S A F E T Y D A T A S H E E T

ECO: 454283
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 #: **23-038017**
NAME: **Sure-Vue™ Color Mono 50 Tests**
USE: The Sure-Vue Color Mono reagent is a suspension of specially treated horse red blood cells. Added coloration of the suspension facilitates the recognition of positive and negative reactions. The serum or plasma being tested is mixed on a test slide with the reagent. The appearance of dark agglutinates against a blue-green background indicates the presence of IM. If no heterophile antibodies are present, the horse cells remain unagglutinated against a green-brown background.

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 1.4 mL Color-Mono Reagent. Color-enhanced treated horse red blood cell suspension. Contains <0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.
1 x 1.0 mL Positive control. Diluted positive human serum. Contains <0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.
1 x 1.0 mL Negative control. Non-reactive diluted human serum. Contains <0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1.
2 x 9 Disposable slides
Contains less than (<) 0.1% total weight of Sodium Azide (NaN_3) as a preservative, CAS# 26628-22-8, EINECS# 247-852-1

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:
Color-Mono Reagent: transparent liquid
Positive Control: transparent liquid
Negative Control: 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 121ºC.
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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