- Skin and Body Protection:** Use body protection appropriate for the task. A laboratory coat is recommended.
- Hygiene Measures:** Handle in accordance with good industrial hygiene and safety practice. Wash hands before and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required

Section 9 – Physical and Chemical Properties

	Extraction Reagent A	Extraction Reagent B
Characteristic	Sodium Nitrite Solution (27.6%)	Acetic Acid Ampoule (1.2%)
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ 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	8.6	2.4
Solubility in Water	Soluble	Soluble
Appearance and Odor	Yellow with no odor	Clean with vinegar like odor

Section 10 – Stability and Reactivity

	Extraction Reagent A	Extraction Reagent B
Characteristic	Sodium Nitrite Solution (27.6%)	Acetic Acid Ampoule (1.2%)
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	None	None
Materials to Avoid	None	None
Hazardous Decomposition Products	No data available	No data available

Section 11 – Toxicological Information

Acute Toxicity

Component Analysis – LD50 / LC50

Chemical Name	CAS #	RTECS #	Information
Sodium Nitrite	7632-00-0	RA1225000	Inhalation LC50 Rat = 5.5 mg/L 4 hr Oral LD50 Rat = 85 mg/kg
Acetic Acid	64-19-7	AF1225000	Inhalation LC50 Rat = 11.4 mg/L 4 hr Oral LD50 Rat = 3310 mg/kg Dermal LD50 Rabbit = 1060 mg/kg

Potential Health Effects

<i>Skin Corrosion/ Irritation:</i>	No data available	<i>Inhalation:</i>	No data available
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Ingestion:</i>	No data available
<i>Respiratory Organ or</i>			
<i>Skin Sensitization:</i>	No data available		
<i>Generative Cell Mutagenicity:</i>	No data available		

Carcinogenicity

The chemicals in the Extraction Reagents are not listed as carcinogens by any of the following: ACGIH, IARC, NTP or OSHA.

Reproductive Toxicity

No data available

Specified Target Organ General Toxicity

Single Exposure No data available **Repeated Exposure** No data available

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Section 12 – Ecological Information

Toxicity	No data available	Mobility in Soil	No data available
Persistence / Degradability	No data available	Other adverse effects	Toxic to aquatic life
Bioaccumulation	No data available		
PBT and vPvB Assessment	No data available		

Section 13 – Disposal Considerations

Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the Extraction Reagents into drains, water courses or onto the ground.

Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country (e.g., Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable regulatory requirements, contact the authorities for information.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)

Not regulated as a hazardous material.

Canadian Transportation

Not regulated as a hazardous material.

International Air Transportation

Not regulated as a dangerous good.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

The Extraction Reagents contain one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Sodium Nitrite (7632-00-0)

SARA 313: 1.0% de minimis concentration

CERCLA: 100 lb. final RQ; 45.4 kg final RQ

Acetic Acid (64-19-7)

CERCLA: 5000 lb. final RQ; 2270 kg final RQ

State Regulations

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

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Sodium Nitrite	7632-00-0	Yes	Yes	No	Yes	Yes	No
Acetic Acid	64-19-7	Yes	Yes	Yes	Yes	Yes	Yes

*** The components contained within this kit do not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.*

Canadian - WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Sodium Nitrite	7632-00-0	1%
Acetic Acid	64-19-7	1%

Additional Regulatory Information
Safety, Health and Environmental regulations/legislation specific for the mixture

No data available

Chemical Safety Assessment

No data available

European Directive 67/548/EEC as amended

Danger Symbol	Risk Phrases	Safety Phrases
Extraction Reagent A (15 mL) Sodium Nitrite (27.6%)  T Toxic	R25: Toxic if swallowed. R50: Very toxic to aquatic organisms.	S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45: In case of accident or if you feel unwell, seek medical advice immediately S61: Avoid release to the environment. Refer to special instructions/safety data sheets.
 N Environmentally Dangerous		

Section 16 – Other Information

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SUPERCEDES: June 6, 2012

REVISIONS: New branding and brand format; addition of GHS specific hazard pictograms.

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Key / Legend

ACGIH = American Conference of Governmental Industrial Hygienists	NFPA = National Fire Protection Association
BAT = Biological Tolerance Values (Germany)	NIOSH = National Institute of Occupational Safety and Health
CAS# = Chemical Abstract Service Number	NOHSC = National Occupational Health & Safety Commission
CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)	NTP = National Toxicology Program
CLV = Ceiling Limit Value (Sweden)	OEL = Occupational Exposure Limit
DOT = Department of Transportation	OSHA = Occupational Safety and Health Administration
DSL = Domestic Substances List	PEL = Permissible Exposure Limit
EEC = European Economic Community	PPE = Personal Protective Equipment
EINECS = European Inventory of Existing Commercial Chemical Substances	RTECS = Registry of Toxic Effects of Chemical Substances
ELINCS = European List of Notified Chemical Substances	SARA = Superfund Amendments and Reauthorization Act
EPA = Environmental Protection Agency	STEL = Short-term Exposure Limit
EU = European Union	STV = Short Term Value (Sweden)
GHS = Globally Harmonized System	TDG = Transportation of Dangerous Goods
HMIS = Hazardous Materials Identification System	TLV = Threshold Limit Value
IARC = International Agency for Research on Cancer	TSCA = Toxic Substances Control Act
IMO = International Maritime Organization	TWA = Time Weighted Average
IATA = International Air Transport Association	VLA-EC = Valor Límite Ambiental Exposición de Corta Duración (Spain): The limit for short-term exposure concentration
LLV = Level Limit Value (Sweden)	VLA-ED = Valor Límite Ambiental Exposición Diaria (Spain): The limit for the daily average concentration
MAK = Maximum Concentration Value in the Workplace	VLCT = VALEUR LIMITE D EXPOSITION A COURT TERME (Limit Value Exposure is Short Term (France)
NDSL = Non-Domestic Substances List	

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