

Autogenous Bacterin

Material Safety Data Sheet

I. Product Identification

Manufacturer's Name:

Hygieia Biological Laboratories, P.O. Box 8300, Woodland, CA 95776
Tel: (916) 661-1442, Fax: (916) 661-1633

Trade Name:

Autogenous bacterin, in Freund's Incomplete Adjuvant

Hazard Summary:

OSHA Hazard Communication Standard, 29 CFR 1910.1200:

Physical Hazards: None

Health Hazards: None

NFPA Hazard Identification:

Degree of Hazard

Health: 0

Fire: 1

Reactivity: 0

Hazard Rating

0 - Least

1 - Slight

2 - Moderate

3 - High

4 - Extreme

Disclaimer of Warranty:

Read the entire MSDS for a more thorough evaluation of the hazards. The information contained in this Material Safety Data Sheet is based upon data available to us from the manufacturers of the components of this vaccine, in-house testing, and published values. It is believed to be correct, but does not purport to be all inclusive, and shall be used only as a guide. No warranty is expressed or implied. This information is furnished upon the condition that the person receiving it shall make his own determination of the suitability of the material for his particular purpose.

II. Ingredients

<u>Component Name</u>	<u>Hazardous in Blend</u>	<u>Percentage</u>	<u>Component Exposure Limit, Units</u>
Phosphate Buffered Saline	No	Less than 80	No Limit
"A" proprietary	No	Less than 30	No Limit
"B" proprietary	No	Less than 5	No Limit
"C" proprietary	No	Less than 5	No Limit
"D" proprietary	No	Less than 2	Less than 1,000 ng/ml endotoxin
Merthiolate	No	Less than 0.01	Concentrate is highly toxic; GRAS at use level present in

Autogenous Bacterin

vaccine. Widely utilized topical antiinfective and pharmaceutical preservative.

III. Health Effect Information

Relative to Phosphate Buffered Saline:

- Eye Contact:** This product may be at most minimally irritating to the eyes upon direct contact. Based upon reports of testing of similar products and/or components. See Health Data section below.
- Skin Contact:** This product is not expected to cause any skin irritation upon direct single or repeated and prolonged contact, however, similar chemical composition products applied to the skin of laboratory animals resulted in minimal to slight dermal irritation. See Health Data section below.
- Inhalation:** This product has a low vapor pressure, and is not expected to present an inhalation hazard at ambient conditions. The sterile solution is osmotically similar to tissue fluids, and is not expected to cause pulmonary edema or other adverse effects. See Health Data section below.
- Ingestion:** Ingestion is relatively nontoxic. See Health Data section below.
- Health Data:** Exposure to a large single dose, or to repeated small doses by eye contact is not expected to be more than minimally irritating. Exposure to a large single dose, or to repeated small doses by skin contact is not expected to be more than minimally irritating at most.

Relative to Ingredients A, B, C, D:

- Eye Contact:** This product may be at most minimally irritating to the eyes upon direct contact. Based upon reports of testing of similar products and/or components. See Health Data section below.
- Skin Contact:** This product is not expected to cause any skin irritation upon direct single or repeated and prolonged contact, however, similar chemical composition products applied to the skin of laboratory animals resulted in minimal to slight dermal irritation. See Health Data section below.
- Inhalation:** This product has a low vapor pressure, and is not expected to present an inhalation hazard at ambient conditions. Use caution to prevent aerosolization or misting as it contains an oil adjuvant; oil aerosols may cause granuloma formation in the respiratory tract with or without pneumonia. According to the manufacturer, the human permissible exposure limit (PEL) and threshold limit value (TLV) of the pure oil mist is 5 mg/m³. Exposures below 5 mg/m³ appear to be without significant health risks. See Health Data section below.
- Ingestion:** Ingestion is relatively nontoxic, unless aspiration occurs. This product is poorly absorbed from the gastrointestinal tract at best, and therefore has laxative properties. Ingestion of large quantities may result in diarrhea, abdominal cramps, and/or

Autogenous Bacterin

vomiting with risk of aspiration and subsequent pneumonitis. See Health Data section below.

Health Data: Exposure to a large single dose, or to repeated small doses by eye contact is not expected to be more than minimally irritating. Exposure to a large single dose, or to repeated small doses by skin contact is not expected to be more than minimally irritating at most. Exposure to a large single dose, or repeated small doses by inhalation, aspiration, or ingestion followed by aspiration can lead to lipid pneumonia, or lipid granuloma. These are low-grade, chronic, localized tissue reactions which are usually not fatal. Shortness of breath and chronic cough are the most common symptoms. Exposure to a very large dose (drowning) may result in chemical pneumonitis, which is characterized by pulmonary edema, hemorrhage, and possible fatality. Signs of lung involvement include increased respiratory and heart rates, with a bluish discoloration of the skin and mucous membranes. Coughing, choking, and gagging are often noted at the time of significant aspiration.

