

SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name:	HIV-2 Positive Sample
Product Number:	26247 (100 µL)
Intended Use:	This HIV-2 reactive sample is intended for use as a tool in evaluating assays that detect HIV-2. This product is for research use only and is not intended for use in diagnostic procedures.
Manufactured by:	Bio-Rad Laboratories, Inc.
Address:	6565 185th Avenue NE, USA Redmond, WA 98052-5039
Website:	www.bio-rad.com
Phone Number:	1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)
SDS e-mail contact:	ro-sds@bio-rad.com
Technical Information Contacts:	Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2-BIORAD (1-800-224-6723). <i>Outside the U.S.A., please contact your regional Bio-Rad office for assistance.</i>
Emergency Phone Number:	This SDS is listed with CHEMTREC 1-800-424-9300 (US) / 001-703-527-3887 (international – can be called collect). Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below and for the Key / legend to abbreviations and acronyms.

Component*	Contents
HIV-2 Positive Sample 1 vial (100 µL)	<ul style="list-style-type: none"> - Heat-treated human serum/plasma containing HIV-2 immunoglobulin, non-reactive for HBsAg and antibodies to HCV. - Preserved with 0.1% sodium azide [NaN₃], EC No 247-852-1 and CAS# 26628-22-8. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration. - Preserved with 0.01% thimerosal [C₉H₉HgNaO₂S], EC No 200-210-4, CAS# 54-64-8. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. (< 0.1%). Requires hazardous waste disposal (US RCRA D009) - P501].

Markings according to the *United Nations (UN) Globally Harmonized System (GHS)*, *United States Hazard Communication Standard (US HCS)*, *European Community (EC) 2008/1272/EC (EC CLP) guidelines* and analogous **GHS-based global regulations:**

This product has been conservatively classified and labeled in accordance with *United Nations (UN) GHS*, *United States Hazard Communication Standard (US HCS)*, related *European Community (EC) 2008/1272/EC (EC CLP) guidelines* and applicable analogous GHS-based global regulations.

0.01% thimerosal [C₉H₉HgNaO₂S], CAS#54-64-8, EC No 200-210-4 (dilution < 0.1%).

Comprehensive GHS Based Classification: Health Hazard Not Otherwise Classified

Label(s): No hazard labeling required (due to dilution).

Signal Word: No signal word required (due to dilution).

Label Hazard Statement: No hazard statement is required (due to dilution).

Precautionary Statements (statements for product intended use and as codified on the product label):

P501 This material and its container must be disposed of as hazardous waste.

Supplemental Precautionary Statements (additional precautions to consider relative to specific customer use):

- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves / protective clothing / eye protection / face protection.
- P312 Call a POISON CENTER or doctor/physician if you feel unwell.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

NOTE: 0.1% Sodium Azide concentration falls under the UN GHS Cat 5 Acute Toxic which is not recognized in much of the world. [Acute toxic Cat. 5 rating would be: Warning; H303, H313; P312].

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data for the chemical raw material (LD₅₀, exposure limits, etc.) Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient Data/Information* box. The UN GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the existing editions and expanded upon from company and literature data. Refer to section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded below, for the list of sources utilized in the assessment and for the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **0.1% w/v**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

- CAS#: 26628-22-8 (100%) LD₅₀ (oral-rat): 27 mg/kg
- EC No: 247-852-1 (100%) LC₅₀ (inhalation-rat): 37 mg/m³
- Index No: 011-004-00-7 (100%) LD₅₀ (skin-rat): 50 mg/kg (100%)
- RTECS#: VY8050000 (100%) Fish LC₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h
- Chemical Formula: NaN₃ (100%)
- Molecular weight: 65.01g/mol (100%)
- Synonyms/Trade Names: Azide, sodium; Azoture de sodium; Azydek sodu; NSC 3072; Kazoe; Natriumazid; Natriummazide; NCI-C06462; Nemazyd; Sodium azide; Sodium, azoture de; Sodium, azoturo di, Smite; U-3886;

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!

