

**SAFETY DATA SHEET (SDS)****SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER**

<b>Product Name:</b>	<b>MONOLISA™ Anti-HBs Calibrator Kit</b>
<b>Product Number:</b>	<b>25219 (20 Tests)</b>
<b>Intended Use:</b>	The Bio-Rad MONOLISA™ Anti-HBs Calibrator Kit is intended for quantitative determination of anti-HBs in human serum or and EDTA, heprin or citrated plasma. The MONOLISA™ Anti-HBs Calibrator Kit is to be used with the MONOLISA™ Anti-HBs (Catalog #25220).
<b>Manufactured by:</b>	<b>Bio-Rad Laboratories, Inc.</b>
<b>Address:</b>	6565 185th Avenue NE Redmond, WA 98052-5039, USA
<b>Website:</b>	<a href="http://www.bio-rad.com">www.bio-rad.com</a>
<b>Phone Number:</b>	1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)
<b>SDS e-mail contact:</b>	<a href="mailto:ro-sds@bio-rad.com">ro-sds@bio-rad.com</a>
<b>Technical Information Contacts:</b>	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). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>
<b>Authorized Representative in the European Community:</b>	<b>FRANCE: Bio-Rad</b> 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 <a href="mailto:fds-msds.fr@bio-rad.com">[fds-msds.fr@bio-rad.com]</a>
<b>Emergency Phone Number:</b>	<b>This SDS is listed with CHEMTREC 1-800-424-9300 (US) / 001-703-527-3887</b> (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.

<b>Component</b>	<b>Content</b>
<b>C2 Anti-HBs EIA 0 mIU/mL Calibrator 1 vial (1.6 mL)</b>	- PBS buffer with bovine serum and blue dye (food grade). - Without therapeutic grade anti-HBs immunoglobulin (0 mIU/mL). - Preserved with <b>0.16% ProClin 950</b> , containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C <sub>4</sub> H <sub>5</sub> NOS); CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<b>C4 Anti-HBs EIA Calibrator 100 mIU/mL 1 vial (1.6 mL)</b>	- PBS buffer with bovine serum and blue dye (food grade) added. - 100 mIU/mL Anti-HBs immunoglobulin of human origin (therapeutic grade). - Preserved with <b>0.16% ProClin 950</b> , containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C <sub>4</sub> H <sub>5</sub> NOS); CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.

Component	Content
<b>C5 Anti-HBs EIA Calibrator</b> <b>400 mIU/mL</b> 1 vial (1.6 mL)	- PBS buffer with bovine serum and blue dye (food grade). - 400 mIU/mL Anti-HBs immunoglobulin of human origin (therapeutic grade). - Preserved with <b>0.16% ProClin 950</b> , containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C <sub>4</sub> H <sub>3</sub> NOS); CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<b>C6 Anti-HBs EIA Calibrator</b> <b>1000 mIU/mL</b> 1 vial (1.6 mL)	- PBS buffer with bovine serum and blue dye (food grade). - 1000 mIU/mL Anti-HBs immunoglobulin of human origin (therapeutic grade). - Preserved with <b>0.16% ProClin 950</b> , containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C <sub>4</sub> H <sub>3</sub> NOS); CAS# 2682-20-4, EC No 220-239-6. 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 (US HCS), European Community (EC) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulations:** 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**

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 (LD<sub>50</sub>, 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. 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: ProClin 950**

Chemical concentrations found in this product: **≤ 0.16% in C2, C4, C5 and C6**

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

Hazardous ingredient concentration in raw material: the concentrated preservative contains:

5-10% of 2-methyl-4-isothiazolin-3-one (active ingredient).

