

SAFETY DATA SHEET

ECO: 454282

Revision Date: 04/28/2015

Rev. 0

SECTION 1. ----- PRODUCT IDENTIFICATION -----

Biokit/Inova Diagnostics, Inc.
9900 Old Grove Road
San Diego, CA 92131 U.S.A.
General information telephone number: 1-858-586-9900
Emergency telephone numbers
National (USA, Canada): 1-800-424-9300
International: 1-703-527-3887

CATALOG #: **23-038004**NAME: **Sure-Vue™ Rubella 100 Tests**

USE: The Sure-Vue Rubella reagent is a suspension of polystyrene latex particles of uniform size coated with soluble rubella virus antigen from disrupted virus. Latex particles allow visual observation of the antigen-antibody reaction. When a serum containing rubella virus antibodies is mixed with the latex reagent, the uniform appearance of the latex suspension will convert to a visible agglutination.

SECTION 2. ----- HAZARDS IDENTIFICATION -----

Emergency Overview

OSHA Hazards

No known OSHA hazards

Other hazards which do not result in classification

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

GHS Classification

N/A

GHS Label elements, including precautionary statements

Pictogram: None

Signal word: None

Hazard Statements

None

Precautionary statements

None

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through the skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: May be harmful if swallowed.

Target Organs: None identified.

Human Source Material: Treat as potentially infectious.

Serum used in the preparation of this product has been tested by FDA approved methods and found non-reactive for the presence of Hepatitis B surface antigen (HBsAg), antibody to human immunodeficiency virus (HIV) and Hepatitis C virus (HCV). No known test method can offer complete assurance that Hepatitis B virus, HIV, HCV, or other infectious agents are absent. Handle these controls and all patient samples at Biosafety Level 2 as recommended in the Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention/National Institutes of Health, Fifth Edition, 2007.

NOTE: Physical and health hazard information for this component has not been determined. Any physical and health information noted is based on evaluation of data for pure ingredients and concentration of ingredients as packaged.

NFPA: HEALTH = 0, FIRE = 0, REACTIVITY = 0

HMIS: HEALTH = 0, FLAMMABILITY = 0, PHYSICAL HAZARDS = 0

SECTION 3. ----- COMPOSITION/INFORMATION ON INGREDIENTS -----

No ingredients are hazardous according to OSHA criteria

Component:

1 x 1.6mL Latex reagent. Suspension of polystyrene latex particles coated with soluble rubella virus antigen from disrupted virus in a buffer. Contains 0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.

1 x 1mL High positive control. Human serum diluted to a titer of 1:160. Contains 0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.

1 x 1mL Low positive control. Human serum diluted to a titer of 1:10. Contains 0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.

1 x 1mL Negative control. Diluted non-immune human serum. Contains 0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.

1 x 35mL Diluent buffer. Phosphate buffered saline (PBS <20% Dipotassium hydrogenorthophosphate) CAS# 7758-11-4, EINECS# 231-834-5, pH 7.2, containing bovine serum albumin. Contains 0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.

120 plastic stirrers

8 ea, 15-section disposable slides

Contains 0.1% total weight of Sodium Azide (NaN₃) as a preservative, CAS# 26628-22-8, EINECS# 247-852-1

Phosphate Buffered Saline (PBS <20% Dipotassium hydrogenorthophosphate), CAS# 7758-11-4, EINECS# 231-834-5

SECTION 4. ----- FIRST-AID MEASURES -----

Eye: Rinse immediately with plenty of clean running water for at least 20 minutes, separating the eyelids.

Skin Contact: Wash off thoroughly with plenty of clean running water. Remove and wash contaminated clothing.

Ingestion: Obtain medical attention.

Inhalation: Remove from exposure. If breathing is difficult, obtain medical attention.

IN CASE OF ACCIDENT OR IF YOU DO NOT FEEL WELL, IMMEDIATELY SEEK MEDICAL ADVICE.

SECTION 5. ----- FIRE FIGHTING MEASURES -----

Non-flammable preparation.

Extinguishing media: Use media in adaption to materials stored in the immediate neighborhood, such as dry chemical.

Special firefighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ----- ACCIDENTAL RELEASE MEASURES -----

After spillage: Wipe up spills with inert absorbent materials and place them in a suitable container. Use personal protective equipment (PPE), such as gloves, safety glasses/goggles to prevent exposure.

SECTION 7. ----- HANDLING AND STORAGE -----

Handling: Normal precautions for handling chemicals must be observed. Wash affected area after handling.

Storage: Keep containers tightly closed when not in use. Store in a dry, well ventilated storage area (2-8°C). Protect from physical damage.

