SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: **GS HBsAg Confirmatory Assay 3.0**
ANTIBODY TO HEPATITIS SURFACE ANTIGEN (HUMAN)

Product Number: **32594** (25 tests)

Intended Use: Qualitative assay intended for the confirmation of Hepatitis B Surface Antigen (HBsAg) reactive specimens detected in the GS HBsAg EIA 3.0.
For *in vitro* diagnostic use.

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, 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. *Refer to section 16 for non-US local Bio-Rad agent contact information.*

Authorized Representative in the European Community: ***FRANCE:*** *Bio-Rad*
3 boulevard Raymond Poincaré
92430 Marnes-la-Coquette
Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33
[fds-msds.fr@bio-rad.com]

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
1 **Antibody to Hepatitis B Surface Antigen** (Human) (HBsAg Confirmatory Reagent), 1 vial (1.0 mL)	- Antibody to HBsAg (Human), non-reactive for HBsAg, and antibody to HCV, HIV-1 and HIV-2. - Preserved with **0.16% ProClin 950** containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); 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. - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.

2 **HBsAg Negative Control** (Human), 1 bottle (12 mL)	- Normal human serum, non-reactive for HBsAg, anti-HBsAg and antibodies to HIV and HCV. - Preserved with **0.16% ProClin 950** containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); 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. - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9. 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), and *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 to *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 at the concentration found in the product. Note that the information here is often based on data from 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 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: <u>ProClin 950</u>

Chemical concentrations found in this product: **<u>≤ 0.16%</u>**

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_4H_5NOS (active ingredient)

LD_{50} (oral-rat): No data available (concentrated solution)
LC_{50} (inhalation-rat): No data available (concentrated solution)
LD_{50} (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]

Chemical Ingredient Data / Information

Chemical Ingredient: **Gentamicin sulfate in C0, C1, C2, R3, R4**
Chemical concentrations found in this product: **< 0.01% from a 50 mg/ml Solution**

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

CAS#: 1405-41-0 (100%)
EC No: 215-778-9 (100%)
RTECS#: LY2625000 (100%)
Synonyms/Trade Names: Gentamicin sulfate salt; Garamycin; Gentiomycin C

LD_{50} (oral-rat): > 5000 mg/kg (100%, 50 mg/ml)
LC_{50} (inhalation-rat): NE
LD_{50} (skin-rabbit): NE

Raw Material GHS / US HCS / EC CLP Classification (10%):

DANGER!
Resp. Sens., Cat. 1, Skin Sens., Cat. 1
H317, H334
P261, P272, P280, P285, P302 + P352, P304 + P341, P333 + P313, P342 + P311, P363, P501

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

Biological Ingredient	Data / Information
Human Serum [Reactive and non-reactive] 	Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and 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* when handling these reagents and all human blood, specimens or patient samples, which represent an unknown, heightened hazard. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manual.* 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 during kit use and sample handling. In case of contact with eyes, immediately rinse with copious water and seek medical attention. 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 equivalent) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices *Standard* and *Universal Precautions*. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

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.
- 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, congestion and dizziness. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, generally at concentrations and volumes greatly exceeding that of this kit.
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: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Decomposition 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.
- 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 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.).
- 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:	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 chemicals and biologicals and/or laboratory hazards. 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. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source specimens, and materials equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Standard* and *Universal Precautions.* All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. 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. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store the kit 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, Package Insert* for additional product information.	
For *in vitro* diagnostic use.	

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION MEASURES

Control Parameters – The product contains no substances with occupational exposure limit values.

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 hazard 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), especially if aerosols might be generated.
Eye / Face Protection:	ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn.
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:	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

Appearance:	Amber colored aqueous liquids.		
Odor/odour:	No applicable information was found.	**Odor/odour threshold:**	Not Established.
pH:	Neutral, pH between 6 and 9		
Boiling point:	Undetermined.	**Melting point:**	Undetermined.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is Not Applicable; UEL/UFL is Not Applicable		
Evaporation rate:	No applicable information was found.		
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:	Not Established.		
Solubility:	The liquid chemical components are soluble 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.
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

Acute Toxicity:	Based on available data, the classification criteria are not met.
Primary Irritant Effect:	Based on available data, the classification criteria are not met.
Serious Eye Damage / Irritation:	Based on available data, the classification criteria are not met.
STOT-Single Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Health Effects:	No significant other health effect is known.

Biohazard Potential

The Human sera in the components was tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and 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

Skin and Respiratory Sensitization:	Contains a small volume of a very dilute, potentially skin-contact sensitizing preservatives, ***ProClin 950*** and ***gentamicin sulfate*** (an antimicrobial biocide that is also a photosensitizer); prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Though the potential for an allergic response is greatly reduced by the dilution, sanitization threshold is unknown; thus, handle accordingly.
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: Reasonably anticipated to be a reproductive toxin. May cause harm to unborn child. ***Gentamicin sulfate*** is known to the State of California to cause developmental toxicity (teratogen), classified under the generic class of ***Aminoglycosides***. (Designation is for concentrated Gentamicin Sulfate, which is diluted to 0.005% in kit components).
STOT-Repeated Exposure:	No applicable information was found.

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:	**Concentrated *2-methyl-4-isothiazolin* [CAS# 2682-20-4] ***:** Fish LC_{50} – Lepomis macrochirus (Bluegill) – 300 µg/l [min. 240 µg/l max. 320 µg/l] - 96 h Fish LC_{50} - Oncorhynchus mykiss (rainbow trout) – 190 µg/l [min. 130 µg/l max. 310 µg/l] - 96 h Fish LC_{50} - 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* *Source: PAN Pesticides Database – Chemical Studies on Aquatic Organisims [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; 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 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.

T**ransport 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 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

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: 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 (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: ***Gentamicin Sulfate*** CAS# 1405-41-0; classified under the generic class of Aminoglycosides. (Listed October 1, 1992)

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – inhl.	Acute toxicity – inhaled
Resp. Sens.	Respiratory sensitisation
Skin Sens.	Skin sensitisation
Skin Corr.	Skin corrosion
Eye Damage.	Serious eye damage
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.
H334	May cause allergy or asthma symptoms or breathing difficulties 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.
P285	In case of inadequate ventilation wear respiratory protection.
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
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.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
P363	Wash contaminated clothing before reuse.
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.
P501	Dispose of this material and its container to hazardous or special waste collection point.

Caution: Contains human source material and inactivated pathogens. Handle as if capable of transmitting potentially infectious agents (*Standard* and *Universal Precautions*).

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.

For *in vitro* diagnostic use.

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.

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) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations
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)
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
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
DGSMA – Dangerous Goods Safety Management Act
DOT – Department of Transportation
EC_{50} – 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
LC_{50} – median lethal concentration, 50%
LD_{50} – 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.

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