- Acute Tox. – oral. Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1
- H300 + H310, H410
- P264, P273, P280, P302 + P350, P310, P501



[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient Data / Information

Chemical Ingredient: Thimerosal

Chemical concentrations found in this product: **0.01% w/v**

Data for chemical used in the product (concentration tested):

CAS#: 54-64-8 (Thimerosal powder, 100%) LD₅₀ (oral-rat): 75 mg/kg
 EC No: 200-210-4 (100%) LC₅₀ (inhalation-rat): NE
 Index No: 080-004-00-7 (100%) LD₅₀ (skin-rabbit): NE
 RTECS#: OV8400000 (100%) + LC₅₀ (96 hr-fish): Oncorhynchus mykiss (rainbow trout) – 21.2 mg/l
 Serious eye damage/eye irritation: Eyes - rabbit - Mild eye irritation
 Respiratory or skin sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.
 Chemical Formula: C₉H₉HgNaO₂S (100%)
 Molecular weight: 404.81 g/mol (100%)
 Synonyms/Trade Names: Merthiolate Sodium, Sodium o-(ethylmercurithio)benzoate ; Ethylmercurithiosalicylic acid, sodium salt
 CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity.

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!


Acute Tox. – inh. Cat. 1, Acute Tox. – skn. Cat. 1, Acute Tox. – oral. Cat. 2, Eye Irrit. Cat. 2B,
 Aquatic Acute Cat. 1, Skin Sens. Cat. 1, Rep. Tox. Cat. 1B

H300 + H310, H317, H361, H320, H330, H400

P260, P264, P273, P280, P284, P302 + P350, P305 + P351 + P338,
 P308 + P313, P310, P501



[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Biological Ingredient	Data / Information
<p>Human Serum, HIV-2 Reactive</p> 	<p>The reactive human serum in this product was heat-treated to inactivate the HIV and all human sera in it were tested and found non-reactive for HBsAg and antibodies to HCV (and HIV if not inactivated). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ <i>Standard</i> and <i>Universal Precautions</i> when handling these reagents and all human blood, specimens or patient samples. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> or WHO <i>Laboratory Biosafety Manual</i>. Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Persons handling blood samples should have the option of receiving hepatitis B vaccination. Employ decontamination procedures, with appropriate decon agent/disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.), before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard</i> and <i>Universal Precautions</i>. Persons handling blood samples should have the option of receiving hepatitis B vaccination.</p>

NA: Not Applicable.
 NE: Not Established or Unknown (unable to locate data).

Related product information:

- Refer to Section 16 for the full text of any Comprehensive GHS-based Classification statements coded above.
- Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.

- According to the concept of *Universal Precautions* (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain an infectious agent. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. The thimerosal-containing components may be toxic to developing fetus, generally at concentrations and volumes that greatly exceed that of this kit. May cause damage to organs through prolonged or repeated exposure. May be harmful if swallowed. May be harmful in contact with skin.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant hazard in the kit volumes and concentrations present.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), <i>Universal Precautions</i> apply. Persons handling human blood samples should be offered hepatitis B vaccination prior to working with human source material.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	May release toxic oxides of carbon, nitrogen or mercury.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- ◆ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
- ◆ In the event of a hazardous material spill, contain the spill if it is safe to do so; immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. **IF ON SKIN (or hair):** Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that suitable spill cleanup materials and PPE are available and used.
- ◆ Prevent material from entering sewers, waterways or confined spaces.

- ◆ Follow established laboratory policy and/or appropriate CDC/NIH biosafety, and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible:
 - Decontaminate Biohazard/Human source material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent/disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.). *Note that the Thimerosal preserved human source biologicals must be decontaminated prior to hazardous chemical waste disposal.*
 - Absorb thimerosal-containing reagents, handle and dispose of as RCRA hazardous waste.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows and absorbent pads, etc.) which is secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious and chemical laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- ◆ Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	<p>This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards.</p> <p>Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Avoid splashing, spills and the generation of aerosols.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.</p> <p>Handle all human source specimens, materials, and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard</i> and <i>Universal Precautions</i>.</p> <p>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.</p> <p>Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course.</p> <p>Consult with your Environmental Health & Safety Office for assistance.</p>
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Storage: Store according to product and label instructions (generally at 2-8°C).

