MATERIAL SAFETY DATA SHEET

IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER (1):

Product Names:	**Chlamydia Swab Collection Kit [34407]** **Chlamydia Brush Collection Kit [34408]**
Product Numbers:	**Catalog 34407 and 34408**
Intended Use:	For the collection and transport of specimens for chlamydia detection using the Bio-Rad Laboratories Chlamydia Microplate EIA test. Not suitable for culture or other chlamydia antigen tests. NOTE: Collection Brush is for use only in the collection of endocervical specimens from non-pregnant women.
Supplier's Name:	**Bio-Rad Laboratories, Inc.**
Address:	6565 185th Avenue NE Redmond, WA 98052-5039
Phone Number:	1-800-2-BIORAD (1-800-224-6723); or (425) 881-8300 (daytime PST)
Emergency Phone Number:	**This MSDS is listed with CHEMTREC (800) 424-9300**. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT with this product.

COMPOSITION / INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (2):

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.

Component *	Content
Cat. No. 34407 contains 100 Swab Collection Packs	- Each consisting of a small sterile dacron swab for collecting the specimen. - A tube with transport medium (phosphate buffered saline, pH 7.4 ± 0.2, with preservative) for transporting samples. - Preserved with 0.01% Thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R 43-61; S 24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).
Cat. No. 34408 contains 100 Brush Collection Packs	- Each consisting of a large sterile swab for removing excess mucus, a sterile cytology brush for collecting the specimen, and a tube with transport medium (phosphate buffered saline, pH 7.4 ± 0.2, with preservative) for transporting samples. - Preserved with 0.01% Thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R 43-61; S 24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).

* Separately purchased component catalog numbers are provided in this column.

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those kit hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.). The kit contains a significantly diluted concentration in an aqueous solution; thus, the assessment below has taken hazard reduction processing into consideration when possible. The EU classification was made according to the latest editions of the EU lists and expanded upon from company and literature data.

Chemical Ingredient	Chemical Data / Information
Thimerosal [0.01% Merthiolate Sodium, $C_9H_9HgNaO_2S$]	CAS# 54-64-8 (Thimerosal powder, 100%) + EINECS/ELINCS No: 200-210-4 (100%) + RTECS# OV8400000 (100%) + Flash Point: NE LD50 (oral-rat): 75 mg/kg (100%) + LC50: NE PEL/TLV: 0.01 mg Hg/m^3 TWA (skin) (100%) + IATA/DOT ID: UN2025 (100%) + CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity ++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: D009 (to 0.2 mg/L - USA) ++ EU Classification: Dilution below 1999/45/EC labeling requirement (< 0.05%); R 43-61; S 24/25-28-36-53-60-61 ++ Thimerosal (merthiolate sodium) is an organo-mercury biocidal preservative which may be detrimental if enough is ingested, targets the central nervous system (CNS) and is a significant sensitizer. Prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals; there are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. The chemical, physical and toxicological properties have not been thoroughly investigated. Thimerosal, classified under the generic class of mercury compounds, is known to the State of California to cause developmental toxicity. Avoid exposure. After contact with skin, wash immediately with plenty of water. Mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects. Avoid release to the environment. Spent mercury-containing solutions with a concentration greater than 0.2 ppm are considered RCRA hazardous waste (D009). This material and its container must be disposed of as hazardous waste and in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. (Note: Mercury (Hg) makes up 49.55% of the thimerosal molecule; thus, a component with 0.01% thimerosal contains ~0.005% (50 ppm) mercury w/v.)

\+ The kit concentration was not tested; the values refer to the solution concentration as tested, designated by percentage within parentheses.
++ The kit concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.
NE: Not Established or Unknown (unable to locate data).
Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity

General Kit Composite Health Hazards:

- No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [dilution not subject to EU Directive labeling]: Phosphate buffered saline solution (pH 7) [34407 and 34408].
- The collection brush is for use in the collection of endocervical specimens from non-pregnant women.
- 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. Follow routine biosafety procedures when collecting and processing specimens for chlamydia detection. Consider specimens and all materials they contact as potentially infectious and dispose of them in an appropriate manner. 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.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis. May cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, generally at concentrations and volumes that greatly exceed 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. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.

If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

FIREFIGHTING MEASURES (5):

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
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.

ACCIDENTAL RELEASE MEASURES (6):

- 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. 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.
- Wear appropriate PPE. Immediately, and on-site if possible:
  - Absorb thimerosal-containing reagents; handle and dispose of as RCRA hazardous waste.
  - Follow established laboratory policy for appropriate spill response and cleanup.
- Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid 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 and national regulations.

HANDLING AND STORAGE INFORMATION (7):

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 chemical, biological and laboratory hazards. 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 specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per Universal Precautions. Refer to Section 8 for more specifics. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store the kit components as specified in the product instructions/package insert provided with the test kit.

Refer to the *Instructions For Use* and/or *Package Insert* for additional product information.