The International Agency for Research on Cancer (IARC) has concluded that there is no evidence for the carcinogenicity of adjuvant components A, B, & C in experimental animals when administered by other than the intraperitoneal route. They are not carcinogenic according to the OSHA hazard communication standard. There is no information available on the carcinogenic potential of the antigen (component D), however, it is believed to be negligible based upon GRAS standards.

When used as directed (subcutaneous injection), the product may invoke a mild inflammatory response at the injection site: typically, one-quarter to one-third of vaccinates will retain the injected vaccine in a depot nodule which is nonpainful, nonsuppurating, remains approximately the size of the deposited volume (2-3" diameter for 5cc dose), and resolves in three to four weeks. The adjuvant has been specifically selected for safety: the components used in Hygieia's version of Freund's Incomplete Adjuvant have been approved by the Food and Drug Administration for use in developing human vaccines.

IV. Emergency and First Aid Procedures:

- Eye Contact:** Immediately flush eyes with large amounts of water and continue flushing until irritation subsides.
- Skin Contact:** Remove contaminated clothing and wash skin with soap and water. If accidental self-injection occurs, seek medical attention immediately to prevent possible granuloma formation.
- Inhalation:** This product has a low vapor pressure, and is not expected to present an inhalation hazard at ambient conditions. If breathing has stopped (drowning), remove victim to fresh air and administer mouth to mouth resuscitation. Seek medical attention immediately.
- Ingestion:** Ingestion is relatively nontoxic. May act as a laxative. Do not induce vomiting due to aspiration hazard. If vomiting occurs, place in coma position (lying on left side, with head lower than body) to prevent aspiration. Seek medical attention immediately.
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Autogenous Bacterin

V. Personal Health Protection Information:

- Eye Protection:** Eye protection is not required under conditions of normal use. If material is handled such that it could be splashed into eyes, wear plastic face shield or splash-proof safety goggles.
- Skin Protection:** No skin protection is required for single, short duration exposures. For prolonged or repeated exposures, use impervious clothing (boots, gloves, aprons, etc.) over parts of the body subject to exposure.
- Respiratory Protection:** Respiratory protection is not required under conditions of normal use. If vapor or mist is generated when the material is handled, use an organic vapor respirator with a dust and mist filter.
- Ventilation:** If vapor or mist is generated when the material is heated or handled, adequate ventilation in accordance with good engineering practice must be provided to maintain concentrations below the specified exposure or flammable level.
- Other:** Consumption of food or beverage should be avoided in work areas. Always wash hands and face with soap and water before eating, drinking, or smoking.

VI. Fire Protection Information

- Flash point:** Above 300 F for all components individually. No data on combination.
Method: Cleveland open cup.
- Autoignition Temperature:** No data
- Flammable Limits in Air, % by volume:** No data (expected to be negligible).
- Extinguishing media:** Use dry chemical, foam, water fog, or carbon dioxide.
- Special fire fighting procedures:**
Use self-contained breathing apparatus, with full face plate and protective clothing. Caution should be exercised when using water or foam, as frothing may occur, especially if sprayed into containers of hot, burning liquid.
- Unusual fire and explosive conditions:**
Carbon monoxide, carbon dioxide and other oxides may be generated as products of burning.

VII. Reactivity

- Stability:** Stable under normal conditions.
- Incompatibility / materials to avoid:** May react with strong oxidizing agents.
- Hazardous decomposition products:** Combustion products: carbon monoxide, carbon dioxide
- Hazardous polymerization:** Will not occur.

Autogenous Bacterin

VIII. Spill or Leak Procedures:

Steps to be taken if material is released or spilled:

Soak up liquid with absorbant and shovel into waste container. Wash residue from spill area with hot water and detergent, and flush to a sewer serviced by a wastewater treatment facility.

Disposal method: Discarded product is not a hazardous waste under RCRA, 40 CFR 261.

Container disposal: Puncture or otherwise destroy empty container before disposal.

IX. Miscellaneous

Handling and storage requirements:

Do not transfer to unmarked containers. Store in closed containers in the refrigerator (35-45F; 2-8C). Normal vaccine handling; in the case of accidental self-injection, seek medical attention.

Practice asepsis when using multiple dose containers.

X. Regulatory Information:

CERCLA and SARA regulations (40 CFR 355, 370, and 372):

This product is not known to contain any SARA Title III, Section 313 reportable chemicals at or greater than 1.0% (0.1% for carcinogens).

TSCA (Toxic Substances Control Act) regulations (40 CFR 710):

The chemical components contained in this product are on the TSCA Chemical Substance Inventory.

The information presented in this MSDS is given in good faith but no warranty, expressed or implied, is made.

Prepared/Reviewed: 09/09