SAFETY DATA SHEETS

This SDS packet was issued with item: 078377345

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078377881

Boehringer Ingelheim Vetmedica

DOT Pictogram: Not a DOT controlled material (United States). HCS Risk Phrases Protective Clothing: Safety glasses/goggles. _____ Section I. Product Identification and Uses _____ Common/Trade name: Lysigin(R) (2852.00) Synonyms: Staphylococcus Aureus Bacterin Chemical name: Not applicable. Chemical formula: Not applicable. Chemical family: Vaccine. Supplier/Manufacturer: Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Hwy St. Joseph, MO 64506 Material uses: Vaccine. CI#: Not available. TSCA TSCA inventory: No products were found. CAS#: Not applicable. Code: MSDS ID#: B2852.00 Molecular weight: Not applicable. _____ Section IA. First Aid Measures Eye contact: Flush eyes with copious amounts of water. Consult physician immediately. Skin contact: Not considered a skin irritant. After contact with skin, wash immediately with plenty of water. If irritation occurs, seek immediate medical attention. Hazardous skin contact: No additional information. Slight inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention. Apply artificial respiration if needed. Hazardous inhalation: No additional information. Slight ingestion: No information available regarding ingestion. Notify physician or Poison Control Center immediately. Hazardous ingestion: No additional information. _____ Section II. Hazardous Ingredients % by CAS # Weight TLV/PEL Name _____ 1) Formaldehyde 50-00-0 0.2 TWA: 2 (ppm) CEIL: 3 (mg/m3) LC50/LD50: ORAL (LD50): Acute: 14200 mg/kg [Rabbit]. DERMAL (LD50): Acute: 15890 mg/kg [Rabbit]. GAS (LC50): Acute: 64000 ppm 4 hour(s) [Rat]. 2) Thimerosal (Merthiolate) LC50/LD50: _____ Section III. Physical Data _____ _____ Physical state and appearance: Liquid. pH (1% soln/water): Not available. Odor threshold: Not available. Odor: Slight. Taste: Not available. Color: Yellow opaque color. Volatility: Not available. Melting/Sublimation point: Not available. Boiling/Condensation point: Not available. Specific gravity: Not available. Vapor density: Not available. Vapor pressure: Not available. Water/oil dist. coeff.: Not available. Ionicity (surface active agent): Not available. Critical temperature: Not available. Instability temperature: Not available. Conditions of instability: No additional remark. Dispersion properties: See solubility in water. Solubility: Not available.

_____ Section IV. Fire and Explosion Data _____ The product is: Non-flammable. Auto-ignition temperature: Not available. Fire degradation products: Not available. Flash points: Not available. Flammable limits: Not available. Fire extinguishing procedures: Not applicable. Flammability: Non-flammable. Risks of explosion: Non-explosive. _____ Section V. Reactivity Data _____ Stability: The product is stable. Hazardous decomp. products: None known. Degradability: Not available. Products of degradation: None known. Not available. Corrosivity: No specific information is available in our database regarding the corrosivity of this product in presence of various materials. Reactivity: No known incompatibilities. _____ Section VI. Toxicological Properties _____ Routes of entry: Accidental injection. TLV: Not available. Toxicity for animals LD50: Not available. LC50: Not available. Chronic effects on humans CARCINOGENIC EFFECTS: Classified A2 (Suspected for human.) by ACGIH [Formaldehyde]. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: PROVEN [Formaldehyde] The substance is toxic to the reproductive system. Repeated or prolonged exposure to the substance can produce target organs damage. Acute effects on humans: Not for human use. Animal inoculation only, accidental injection to humans can cause serious local reactions. Consult a physician immediately if accidental injection occurs. There is no danger of infection as the vaccine is packaged in a sterile, nonviable product. _____ Section VII. Preventive Measures _____ Waste information: Dispose of in accordance with all laws. Waste stream: Not available. Storage: Store at a temperature not over 45 degrees F. Do not freeze. Precautions: No additional information. Small spill and leak: Absorb with an inert material and place in an appropriate waste disposal container. For formaldehyde, neutralize with sodium bisulfite. Large spill and leak: No additional information. Protective Clothing: Safety glasses/goggles. Section VIII. Classification _____ DOT Pictogram: Not a DOT controlled material (United States). Not applicable. Maritime transportation: Not available. HCS Federal and State Regulations TSCA inventory: No products were found. HMIS (U.S.A.) Health Hazard Fire Hazard 0 Reactivity 0 Personal Protection а

