

SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: EIA Wash Solution Concentrate

Product Number: 25261 (15 bottle kit)

Intended Use: These are **replacement** or **separately purchased** components, identical to those found in the kits, which are to be used exclusively with these Bio-Rad Laboratories products:
 GS HIV-1/HIV-2 *PLUS O* EIA, Catalog Number 32588, 32589, 25256
 GS HBsAg EIA 3.0, Catalog Number 32591, 32592, 25258
 GS HIV Combo Ag/Ab EIA, Catalog Number 26217
 GS HIV-2 EIA, Catalog Number 32536
 MONOLISA™ Anti-HBc IgM EIA, Catalog Number 26174
 MONOLISA™ Anti-HBc EIA, Catalog Number 26186
 MONOLISA™ Anti-HBs EIA, Catalog Number 26220
 MONOLISA™ Anti-HAV IgM, Catalog Number 72495
 MONOLISA™ Anti-HAV, Catalog Number 72496
 Catalog Number 26191
 Refer to the Bio-Rad Laboratories product SDSs and kit instructions for safe handling of this kit optional material in the assay process.

Manufactured by: Bio-Rad Laboratories, Inc.

Address: 6565 185th Avenue NE
Redmond, WA 98052-5039, USA

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; in the United States of America call toll free 1-800-2-BIORAD (1-800-224-6723). *Outside the U.S.A., please contact your regional Bio-Rad office for assistance.*

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. The GHS, US HCS, EC CLP, and related classifications were made according to the latest editions and expanded upon from company and literature data. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

Component	Content
R2. Wash Solution Concentrate (30X), 15 bottles (120 mL)	- Sodium chloride (NaCl) [CAS# 7647-14-5, EC No 231-598-3] aqueous solution with < 2% Tween 20 (C ₅₈ H ₁₁₄ O ₂₆) [CAS# 9005-64-5, EC No 585-580-06-X] (clear liquid). Not subject to GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.

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

The chemical dilutions in this product are not subject to classification or labeling according *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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature (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 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 list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.

Chemical Ingredient: This product contains no chemical constituents that require regulatory control or disclosure at the concentration found in the product.

Related product information:

- ◆ Refer to section 2 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.
- ◆ No significant adverse health effects are expected by any route for the **Tween 20** [C₅₈H₁₁₄O₂₆, CAS #9005-64-5] and miscellaneous salts and water in the kit volumes and/or concentrations present [chemical or dilution is not subject to GHS, EC CLP, or GHS-based hazard labeling].
- ◆ 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:	No known significant health hazards.
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.
Inhalation:	Remove person from exposure area to fresh air. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively.
If Swallowed:	Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
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 and 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 appropriate spill cleanup materials and PPE are available and used.
- ◆ Follow established laboratory policy and applicable 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. Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g., spill pillows, absorbent pads), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, Chemical, and 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.</p> <p>Keep containers tightly closed; avoid splashing, spills, and the generation of aerosols.</p> <p>Handle all human source materials, specimens, and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard and 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>
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 for use.	
These are separately purchased components, identical to those found in the products, which are to be used exclusively with the Bio-Rad Laboratories products listed in Section 1.	

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.

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 hazard inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation:	Adequate lab ventilation is required
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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 be 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 / 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:	Clear aqueous liquids.		
Odour / Odor:	No applicable information was found.	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:	No applicable information was found.		
Fire hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor pressure:	No applicable information was found.		
Vapor density:	No applicable information was found.		
Relative density:	Approximately 1.		
Solubility:	Miscible in water.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		
Danger of explosion:	Product is not known to present an explosion hazard.		
No other standard characteristics applicable to the identification or hazards of the product are known.			

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:	None known when used as intended.



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Materials to Avoid:	None known when used as intended.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
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

Toxicity:	No significant toxic effect known.
Primary Irritant Effect:	No significant irritant effect known.
Serious Eye Damage / Irritation:	Data is not available
STOT-Single Exposure:	No applicable information was found.
STOT-Repeated Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	No significant other acute health effect known.

Chronic Toxicity

Sensitization:	No sensitization effect known.
Carcinogenicity:	No carcinogenic effect known
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.

Additional Toxicological Information: 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:	This information is not available.
Persistence and degradability:	This information is not available.
Bioaccumulation potential:	This information is not available.
Mobility in soil:	This information is not available.
PBT and vPvB assessment:	This information is not available.
Other adverse effects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

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.



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Recommended Product Disposal: Dispose of product and packaging waste in accordance with all applicable local, regional, national, and international regulations.

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

Recommended Unclean Packaging Disposal: Dispose 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 Product Multi-Modal Transportation: According to US DOT, IMDG, IATA, and UN "Model Regulations", the product must be transported as follows: No known transport restrictions.

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

SECTION 15: REGULATORY INFORMATION

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

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:

- United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
- Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
- People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
- 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)
- Mexico** – Standard **NMX-R-019-SCFI-2011**
- European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC**, etc.)
- Canada** – Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.
- Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
Australian Inventory of Chemical Substances (AICS): All pertinent ingredients are listed.
- 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
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)

United States SARA:

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: SARA 313: 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: The Product does not contain listed substances.

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s): None

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.

These are Replacement, optional, or separately purchased components, identical to those found in the products, which are to be used exclusively with the Bio-Rad Laboratories products listed in Section 1.

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 Commission (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC (EC CLP)
- 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]
- EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC
- 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 (ACIS) Listing
- California Proposition 65

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 Labeling of Chemicals (GHS) Fourth edition unless otherwise specified.

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
DGSM Act – Dangerous Goods Safety Management Act
DOT – Department of Transportation, USA
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
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%
MSDS – Material Safety Data Sheet
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, USA
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:

Department issuing SDS: Environmental Health and Safety.

Contact for general SDS information: Seattle Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA, Phone: 425-881-8300 (8 am to 5 pm PT), ro-sds@bio-rad.com

Customer support contact: Clinical Diagnostics Group, 4000 Alfred Nobel Drive, Hercules, CA 94547, USA
Phone: 1-800-224-6723, www.bio-rad.com/diagnostics

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