Caution, consult accompanying documents. Read and follow all the precautions and warnings in the kit product instructions (. Refer to the *Instructions For Use / Product Package Insert* for additional product information.

This HIV-2 reactive sample is intended for use as a tool in evaluating assays that detect HIV-2. This product is for research use only and is not intended for use in diagnostic procedures.

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – Component chemicals with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
AUSTRALIA:	CL	0.11 ppm (0.3 mg/m ³)	JUL2008
AUSTRIA:	MAK-TMW KZW	0.1 mg/m ³ 0.3 mg/m ³ , skin	2007
BELGIUM:	TWA STEL	0.1 mg/m ³ , 0.3 mg/m ³ , skin	MAR2002
DENMARK:	TWA	0.1 mg/m ³ , skin	MAY2011

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
EC (European Union):	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	JUN2000
FINLAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	NOV2011
FRANCE:	VME VLE	0.1 mg/m ³ 0.3 mg/m ³ , Skin	FEB2006
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
HUNGARY:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³	SEP2000
ICELAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	NOV2011
ITALY	TWA	<i>Valore a breve termine: C 0,29 mg/m³, C 0,11* ppm A4; sodio azide; *come azido idrazonico, vapore</i>	
KOREA:	CL	0.1 ppm (0.3 mg/m ³)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m ³ , skin	2003
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m ³)	JAN2002
PERU:	TWA STEL	0.1 mg/m ³ 0.29 mg/m ³	JUL2005
SWEDEN:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , Skin	JUN2005
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m ³ 0.4 mg/m ³ , inhal	JAN2011
UNITED KINGDOM:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	OCT2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA-Ceiling REL-Ceiling	0.11* ppm / 0.29** mg/m ³ 0.1* ppm / 0.3** mg/m ³	ACGIH, 1996, 2013 NIOSH Recommended Exposure Limits *as HN ₃ vapor; **as NaN ₃ ; Skin
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>			

Concentrated Thimerosal [CAS# 54-64-8] - OEL:			
AUSTRALIA:	TWA STEL	0.01 mg(Hg)/m ³ 0.03 mg(Hg)/m ³	JUL2008
BELGIUM:	TWA	0.1 mg(Hg)/m ³ , skin	MAR2002
FRANCE:	VME	0.1 mg(Hg)/m ³ , skin	FEB2006
HUNGARY:	TWA STEL	0.01 mg(Hg)/m ³ 0.04 mg(Hg)/m ³ , skin	SEP2000
NORWAY:	TWA	0.05 mg(Hg)/m ³	JAN1999
THE PHILIPPINES:	TWA	0.05 mg(Hg)/m ³	JAN1993
POLAND:	MAC(TWA) MAC(STEL)	0.05 mg(Hg)/m ³ 0.15 mg(Hg)/m ³	JAN1999
RUSSIA:	TWA STEL	0.05 mg(Hg)/m ³ 0.2 mg(Hg)/m ³ , skin	JUN2003
SWEDEN:	TWA	0.01 mg (Hg)/m ³ , skin	JUN2005
SWITZERLAND:	MAK-W	0.01 mg/m ³ , inhal, skin, sen	JAN2011
THAILAND:	STEL	0.05 mg (Hg)/m ³	JAN1993
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	PEL-T-TWA PEL-CEIL REL-T-TWA	0.01 mg/m ³ 0.1 mg/m ³ 0.05 mg/m ³	OSHA 29,1910.1000 Z-1, 1989, 1994

Concentrated Thimerosal [CAS# 54-64-8] - OEL:		
REL-CEIL	0.1 mg/m ³	NIOSH Recommended Exposure Limits
<i>Remarks:</i> Skin Contact does contribute to exposure. See Table Z-2.		
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>		

Additional information: The lists that were valid during the creation were used as basis.

