



SAFETY DATA SHEET

Creation Date: 26 May 2015

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1. Identification of the substance or mixture and of the supplier

Product Name Actinobacillus pleuropneumoniae Bacterin (EMULSIBAC-APP)
Synonyms None
Recommended Use For vaccination of pigs
Manufacturer MVP Laboratories, Inc.
 4805 G Street
 Omaha, NE 68117
 (402) 331-5106
Emergency Phone (800) 856-4648 or (402) 331-5106

2. Hazards Identification

Classification

No known OSHA Hazards

HMIS Classification

Health hazard: 0
 Flammability: 0
 Physical hazards: 0

NFPA Rating

Health hazard: 0
 Fire: 0
 Reactivity Hazard: 0

Signal Words NONE

Pictogram NONE

Health Hazards

Inhalation: NONE
 Skin: NONE
 Eyes: May cause eye irritation
 Ingestion: May be harmful if swallowed

3. Composition/Information on Ingredients

Substance Killed bacterial antigens of *Actinobacillus pleuropneumoniae*
 Other minor ingredients may include:
 Gentamicin CAS No. 1403-66-3
 EMULSIGEN adjuvant (CAS No. not assigned)
 Formaldehyde CAS No. 50-00-0

Statement of Hazard Contains formaldehyde: Potential cancer hazard
 May cause eye, skin and respiratory tract irritation
 May cause sensitization of the skin and respiratory system

Injection In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

EU Hazard Symbols:



EU Risk Phrases:

R43 – May cause sensitization by skin contact

Note:

This document has been prepared in accordance with standards for workplace safety which requires 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 on the potential for exposure in your workplace.

4. First Aid Measures

- Eye:** If irritation or redness develops from exposure, flush eyes with clean water. If symptoms persist, seek medical attention.
- Skin:** First aid is not normally required. Wash thoroughly with soap and water. If irritation occurs or persists, get medical attention.
- Ingestion:** May be harmful if aspirated. Inhalation exposure to mists at current workplace exposure limits is unlikely to cause pulmonary abnormalities.
- Notes to Physician:** Injection of products containing oil-in-water adjuvants may produce a reaction at the site of injection. Treat accordingly.

5. Fire-Fighting Measures

- Extinguishing Media** Dry chemical, carbon dioxide, foam, or water spray is recommended. Water or foam may cause frothing of materials heated above 212 °F. Carbon dioxide can displace oxygen. Use caution when applying carbon dioxide in confined spaces.
- Unusual Fire and Explosion Hazards** This product is a nonflammable aqueous solution and is not expected to support combustion.
- Fire Fighting Instructions** Wear appropriate protective equipment as conditions warrant (see Section 8).
Isolate immediate hazard area and keep unauthorized personnel out. Stop Spill/release if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk.
Water spray may be useful in minimizing or dispersing vapors and to protect personnel. Cool equipment exposed to fire with water, if it can be done with minimal risk. Avoid spreading burning liquid with water used for cooling purposes.
See Section 9 for Flammable Properties including Flash Point and Flammable (Explosive) Limits

6. Accidental Release Measures

<u>Personal Precautions</u>	This product is a nonflammable aqueous solution and is not expected to support combustion.
<u>Spill Precautions</u>	Stay upwind and away from spill/release. Notify persons downwind of the spill/release, isolate immediate hazard area and keep unauthorized personnel out. Stop spill/release if it can be done with minimal risk. Wear appropriate protective equipment, including respiratory protection, as conditions warrant (see Section 8)
<u>Environmental Precautions</u>	Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways. Dike far ahead of spill for later recovery and disposal. Spilled material may be absorbed into an appropriate absorbent material.
<u>Methods for Cleaning Up</u>	Immediate cleanup of any spill is recommended. Notify fire authorities and appropriate federal, state and local agencies. If spill of any amount is made into or upon navigable waters, the contiguous zone, or adjoining shorelines, notify the National Response Center (phone number 800-424-8802)

7. Handling and Storage

<u>Handling</u>	Ensure adequate ventilation. Do not breathe vapors or spray mist. Avoid contact with skin or eyes. When handling, use appropriate protective equipment (See Section 8). Avoid accidental injection.
<u>Storage</u>	Store at 2-10°C. Keep container(s) tightly closed. Use and store this material in cool, dry, well-ventilated areas away from heat and all sources of ignition. Store only in approved containers. Keep away from any incompatible material (see Section 10). Protect container(s) against physical damage.