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

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

Ventilation:	Adequate lab ventilation is required.
Eye Protection:	Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
Protective Gloves:	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.
Protective Clothing:	Wear a lab coat, clinic jacket, gown, apron and/or smock.
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.
Note:	Exposure limit values and health hazard data were given in Section 3. Environmental controls are included in the following sections.

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Variable.
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.
Flash Point:	Not established.
Auto Igniting:	Product is not known to be self-igniting.
Danger of Explosion:	Product is not known to present an explosion hazard.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	The liquid chemical components are soluble in water.
pH:	Neutral, pH between 6 and 8.
Specific Gravity:	Not established.

No other standard characteristics applicable to the identification or hazards of the kit are known.

STABILITY AND REACTIVITY INFORMATION (10):

Stability:	Stable under ordinary conditions of use and storage.
Conditions and/or 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.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

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

Acute Health Effects:

Toxicity: May be detrimental in contact with skin. May be detrimental if enough is ingested (typically in quantities above those found in the kit).

Primary Irritant Effect: May cause slight irritation by all routes of entry.

Other Acute Health Effects: Targets the Central Nervous System (CNS), lungs, gastrointestinal tract, liver, kidneys and blood (large or prolonged dosages).

Chronic Toxicity:

Sensitization: Significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals, including triggering asthma.

Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.

Reproductive Hazard: Thimerosal (merthiolate sodium), an organo-mercury biocidal preservative mercury compound, is known to the State of California to cause developmental toxicity.

Additional Toxicological Information:

Mercury compounds such as thimerosal (merthiolate sodium), an organo-mercury biocidal preservative, are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects; avoid release to the environment.

ECOLOGICAL INFORMATION (12):

The ecological information for the dilute organo-mercury preservative, thimerosal, has not been thoroughly investigated; however, mercury and its compounds are expected to significantly bioaccumulate. United States regulation considers mercury hazardous to the environment to 0.2 ppm mercury (0.01% thimerosal contains ~50 ppm mercury, which makes up ~50% of the molecule); at or above this level, any waste must be handled as dangerous waste.

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional and national 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 and/or Packaging Disposal:

Waste containing **thimerosal**, an organo-mercury compound, is a regulated hazardous waste if the final concentration is ≥ 0.2 mg/L (0.2 ppm). The components in this kit that contain 0.01% thimerosal equates to 0.005 % = 50 mg/L (50 ppm) mercury w/v. If the thimerosal-containing waste has a final concentration that is ≥ 0.2 mg/L (≥ 0.2 ppm) mercury, it requires disposal as a toxic environmental pollutant material in an RCRA approved waste facility (or equivalent); the US RCRA Waste Disposal Code for this waste is D009; check your national, regional and local ordinances accordingly.

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

TRANSPORT INFORMATION (14):

Shipping and disposal of product and packaging waste must be conducted in accordance with all applicable local, regional and national 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 Transport: No known transport restrictions.

The air and land transportation information for this product when used as intended (discarded kit components and waste) is:

Component 34407, 34408 in this kit contains approximately 0.005 % = 50 mg/L = 50 ppm mercury (w/v) from the 0.01% **thimerosal** preservative. Therefore, any discarded kit components and waste generated from their use, which result in a final concentration that is greater than or equal to 0.2 mg/L (0.2 ppm) must be transported as follows:

Proper Shipping name: **Hazardous Waste Liquid n.o.s.**

DOT Class: 9 Packing group: III DOT ID Number: UN 3082

REGULATORY INFORMATION (15):

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

California Proposition 65: WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE REPRODUCTIVE TOXICITY.

Chemical(s) known to cause cancer: The product does not contain listed substances.

Chemical(s) known to cause reproductive toxicity: Thimerosal (merthiolate sodium), CAS# 54-64-8; classified under the generic class of mercury compounds

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.

WHMIS Classification: This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

Markings According to European Guidelines: The dilution of chemicals in this product is not subject to EU labeling classification or identification according to EU lists, Directives and other sources of literature known to us.

Hazard Determining Substance(s) of Labeling (rated under 1999/45/EC unless otherwise specified):

0.01% thimerosal (< 0.05%), EINECS/ELINCS No: 200-210-4, CAS# 54-64-8 [R 43-61; S 24/25-28-36-53-60-61]

Risk Phrases:

R 43	May cause sensitisation by skin contact.
R 61	May cause harm to unborn child (designation is for concentrated thimerosal [mercury compounds], which is diluted to 0.01% in kit components).

Safety Phrases:

S 24/25	Avoid contact with skin and eyes.
S 28	After contact with skin, wash immediately with plenty of soap and water.
S 36	Wear suitable protective clothing.
S 53	Avoid exposure – obtain special instructions before use.
S 60	This material and its container must be disposed of as hazardous waste.
S 61	Avoid release to the environment. Refer to special instructions/safety data sheet.

OTHER INFORMATION (16):

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 separately purchased kit components, identical to those found in the kits, which are to be used exclusively with the Bio-Rad Laboratories kits.

This Revision: Reviewed existing information and made minor updates.

Contact for general information:

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