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes, and eyes, or hazardous inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation:	Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
Eye / Face Protection:	Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
Protective Gloves:	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.
Protective Clothing:	Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
Respiratory Protection:	Do not breathe mist / vapors/vapours / spray.
Other:	All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Amber / yellow liquid.		
Odor/odour:	No applicable information was found.	Odor/odour threshold:	Not established.
pH:	Neutral, pH between 6 and 8.		
Boiling point:	Undetermined	Melting point:	Undetermined
Flash point:	Not applicable. Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u>		
Evaporation rate:	Data is not available.		
Fire hazard:	Although the components have not been tested for fire hazard and explosion data, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor/vapour pressure:	No applicable information was found.		
Vapor/vapour density:	No applicable information was found.		
Relative density:	Undetermined.		
Solubility:	Miscible in water.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto-igniting:	Product is not self-igniting.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		

Danger of explosion:	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
No other standard characteristics are known to be applicable to the identification or hazards of the product components.	

SECTION 10: STABILITY AND REACTIVITY INFORMATION

NOTE: Chemical reactions that could result in a hazardous situation (e.g. generation of flammable or toxic chemicals, fire or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical Stability / Reactivity:	Components are stable with no known inherent significant reactivity.
Conditions and/or Materials to Avoid:	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring diluted solutions down the drain to prevent such explosive build-up.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen or mercury.
Hazardous Polymerization:	Has not been reported to occur.

SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Acute Toxicity:	Harmful in contact with skin and if swallowed. Toxic if enough is ingested; it has been evident to kill at low concentrations if enough is ingested (typically in quantities above those found in the kit).
Primary Irritant Effect:	May slightly irritate respiratory system, eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	May slightly irritate eyes, depending on amount and contact time.
STOT-Single Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	<i>Thimerosal</i> targets the central nervous system (CNS), lungs, gastrointestinal tract, liver, kidneys and blood (large or prolonged dosages)

Biohazard Potential

The reactive human serum in this product was heat-treated to inactivate the HIV and all human sera in it were tested and found non-reactive for HBsAg and antibodies to HCV (and HIV if not inactivated). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, the WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin Sensitization:	<i>Thimerosal</i> (organ-mercury compound) is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. There are ample cases of sensitization resulting from exposure to dilute thimerosal solutions.
Carcinogenicity:	No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.
Germ Cell Mutagenicity:	No applicable information was found.

Reproductive hazard:	<i>Thimerosal</i> (merthiolate sodium), an organo-mercury biocidal preservative mercury compound, is a known reproductive toxin, listed by the State of California to cause developmental toxicity.
STOT-Repeated Exposure:	No applicable information was found.

Additional Toxicological Information

Mercury compounds, such as *thimerosal* (merthiolate sodium), an organo-mercury biocidal preservative, are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects; avoid release to the environment. To the best of our knowledge the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.

Ecotoxicity:	<p>100% Sodium Azide [CAS# 26628-22-8] *: Fish LC₅₀ - <i>Lepomis macrochirus</i> - 0.68 mg/l - 96 h Daphnia EC₅₀ - <i>Daphnia pulex</i> (Water flea) - 4.2 mg/l - 48 h</p> <p>Concentrated Thimerosal [CAS# 54-64-8] *: Fish LC₅₀ - <i>Oncorhynchus mykiss</i> (rainbow trout) – 21.2 mg/l - 48 h * Source: Raw Material Vendor Safety Data Sheets, RTECS and/or CCOHS Cheminfo</p>
Persistence and degradability:	No information found.
Bioaccumulation potential:	Mercury and its compounds are expected to significantly bioaccumulate.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse effects:	<p>The ecological information for the dilute organo-mercury preservative, <i>Thimerosal</i> has not been thoroughly investigated however, United States regulation considers mercury hazardous to the environment to 0.2 ppm mercury (0.01% thimerosal contains ~50 ppm mercury, which makes up ~50% of the molecule); at or above this level, any waste must be handled as dangerous waste.</p> <p>An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.</p>

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional national and international regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- All potentially infectious **human source** material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly. *Note that the Thimerosal preserved human source biologicals must be decontaminated prior to hazardous chemical waste disposal.*
- Waste containing **Thimerosal**, an organo-mercury compound, is a regulated hazardous waste if the final concentration is ≥ 0.2 mg/L (0.2 ppm). The components in this kit that contain 0.01% Thimerosal equates to 0.005% = 50 mg/L (50 ppm) Mercury w/v. If the Thimerosal-containing waste has a final concentration that is ≥ 0.2 mg/L (≥ 0.2 ppm) Mercury, it requires disposal as a toxic environmental pollutant material in a RCRA approved waste facility (or equivalent); the US RCRA Waste disposal Code for this waste is D009; check your applicable ordinances accordingly.