CAS#: 2682-20-4 (active ingredient)

EC No: 220-239-6 (active ingredient)

RTECS#: NE

Chemical Formula: C<sub>4</sub>H<sub>3</sub>NOS (active ingredient)

LD<sub>50</sub> (oral-rat): No data available (concentrated solution)

LC<sub>50</sub> (inhalation-rat): No data available (concentrated solution)

LD<sub>50</sub> (skin-rabbit): No data available (concentrated solution)

pH value: 3.0-6.0 (concentrated solution)

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

**DANGER!**


Acute Tox. -- inhl. Cat. 3, Skin Corr. Cat. 1B, Eye Damage Cat. 1, Skin Sens. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1

H314, H317, H331, H410

P261, P264, P271, P272, P273, P280, P301 + P330 + P331, P303 + P361 + P353, P305 + P351 + P338, P310, P403 + P233, P405, P501

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



Biological Ingredient	Data / Information
<p><b>Anti-HBs Human Immunoglobulin, Therapeutic grade, inactivated (human origin) and Human Source Material</b></p> 	<p>The MONOLISA™ Anti-HBs Calibrator kit components C4, C5 and C6 contain therapeutic grade Anti-HBs immunoglobulin of human origin, which has been inactivated.</p> <p>The human source material used to make the Calibrators has been tested and certified non-reactive for HBsAg, and antibodies to HCV and HIV-1/HIV-2.</p> <p>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 or specimens. 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> and 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. Employ decontamination procedures with appropriate decon agent or 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); typically for concentrate form unless otherwise specified.

**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.
- ◆ No significant adverse health effects are expected by any route for the miscellaneous salts, buffers, water, animal serum (bovine), dyes, catalytic or other non-reactive ingredients, in the kit volumes and/or concentrations present. [Chemical or dilution is not subject to GHS, US HCS, EC CLP or other GHS-based hazard labeling.]
- ◆ 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 the products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. 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 over exposure may include mild non-specific irritation. Universal Precautions apply.
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. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. Treat symptomatically and supportively.

If Swallowed:	If ingested, wash 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), Universal Precautions apply. Persons taking immunosuppressant drugs may be more susceptible to infectious pathogens. Persons handling human blood samples should be offered Hepatitis B vaccination prior to working with human source material.

### SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	May emit toxic oxides of carbon and nitrogen under fire conditions.
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 clean-up materials and PPE are available and used.
- ◆ Prevent material from entering sewers, waterways or confined spaces.
- ◆ 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 clean up. 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 or 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.).
- ◆ 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, etc.), 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.</p> <p>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 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 &amp; Safety Office for assistance.</p>
Storage:	Store according to product and label instructions (generally at 2-8 °C).
<p>Caution, consult accompanying documents. Read and follow all the Precautions and Warnings in the kit product instructions. Refer to the <i>Instructions For Use, Package Insert</i> for additional product information.</p>	
<p>The MONOLISA™ Anti-HBs Calibrator Kit is to be used with the MONOLISA™ Anti-HBs (Catalog #25220)</p>	

**SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES**

**Control Parameters** – The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

*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 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 / 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. Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance:</b>	Blue aqueous liquid.		
<b>Odor/odour:</b>	No applicable information was found.	<b>Odor/odour threshold:</b>	Not Established.
<b>pH:</b>	Neutral, pH between 6 and 8.		
<b>Boiling point:</b>	Undetermined.	<b>Melting point:</b>	Undetermined.
<b>Flash point:</b>	Not Applicable Flammable limits: LEL/LFL is <u>Not Applicable</u> ; UEL/UFL is <u>Not Applicable</u>		
<b>Evaporation rate:</b>	No applicable information was found.		
<b>Fire hazard:</b>	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.		
<b>Vapor/vapour pressure:</b>	No applicable information was found.		
<b>Vapor/vapour density:</b>	No applicable information was found.		
<b>Relative density:</b>	Approximately 1.		
<b>Solubility:</b>	The liquid chemical components are soluble in water.		
<b>Partition coefficient (n-octanol/water):</b>	No applicable information was found.		
<b>Auto igniting:</b>	Product is not known to be self-igniting.		
<b>Decomposition temperature:</b>	No applicable information was found.		
<b>Viscosity:</b>	No applicable information was found.		
<b>Danger of explosion:</b>	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 Materials to Avoid:	None known when used as intended.
Hazardous Decomposition Products:	May emit toxic oxides of carbon and nitrogen under fire conditions.
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:	May be detrimental in contact with skin.
Primary Irritant Effect:	May slightly irritate 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:	No significant other acute health effect known.