8. Exposure Controls/Personal Protection

This product contains killed bacterial antigens, gentamicin, formaldehyde and EMULSIGEN® adjuvant.

Personal Protective Equipment (PPE):

<u>Eye/Face</u>	While contact with this material is not expected to cause irritation, the use of approved eye protection to safeguard against potential eye contact is considered good practice.
<u>Skin</u>	Not required based on the hazards of the material. However, it is considered good practice to protective clothing such as lab coats, disposable coveralls, gloves and safety glasses in laboratory or production areas when handling this product.
<u>Respiratory</u>	General room ventilation is adequate unless the process generates mist or fumes. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.
<u>Other</u>	A source of clean water should be available in the work area for flushing eyes and skin. Impervious clothing should be worn as needed. Suggestions for the use of specific protective materials are based on readily available published data. Users should check with specific manufacturers to confirm the performance of their products.

9. Physical and Chemical Properties

Note Unless otherwise stated, values are determined at 20 °C (68 °F) and 760 mm Hg (1 atm). Data represent typical values and are not intended to be specifications.

Appearance:	White
Physical Form:	Liquid
Odor:	Odorless
Odor Threshold:	No data
pH:	7.0 ± 1.0 pH unit
Vapor Pressure:	No data
Vapor Density (air=1):	No data
Boiling Point/Range:	No data
Melting/Freezing Point:	No data
Solubility in Water:	Miscible
Partition Coefficient (n-octanol/water) (Kow):	No Data
Specific Gravity	1.0±0.2
Evaporation Rate (nBuAc=1):	No data
Flash Point:	Non-flammable
Flammability:	No data
LEL (vol % in air):	No data
UEL (vol % in air):	No data
Autoignition Temperature	No data
Decomposition Temperature	No data
Viscosity	No data
Polymerization	Will not occur

10. Stability and Reactivity

Reactivity Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure

Conditions to Avoid Avoid freezing and high temperatures and all sources of ignition (see Sections 5 and 7). Storage or prolonged exposure to higher temperatures may adversely affect potency.

Materials to Avoid (Incompatible materials) Avoid contact with strong oxidizing agents such as hydrogen peroxide, bromine, chlorine and strong acids and strong bases. Also avoid organic solvents or heavy metals as they may adversely affect potency.

Hazardous Decomposition Products None expected

Hazardous Polymerization Will not occur.

11. Toxicological Information

Acute Data

General Information: The antigens in this product are not infectious. All antigens have been killed and tested to assure inactivation. The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the product have not been evaluated.

Acute Toxicity: Species, Route, End Point, Dose

Product: No data available

MVP Laboratories – Actinobacillus Pleuropneumoniae Bacterin (EMULSIBAC-APP)

Gentamicin:	Rat Oral:	LD50 6600 mg/Kg
	Rat Subcutaneous:	LD50 710 mg/Kg
	Rat Intramuscular:	LD50 463 mg/Kg
	Mouse Intramuscular:	LD50 167 mg/Kg
Formaldehyde:	Rat Oral (LD50)	800 mg/Kg
	Mouse Oral Toxicity (LD50):	42 mg/Kg
	Rabbit Skin (LD50):	270 uL/Kg
	Mouse Inhalation:	454000 mg/m
EMULSIGEN	All species	No data available

Irritation / Sensitization: Study type, Species, Severity

Product:	All species	No data available
Gentamicin:	Rabbit Eye irritation:	Not irritating
Formaldehyde:	Rabbit Eye irritation:	Severe/Corrosive
	Rabbit Skin:	Moderate to Severe
	Respiratory Tract	Severe irritation and lung corrosion
	Ingestion	Harmful if swallowed, may be fatal
EMULSIGEN®	All species	No data available

Repeated Dose Toxicity: Duration, Species, Route, Dose, End Point, Target Organs

Product:	All species	No data available
Gentamicin:	All species	No data available
Formaldehyde:	90 Days Dog Inhalation	Not Specified Lungs
	90 Days Rat Inhalation	Not Specified Lungs
	90 Days Monkey Inhalation	Not Specified Lungs
	9 Days Rat Inhalation	15ppm LOAEL Respiratory System
	Subchronic Effects: Rats exposed to 15ppm formaldehyde vapor for six hours/day for up to 9 days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities.	
	Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.	
	Chronic Effects/Carcinogenicity: In rats, several inhalation studies have shown that formaldehyde induces squamous cell carcinomas and necrosis of the nasal cavity. Formaldehyde also showed co-carcinogenic effects when inhaled, ingested, or applied to the skin of rodents.	