- **Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up; check your applicable ordinances accordingly.

Do not allow undiluted product or large quantities of it to reach ground water or water course.

Recommended Unclean Packaging Disposal: Dispose of in accordance with all applicable local, regional, national and international regulations.

SECTION 14: TRANSPORT INFORMATION

Shipping of product, packaging and waste must be conducted in accordance with all applicable local, regional, national and international regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health & Safety Office for your specific shipping procedures.

Recommended Unused Product Multi-Modal Transportation: According to US DOT, IATA and UN “Model Regulations”, the product must be transported as follows: No known transport restrictions.

Recommended Used Product Disposal Transportation: Potential air and land transportation information for discarded kit components and waste from this product when used as intended is:

- ◆ This product contain approximately 0.005 % = 50 mg/L = 50 ppm mercury (w/v) from the 0.01% **thimerosal** preservative. Therefore, any discarded product generated from its use, resulting in a final concentration that is greater than or equal to 0.2 mg/L (ppm) must be transported as follows:

Proper Shipping Name: **Environmentally Hazardous substance, liquid n.o.s.**

UN Class: **9**

Packing group: **III**

UN ID Number: **UN 3082**

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

SECTION 15: REGULATORY INFORMATION

Composite HMIS Rating: Health: 2 Flammability: 0 Reactivity: 1

Carcinogenicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA (Occupational Health and Safety Administration, U.S. Department of Labor).

National Regulations – Other Domestic / Foreign Laws:

Hazard communication compliance – This SDS contains the required information for preparation in accordance with the following GHS-based global regulations:

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
2. **Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
3. **People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
4. **New Zealand** – Hazardous Substances and New Organisms Act 1996 (HSNO), Hazardous Substances (Classification) Regulations 2001 and Thresholds and Classifications January 2012 (as published in 2008)
Composite HSNO Hazard Class: Based on available data, the classification criteria are not met
5. **Mexico** – Standard **NMX-R-019-SCFI-2011**
6. **Korea** – *Public Notice Public Notice 2013-37 Standard for Classification and Labeling of Chemical Substances and Material Safety Data Sheets*
7. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
8. **European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
9. **Canada** – Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.
Composite WHMIS Hazards: Health Hazard Not Otherwise Classified
10. **Brazil** – Regulation **NRB 1472**
11. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
12. Analogous GHS-based global regulations

Inventory status

Country(s) or region	Inventory name	In Compliance (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS) or Europe European List of Notified Chemical Substances (ELINCS)	Yes
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	inventory (CSNN)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Regulation (EC) No. 1907/2006 (REACH):

Chemicals included in the Candidate List of Substances of Very High Concern (SVHC): None

REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

United States SARA:

SARA 302 (extremely hazardous substance) components: The following components are subject to reporting levels established by SARA Title III, Section 302 in greater quantities than found in this product: **Sodium Azide**, CAS# 26628-22-8; Revision Date: 2007-07-01

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.

California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986): WARNING: This Product Contains a Chemical(s) Known to the State of California to Cause Reproductive Toxicity.