**Biohazard Potential:**

The MONOLISA™ Anti-HBs Calibrator kit components C4, C5 and C6 contain therapeutic grade Anti-HBs immunoglobulin of human origin which has been inactivated. The human source material used to make the Calibrators has been tested and certified non-reactive for HBsAg, and antibodies to HCV and HIV-1/HIV-2. 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*, 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:	Contains a small volume (below US HCS, EC CLP and global GHS thresholds) of a very dilute, sensitizing chemical ( <b>ProClin 950</b> ); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly.
Carcinogenicity:	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:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

**Additional Toxicological Information:** The chemical, physical and toxicological properties have not been thoroughly investigated.

**SECTION 12: ECOLOGICAL INFORMATION**

This product was not tested. The following assessment is based on information for the ingredients.	
Ecotoxicity:	<b>Concentrated 2-methyl-4-isothiazolin</b> [CAS# 2682-20-4]**: Fish LC <sub>50</sub> – Lepomis macrochirus (Bluegill) – 300 µg/l [min. 240 µg/l, max. 320 µg/l] - 96 h Fish LC <sub>50</sub> - Oncorhynchus mykiss (rainbow trout) – 190 µg/l [min. 130 µg/l, max. 310 µg/l] - 96 h Fish LC <sub>50</sub> - Oncorhynchus mykiss (rainbow trout) – 70 µg/l [min. 60 µg/l, max. 90 µg/l] - 96 h ** Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo PAN Pesticides Database – Chemical Studies on Aquatic Organisms [obtained 3/7/2012]
Persistence and degradability:	No information found.
Bioaccumulation potential:	No information found.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
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.

**Recommended Product Disposal:** All **human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material.

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 Unused 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: 1 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:

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 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:* Based on available data, the classification criteria are not met.
10. **Brazil** – Regulation **NRB 14725**
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**

<u>Country(s) or region Inventory name</u>	<u>In Compliance (yes/no)*</u>
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:* No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

*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:** The Product does not contain listed substances.

**SECTION 16: OTHER INFORMATION**

**Hazard statement abbreviation(s):**

Acute Tox. – inhl.	Acute toxicity – inhaled
Skin Corr.	Skin corrosion
Eye Damage.	Serious eye damage
Skin Sens.	Skin sensitisation
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Category
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H410	Very toxic to aquatic life with long lasting effects.
P261	Avoid breathing mist / vapors/vapours / spray.
P264	Wash skin thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
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.
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/ physician.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents and container in accordance to local, regional, national and international regulations.
Caution:	Contains human source material. 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. Warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

The MONOLISA™ Anti-HBs Calibrator Kit is to be used with the MONOLISA™ Anti-HBs (Catalog #25220).

**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 (HCS) 1910.1200  
 Canadian Workplace Hazardous Materials Information System (WHMIS)  
 Mexican Standard NMX-R-019-SCFI-2011 [regulatory translation if available and summaries]  
 European Community (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC  
 Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the Work Health and Safety Act)  
 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)  
 International Agency for Research on Cancer (IARC)  
 Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*  
 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*  
 PAN Pesticides Database – Chemical Studies on Aquatic Organisms  
 Australian Inventory of Chemical Substances (ACIS) 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  
 DGSM – Dangerous Goods Safety Management Act  
 DOT – Department of Transportation  
 EC<sub>50</sub> – 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  
 HNO – 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  
 LC<sub>50</sub> – median lethal concentration, 50%  
 LD<sub>50</sub> – 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 (Canadian)  
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.

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