SECTION 8. ----- EXPOSURE CONTROLS/PERSONAL PROTECTION -----

Contains no substances with occupational exposure limit values.

Respiratory protection: Where risk assessment shows air purifying respirators are appropriate use a full face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a back up to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Eye protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Skin and body protection: Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

Recommend the use of safety pipette device.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Latex Reagent: transparent liquid with suspended white particles

High Positive Control: transparent liquid

Low Positive Control: transparent liquid

Negative Control: transparent liquid

Diluent Buffer: transparent liquid

Odor: Solutions are odorless

Boiling point: N/A

Melting point: 275°C (527°F) decomposes

Flash point: N/A

Ignition temperature: N/A

Explosion limits: N/A

Vapor pressure: N/A

Density: N/A

Viscosity: N/A

Solubility in water: Solutions are soluble, 400mg/mL

Specific Gravity: 1.8 (water = 1.0)

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Polymerization: Will not occur.

Conditions and materials to avoid:

- Avoid contact with metals and acids
- Explodes when heated
- May be shock sensitive

Incompatibles

- Acid chlorides
- Nitrogen oxides
- Azide reacts with many heavy metals such as lead, copper, mercury, silver and gold to form explosive compounds. Copper and lead azides are more sensitive than nitroglycerin. Azide reacts with metal halides to give a range of metal azide halides, many of which are explosive. Incompatible with chromyl chloride, hydrazine, bromine, carbon disulfide, dimethyl sulfate, dibromomalonitrile.

Hazardous reactions: N/A

Hazardous decomposition products: Toxic fumes of Nitrogen Oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral LD50

No data available

Inhalation LC50

No data available

Dermal LD50

No data available

Other information on acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity**IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as known or anticipated carcinogen by NTP.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

No data available

Teratogenicity

No data available

Specific target organ toxicity – single exposure (Globally Harmonized System)

No data available

Specific target organ toxicity – repeated exposure (Globally Harmonized System)

No data available

Aspiration hazard

No data available

Potential health effects**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion

May be harmful if swallowed.

Skin

May be harmful if absorbed by the skin. May cause skin irritation.

Eyes

May cause eye irritation.

Signs and Symptoms of Exposure

No data available

Synergistic effects

No data available

Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been fully investigated.

RTECS: Not available

SECTION 12. ----- ECOLOGICAL INFORMATION -----**Toxicity**

No data available.

Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

PBT and vPvB Assessment

No data available.

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Toxic to aquatic life.

SECTION 13. DISPOSAL CONSIDERATIONS

Observe all Governmental environmental regulations for waste disposal. Chemical waste generators must determine if a discarded chemical is classified as a hazardous waste. Contact a licensed professional waste disposal service for disposal of unused product.

Some reagents in this kit contain Sodium Azide as a preservative. Sodium Azide has been reported to form lead or Copper Azide in laboratory plumbing which may explode on percussion. Use proper disposal procedures.

Product

Offer surplus and non-recyclable solutions to a licensed company.

Contaminated packaging

Disposed of as an unused product.

Remains of biological samples, reagents and controls should be collected in a suitable container for this purpose and autoclaved for 1 hour at 121°C.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

SECTION 14. TRANSPORT INFORMATION**DOT (US)**

Not dangerous goods.

IMDG

Not dangerous goods

IATA

Not dangerous goods.

SECTION 15. REGULATORY INFORMATION

According to 1999/45/EC Directive and 91/155/EEC Directive and following modifications.

OSHA Hazards

No known OSHA hazards.

TSCA Status

Not on TSCA Inventory.

DSL Status

Not on the Canadian DSL nor NDSL lists.

SARA 302 Components

The following components are subject to the reporting requirements of SARA Title III, Section 302.

Sodium azide, CAS# 26628-22-8, EINECS# 247-852-1

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

Sodium azide, CAS# 26628-22-8, EINECS# 247-852-1

Pennsylvania Right To Know Components

Water, CAS# 7732-18-5, EINECS# 231-791-2

Sodium azide, CAS# 26628-22-8, EINECS# 247-852-1

New Jersey Right To Know Components

Water, CAS# 7732-18-5, EINECS# 231-791-2

California Prop. 65 Components

This product does not contain any chemicals that are at a concentration known to State of California to cause cancer, birth, or any other reproductive defects.

SECTION 16. ----- OTHER INFORMATION -----

Each donor unit used in the preparation of the controls of this kit was tested by an approved method for the presence of the antibodies to HIV and HCV as well as for HBsAg and found to be negative.

WARNING: Because no test method can offer complete assurance that HIV, HCV, HBsAg or other infectious agents are absent, the controls of this kit should be handled carefully using Universal Precautions.

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