Chemicals known to cause reproductive Toxicity: **Thimerosal** (Merthiolate Sodium), CAS# 54-64-8; classified under the generic class of Mercury compounds. (Listed July 1, 1990)

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – inhl.	Acute toxicity – inhaled
Skin Sens.	Skin sensitizer
Eye Irrit.	Eye irritation)
Rep. Tox.	Reproductive Toxicant
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H317	May cause an allergic skin reaction.
H320	Causes eye irritation.
H330	Fatal if inhaled.
H361	Suspected if damaging fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
P260	Do not breathe mist / vapors/vapours / spray.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284	Wear respiratory protection.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER or doctor/ physician
P501	Dispose of contents/container to in accordance with local/regional/national/international regulation.
P501	This material and its container must be disposed of as hazardous waste.
Caution	Contains human source material and inactivated pathogen. Handle as if capable of transmitting potentially infectious agents (<i>Standard and Universal Precautions</i>).

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

This HIV-2 reactive sample is intended for use as a tool in evaluating assays that detect HIV-2. This product is for research use only and is not intended for use in diagnostic procedures.

Chemical safety assessment: Mixtures covered in this SDS were classified using the US HCS, EC CLP and/or UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Fourth edition unless otherwise specified.

Sources of key data used to compile the Safety Data Sheet:

- Raw Material Vendor Safety Data Sheets
- United Nations (UN) Globally Harmonized System (GHS)
- United States OSHA Hazard Communication Standard (US HCS) 1910.1200
- Canadian Workplace Hazardous Materials Information System (WHMIS)
- Mexican Standard (NMX-R-019-SCFI-2011) [regulatory translation and summaries]
- European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations
- Australian Code of Practice – Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the *Work Health and Safety Act*)
- New Zealand – Hazardous Substances and New Organisms Act 1996 (HSNO)
- The People's Republic of China National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
- Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030 [regulatory translation if available / summaries]
- Korean Public Notice 2008-26 [regulatory translation if available and summaries]
- Japanese Industrial Standard JIS Z7252, JIS Z7253 [regulatory translation if available and summaries]
- Registry of Toxic Effects of Chemical Substances (RTECS)
- Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*
- International Agency for Research on Cancer (IARC)
- American Conference of Governmental Industrial Hygienists (ACGIH)
- Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
- National Toxicity Program (NTP)
- National Institute for Occupational Safety and Health (NIOSH)
- World Health Organization. *Laboratory Biosafety Manual*
- CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
- Australian Inventory of Chemical Substances listing
- California Proposition 65

Key / legend to abbreviations and acronyms used in the safety data sheet:

- ACGIH – American Conference of Governmental Industrial Hygienists
- ACIS – Australian Inventory of Chemical Substances
- ANSI – American National Standards Institute
- CAS – Chemical Abstracts Service
- CCOHS – Canadian Centre for Occupational Health and Safety
- CDC – Centers for Disease Control, USA
- CNS – Central Nervous System
- DOT – Department of Transportation
- EC₅₀ – half maximal effective concentration
- EC CLP – European Commission regulation for the Classification, Labeling and Packaging of chemical substances and mixtures
- EU – European Union
- GHS – Globally Harmonized System
- HNOC – Hazard Not Otherwise Classified
- HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)
- IARC – International Agency for Research on Cancer
- IARC – International Agency for Research on Cancer
- IATA – International Air Transport Association
- ICAO - International Civil Aviation Organization
- IDLH – Immediately Dangerous to Life or Health
- IMDG – International Maritime Dangerous Goods
- IPCS – International Programme on Chemical Safety
- ISHA – Industrial Safety and Health Act
- LC₅₀ – median lethal concentration, 50%
- LD₅₀ – median lethal dose, 50%
- NIOSH – National Institute for Occupational Safety and Health
- NTP – National Toxicity Program

OEL – Occupational Exposure Limit
PEL – Permissible Exposure Limit
ppm – parts per million
RTECS – Registry of Toxic Effects of Chemical Substances
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
STOT – Specific Target Organ Toxicity
TCCA – Toxic Chemical Control Act
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US HCS – Hazard Communication Standard, USA
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS – Workplace Hazardous Materials Information System, Canada
WHO – World Health Organization (United Nations)

Additional information: The lists that were valid during the creation were used as basis.

This Revision: Updated, reformatted and added new GHS information.

Bio-Rad Laboratories:

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Phone: 1-800-224-6723, www.bio-rad.com/diagnostics

Contact 24/7/365: 1-800-424-9300

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