Reproduction & Development Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Gentamicin:	Embryo/Fetal Development	Rat Intramuscular 75 mg/Kg LOAEL	Developmental Toxicity
Formaldehyde:	Embryo/Fetal Development	Mouse Oral 185 mg/Kg/day	Not teratogenic, Maternal toxicity
	Embryo/Fetal Development	Rat Inhalation 40 ppm	Not teratogenic, Maternal toxicity
	Reproductive Effects	Not considered to be a reproductive hazard	
	Teratogenic Effects	Formaldehyde has been tested by inhalation, oral, and dermal routes and has been shown to be teratogenic in animals	

Genetic Toxicity: Study Type, Cell Type, Organism, Results

Product:	All species	No data available
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Formaldehyde: *In vitro* Bacterial Mutagenicity (Ames) Bacteria Positive
In Vitro Chromosome Aberration Rodent Positive
In vitro Sister Chromatid Exchange Rodent Positive
In vivo Chromosome Aberration Not Specified Positive

Mutagenicity Formaldehyde has been reported to be active in many short-term tests, both *in vitro* and *in vivo*.

Carcinogenicity: Duration, Species, Route, Dose, End Point, Effects

Product:	All species	No data available
Formaldehyde:	Rat Inhalation	2 years, 6 ppm LOAEL Tumors
	Mouse Inhalation	2 years 15 ppm

Carcinogen Status:
IARC: Group 1
NTP: Reasonably anticipated to be a carcinogen
OSHA: Present

12. Ecological Information

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. Disposal Considerations

Formaldehyde RCRA – U Series Waste
Container contents should be completely used and containers should be emptied prior to discard.

14. Transportation Information

U.S. Department of Transportation (DOT):

Shipping Description Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

15. Regulatory Information

The composition of this product is a Trade Secret. The antigens in this product are not infectious. All antigens have been killed and tested to assure inactivation. The product contains Gentamicin and Formaldehyde.

Formaldehyde: OSHA Label
Contains formaldehyde: potential cancer hazard
May cause eye, skin and respiratory tract irritation
May cause sensitization of the skin and respiratory system

EU Symbol	Xi
EU Indication of danger:	Irritant
EU Risk Phrases	R43 May cause sensitization by skin contact

Canada WHMIS Classifications	Class D, Division 2, Subdivision A
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CERCLA/SARA 313 Emission reporting	0.1% e minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities	100 lb final RQ
CERCLA/SARA – Section 302 Extremely Hazardous TPQs	45.4 Kg final RQ
Substances EPCRA RQs	100 lb EPCRA RQ

	California Proposition 65 OSHA – Specifically Regulated Chemicals	cardnogen, initial date 1/1/88 (gas) 0.5 ppm Action Level 0.75 ppm TWA 2 ppm STEL Irritant and potential cancer hazard – see 29CFR 1910.1048
	Inventory – United States TSCA – Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for drugs and poisons EU EINECS List	Present Present Schedule 2 Schedule 6 200-001-8
Gentamicin:	California Proposition 65 Australia (AICS): Standard for the uniform scheduling for drugs and poisons: EU EINECS List	Aminoglycoside developmental Present Schedule 4 215-765-8
Legend:		
AICS	Australia Inventory of Chemical Substances	CERCLA U.S. EPA Comprehensive Environmental Response, Compensation and Liability Act
EINECS	European Inventory of Existing Commercial Chemical Substances	SARA Superfund Amendments and Reauthorization Act
TSCA	United States Section 8(b) Inventory	

16. Other Information

<u>Issue Date:</u>	01 June 2015
<u>Status:</u>	Final
<u>Previous Issue Date:</u>	02 October 2006
<u>Previous Code:</u>	N/A
<u>Revised Sections or Basis for Revision:</u>	Completed for Global Harmonization Compliance
<u>SDS Code:</u>	B008

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