1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Autogenous Bacterial Extract
USDA Product Codes 2052.01, 2052.00, 2051.00
Further description: Adjuvanted with one or combination of the following: Mineral Oil Emulsion, Aluminum Hydroxide, Emulsigen® and Copolymer based adjuvant.
Trade Name: Autogenous Bacterial Extract
Synonyms: SRP Vaccine
Chemical Family: Mixture

Relevant Identified Uses of the Mixture and Uses Advised Against

Intended Use: Veterinary Vaccine

Details of the Supplier of the Safety Data Sheet

Epitopix
360 NW 45th St
Willmar, MN 56201
American Association of Poison Control Centers Phone: 1-800-222-1222
Product Support/Technical Services Phone: 320-222-9807

2. HAZARDS IDENTIFICATION

Appearance: White, opaque or semi-opaque liquid

Classification of the Substance of Mixture

GHS Classification: Not classified as hazardous
EU Classification: Not classified

Label Elements

Signal Word: Not classified
Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

Short Term: In the event of the accidental injection, an allergic reaction may occur. If accidental injection happens, the worker should be seen by qualified medical personnel as soon as possible.

This product is a vaccine for use in animals. This vaccine is not pathogenic to humans or animals.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The actual composition of this product varies, depending on the needs of the requesting veterinarian. This product MAY contain any of the following items in various configurations.

Hazardous

Ingredient	CAS Number	GHS Classification	%
Formaldehyde	50-00-0	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Car. 2 (H351) Acute Tox. 3 (H331)	≤ 0.075%
Aluminum hydroxide	21645-51-2	Not Listed	*
Polymyxin B (sulfate)	1405-20-5	Acute Tox. 4 (H302)	##
Gentamicin sulfate	1405-41-0	Not Listed	##
Mineral Oil, white	8042-47-5	Not Listed	*

Non-Hazardous

Ingredient	CAS Number	GHS Classification	%
Polyoxyethylene sorbitan trioleate (TWEEN® 80)	9005-70-3	Not Listed	*
EMULSIGEN® Oil-in-water emulsion	Not Assigned	Not Listed	*
Copolymer adjuvant	Not Assigned	Not Listed	*
Sorbitan trioleate (SPAN® 85)	26266-58-0	Not Listed	*
Bacterial Extract Protein	Not Assigned	Not Listed	*

Killed Bacterial Whole Cell	Not Assigned	Not Listed	*

Additional Information: * Proprietary ## Trace

For the full text of the R phrases and GHS abbreviations mentioned in the Section, see Section 16.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation or symptoms occur or persist, consult a physician

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. If irritation or symptoms occur or persist, consult a physician.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. If irritation or symptoms occur or persist, consult a physician.

Injection: Seek medical attention immediately! Immediately apply ice to the area of injection to help reduce potential swelling. The affected area should be cleaned as soon as possible. The antigen portion of the vaccine is of little risk to the victim and cannot be transmitted to people as it is either a protein or killed/inactivated microorganism(s). However, there is a risk of bacterial infection since the injection site was not sterile. For this reason, antibiotics and a tetanus shot may be prudent. Because the vaccine may be an emulsion of mineral oil with surfactants, the fluid must be removed. Medical personnel should lance, locally debride and remove the emulsion before tissue reaction begins and causes inflammation.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Fire/Explosion Hazards: Not flammable.

Advice for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Wash thoroughly after handling. Releases into the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Protect from direct sunlight and extreme temperatures.
Storage Temperature: 2-7°C. Do not freeze.
Specific end use(s): Veterinary Vaccine

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Mineral Oil, White

ACGIH Threshold Limit Value (TWA): 5 mg/m^3

ACGIH Threshold Limit Value (STEL): 10 mg/m^3 (oil mist)
OSHA PEL (TWA): 5 mg/m3 (mist)

Formaldehyde

ACGIH Ceiling Threshold Limit: 0.3 ppm
ACGIH – Sensitizer Designation: Sensitizer
OSHA – Final PELS-TWAs: 0.75 ppm
OSHA - Specifically Regulated Chemicals: 2 ppm, 0.5 ppm, 0.75 ppm

Aluminum hydroxide

ACGIH Threshold Limit Value (TWA) – 1 mg/m^3

Recommended Personal Protective Equipment (PPE):

Respiratory Protection: Under normal conditions of use, as stated on the product label, no respiratory protection is necessary.

Skin Protection: Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Avoid dermal contact.

Eye Protection: Safety glasses or goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available
Molecular Formula: Mixture
Color: White, opaque
pH: 6.0-8.0
Solubility in water: Insoluble

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperature may adversely impact effectiveness. Do not freeze.
Hazardous Decomposition Products: None expected under normal conditions.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from killed microorganisms. Toxicological properties of the formulation have not been investigated.

Acute Toxicity

Skin: Mineral oil – slight irritant. Formaldehyde – moderate to severe irritation and sensitizer

Eye: Mineral oil – moderately irritating. Formaldehyde – severe irritation

Oral: Mineral Oil: Oral LD50 in mouse = 22,000 mg/kg. Formaldehyde – Oral LD50 in rat = 800 mg/kg. Gentamicin – Oral LD50 in rSDSat = 6600 mg/kg. Polymyxin B (sulafate) – Oral LD50 in mouse = 790 mg/kg

Injection: Gentamicin: Subcutaneous LD50 in rat = 710 mg/kg, Intramuscular LD50 in mouse = 167 mg/kg. Polymyxin B (sulfate): Subcutaneous LD50 in mouse = 59500 ug/kg, Intraperitoneal LD50 in mouse = 20500 ug/kg

Reproduction & Developmental Toxicity

Gentamicin: Embryo/Fetal Development in rat, intramuscular, 75 mg/kg/day, LOAEL, Developmental toxicity.

Formaldehyde: Embryo / Fetal Development in mouse, oral 185 mg/kg/day, not teratogenic, maternal toxicity. Embryo / Fetal Development in rat, inhalation, 40 ppm, not teratogenic, maternal toxicity.

Carcinogenicity

Formaldehyde: Known carcinogen to humans.

12. EC0LOGICAL INFORMATION

Ecotoxicity Date: This product has not been tested for ecotoxicity.

Environmental Data: There is no environmental data available for the product.

13. DISPOSAL CONSIDERATIONS

Material Waste: Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate.

14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, ICAO, IMO and ADR.

15. REGULATORY INFORMATION

OSHA Status: This product is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29CFR1910.1200.

TSCA Status: This product is a food, food additive, drug, cosmetic, or medical or veterinary device or product as defined by section 201 of the Federal Food, Drug and Cosmetic Act and therefore is exempt from TSCA regulation.

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 – Toxic if swallowed
H302 – Harmful if swallowed
H314 – Causes severe skin burns and eye damage
H317 – May cause an allergic skin reaction
H351 – Suspected of causing cancer
H330 – Fatal if inhaled
H331 – Toxic if inhaled