

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

Product Identifier

Material Names:

- Salmonella Newport Bacterial Extract– USDA Product Code 2811.00
- Escherichia Coli Bacterial Extract – USDA Product Code 264E.01
- Klebsiella Pneumoniae Bacterial Extract – USDA Product Code 2879.00

Tradenames: Vaxxon® SRP® Salmonella, SRP® Salmonella, E. coli O157 SRP®, KlebVax,
Vaxxon® Klebsiella SRP®, Klebsiella Vetovax™ SRP®, Salmonella Vetovax™ SRP®

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

www.vaxxinova.us.com

American Association of Poison Control Centers Phone: 1-800-222-1222

Product Support/Technical Services Phone: (844) SRP-VAXX (777-8299)

2. HAZARDS IDENTIFICATION

Appearance: White, 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 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

Hazardous

Ingredient	CAS Number	GHS Classification	Amount
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% (750 PPM)
Polymyxin B Sulfate	1405-20-5	Acute Tox. 4 (H302)	≤30 µg/mL

Non-Hazardous

Ingredient	CAS Number	GHS Classification	%
EMULSIGEN®, Oil-in-water emulsion	Not Assigned	Not Listed	*
Buffered saline solution	Not Assigned	Not Listed	*
Bacterial Extract Protein	Not Assigned	Not Listed	*

Additional Information: * Proprietary

For the full text of the 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. For vaccines containing mineral oil, medical personnel must determine the need for removal of the vaccine fluid based on location of injected area and degree of swelling. For vaccines not containing oil, ice may be applied to reduce swelling. The vaccine antigen is inactivated and is not infectious.

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: 2-8°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.

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

Polymyxin B sulfate

Polymyxin B sulfate does not contain any hazardous material with occupational exposure limits established by the region specific regulatory bodies.

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 2-8°C. Prolonged exposure to higher temperature may adversely affect potency. 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: Formaldehyde – moderate to severe irritation and sensitizer.

Eye: Formaldehyde – severe irritation.

Oral: Formaldehyde – Oral LD50 in rat = 800 mg/kg. Polymyxin B Sulfate – Oral LD50 in mouse 790 mg/kg.

Injection: Polymyxin B Sulfate - Subcutaneous LD50 in Mouse = 59,000 µg/kg, Intraperitoneal LD in mouse = 20,500 µg/kg.

Reproduction & 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. ECOLOGICAL INFORMATION

Ecotoxicity Data: 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 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
- H330 – Fatal if inhaled
- H331 – Toxic if inhaled
- H351 – Suspected of causing cancer