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

Product Name:	ImmunoFLOW Mycoplasma Control
Product Number:	3925
Intended Use:	Mycoplasma IgM Control contains specific IgM type antibodies to Mycoplasma pneumoniae complement–fixing antigen and is used in conjunction with the appropriate ImmunoFLOW Assay Test System.
Supplier's Name:	GenBio
Address:	15222 Avenue of Science Suite A San Diego, CA 92128
Phone Number:	(858) 592-9300
Emergency Phone Number:	

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

This serum control 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
C1 Mycoplasma IgM Control 1 vial (0.50 mL)	Reactive serum for Mycoplasma IgM antibodies diluted in 0.01M phosphate buffer solution with sodium chloride [CAS# 7647-14-5, EINECS/ELINCS No. 231-598-3] and 0.02% 2-(Methacryloyloxyethyl)-2'-(trimethyl- ammoniumethyl) phosphate, inner salt copolymer (pH 7.0-7.6). Preserved with < 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8, dilution below EU regulated labeling levels (1999/45/EC–dilution < 0.1%).

HAZARDS IDENTIFICATION – HAZARDOUS COMPONENTS (3):

The following information is furnished for those serum control hazardous constituents that require regulatory control or disclosure at the concentration found in the control. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.). The serum control 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
Sodium Azide [<0.1% NaN_3 in C1]	CAS#: 26628-22-8 (100%) + EINECS/ELINCS No: 247-852-1 (100%) + RTECS#: VY8050000 (100%) Flash Point: NE LD50 (oral-rat): 27 mg/kg (100%) + LC50 (inhalation-rat): 37 mg/m3 (100%) + PEL/TLV: 0.3 mg/m3 (ceiling) (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + HMIS Codes: H=1, F=0, R=1 ++ RCRA Code: P105 (undiluted, 100%) + EU Classification: None (due to dilution, < 0.1%); S 35-36 ++ Sodium azide is a biocidal preservative, which may be detrimental if enough is ingested (quantities above those found in the kit). Avoid contact with metals; sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup. This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulations. The potential for adverse health effects is unknown for the highly diluted, small volume of sodium azide in this kit, but unlikely if handled appropriately, with the requisite Good Laboratory Practices and Universal Precautions.
Human Serum [reactive in C1]	The Human sera in the components of this product were tested by an FDA approved method and found non-reactive for Hepatitis B surface antigen (HBsAg), and antibody to Hepatitis C virus (HCV) and Human immunodeficiency virus type 1 and 2 (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 along with this control represent an unknown, heightened hazard. Employ 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.* 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 equiv.) 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 and Universal Precautions. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

+ 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); typically for concentrated form unless otherwise specified.

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 serum control volumes and concentrations present (dilution not subject to EU Directive labeling:
  - Diluted (<0.5%) **Disodium orthophosphate heptahydrate** [$HNa_2O_4P{\cdot}7H_2O$], CAS# 7782-85-6, EINECS/ELINCS No. unlisted. (C1)
  - Diluted (<0.1%) **Sodium dihydrogen phosphate monohydrate** [$NaH_2PO_4{\cdot}H_2O$], EINECS/ELINCS No. 231-449-2, CAS# 10049-21-5. (C1)
  - Diluted (<1%) **Sodium Chloride** [NaCl], CAS# 7647-14-5, EINECS/ELINCS No. 231-598-3. (C1)
  - No significant adverse health effects are expected by any route for the miscellaneous salts, buffers, protein-stabilizers, antibodies, water or other non-reactive ingredients, in the serum control volumes and/or concentrations present.
- 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 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.

EMERGENCY FIRST AID MEASDURES (4):

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. Moderately irritating to eyes; greater exposures can cause eye damage, including permanent impairment of vision.
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, 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 Blood borne 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.

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 perform the following 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 appropriate inert materials (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 serum control 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 according to product label instructions (generally at 2-8°C).

Read and follow all the precautions and warnings in the serum control product instructions. Refer to the *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. 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 Protection: Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.

Protective Gloves: Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.

Protective Clothing: Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for

handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.

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.

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, generally aqueous liquids. Exceptions are the related packaging materials. Refer to Section 2.
Fire Hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the serum control packaging materials may burn under fire conditions.
Flash Point:	Not applicable.
Auto Igniting:	Product is not known to be self-igniting.
Danger of Explosion:	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	The liquid chemical components are soluble in water.
pH:	All of the liquid chemical components are between pH 5 and 9.
Specific Gravity:	Variable.

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

STABILITY AND REACTIVITY INFORMATION (10):

Stability:	Components are stable with no known inherent significant reactivity.
Materials to Avoid:	None identified.
Conditions to Avoid:	Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
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 serum control component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Toxicity: May be detrimental in contact with skin, if swallowed, and to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention.

Primary Irritant Effect: A skin and severe eye irritant; prolonged contact may cause eye injury.

Other Acute Health Effects: Risk of serious damage to eyes.

Biohazard Potential

The Human sera in the components of this product were tested by an FDA approved method and found non-reactive for Hepatitis B surface antigen (HBsAg) and antibody to Hepatitis C virus (HCV) and Human immunodeficiency virus type 1 and 2 (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 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 or equivalent. Persons handling blood samples should have the option of receiving Hepatitis B vaccination.

Chronic Toxicity

Sensitization: No sensitizing effect known. Though, the potential for an allergic response is small, handle accordingly.

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

Reproductive Hazard: No reproductive effect known.

Additional Toxicological Information

To the best of our knowledge, the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

ECOLOGICAL INFORMATION (12):

Toxicity:
no data available
Persistence and degradability:
no data available
Bioaccumulative potential:
no data available
Mobility in soil:
no data available
PBT and vPvB assessment:
no data available
Other adverse effects:
no data available

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 serum control components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- **Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup; check your national, regional and local ordinances accordingly.
- **All human source and other potentially infectious material** must be appropriately decontaminated or disposed of as infectious material; check your national, regional and local ordinances accordingly.

Recommended cleansing agent: Water, if necessary with appropriate cleanser. Contact your Environmental Health & Safety Office for your specific cleansing materials and procedures.

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

TRANSPORTATION INFORMATION (14):

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

REGULATORY INFORMATION (15):

Composite HMIS Rating	Health: 1	Flammability: 0	Reactivity: 1
California Proposition 65:	The product does not contain listed substances.		
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:

This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC and 2001/60/EC).

Hazard Designation of Composite Product: None

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

< 0.1% Sodium azide, EINECS/ELINCS No: 247-852-1, CAS# 26628-22-8 [S 35-36].

Risk Phrases:

Caution Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

Safety Phrases:

S 35: This material and its container must be disposed of in a safe way.
S 36: Wear suitable protective clothing.

OTHER INFORMATION (16):

This serum control 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.

Contact for general information:

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