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National Fire Protection Association (U.S.A.) Health 0 Fire Hazard 0 Reactivity 0 Specific hazard _____ Section IX. Protective Measures Protective clothing: Safety glasses. Engineering controls: Good general ventilation should be sufficient to control airborne levels. _____ Section X. Other Information _____ References: Not available. No additional remark. Validated by Safety on 6/25/1999. Verified by Company. CALL 1(800) 821-7467 Emergency Medical: (816) 232-2525 or (800)530-5432 Chemtrec: (800)424-9300 _____ While the company believes the data set forth herein are accurate as of the date hereof, the company makes no warranty with respect thereto and expressly disclaims all liability for reliance thereon. Such data are offered solely for your consideration, investigation and verification. DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES: although preparer and owner have taken reasonable care in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness information contained herein, and assume no of the responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each user should make a

determination as to the suitability of the information for their particular purpose(s). A request has been made to the manufacturer to approve the contents of this material safety data sheet. Upon receipt of any changes a new MSDS will be made available.

COMPAS Code: 46702761

Boehringer Ingelheim

MATERIAL SAFETY DATA SHEET

1

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Lysigin[®] **Product No.:** Not applicable **MSDS ID#:** B2852.00 **GHS Product Identifier:** Not applicable

Molecular Formula: Mixture, not applicable Molecular Weight: Mixture, not applicable CAS Number: Mixture, not applicable Chemical Family: Vaccine

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Hwy St. Joseph, MO 64506-2002 **Transportation Emergency:** For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency (24HR): (866) 638-2226 **Non-Emergency Telephone:** (800) 821-7467

Intended Use: Recommended for vaccination of healthy, susceptible cattle as an aid in the prevention of mastitis caused by *Staphylococcus aureus*.

2

HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Modified bacterin in a liquid saline solution, packaged in 50mL bottle. **Color:** Yellow opaque **Odor:** No data available



WARNING! Allergic reactions can occur. For use in cattle only. Not for human use.

Precautionary Statements

Keep only in original container. Keep at a temperature between 2 - 7°C. Do not freeze. Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling. Wear suitable gloves and eye/face protection. Spills: Cover with absorbent or contain. Collect and incinerate. If swallowed, seek medical advice immediately and show this container or label. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Keep out of reach of children. Keep away from food, drink, and animal feedstuffs.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause mild transient eye irritation.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Skin

OSHA Regulatory Status: Non-hazardous (Exempt)

Environment: No data available

3

COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Staphylococcus aureus,			proprietary		
modified bacterin					

The full texts for all R-Phrases are displayed in Section 16, if applicable.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Note to Physician: For animal injection only. Not for human use.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

8

9

7 HANDLING AND STORAGE

Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

Storage: Store at $2^{\circ}-7^{\circ}$ C ($35^{\circ}-45^{\circ}$ F). Do not freeze. Store out of direct sunlight to protect product integrity. Shake well before using.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: None Established

Engineering Controls: Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Respiratory Protection: Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

PHYSICAL AND CHEMICAL PROPERTIES

Color: Yellow opaque
Odor: No data available
Odor Threshold: No data available
Physical State: Modified bacterin in a liquid saline solution, packaged in 50mL bottle.
pH: No data available
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: No data available

Flammability Limit – Upper (%): No data available Flammability Limit – Lower (%): No data available Evaporation rate: No data available Vapor Pressure: No data available Vapor Density (Air=1): No data available Specific Gravity: No data available Solubility: No data available Partition Coefficient (n-Octanol/water): No data available Autoignition Temperature: Not applicable Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Temperatures below 2° C (35° F)

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

11 TOXICOLOGICAL INFORMATION

Lysigin[®] is considered non-toxic.

Specified Substances

Acute Toxicity: No data available

Chronic Toxicity – Possible hypersensitization (development of abnormal sensitivity).

Listed Carcinogens: None listed.

12 ECOLOGICAL INFORMATION

Ecotoxicity: No data available Persistence and degradability: No data available Mobility in soil: No data available Other adverse effects: No data available

Germany WGK: Not applicable.

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

14 TRANSPORT INFORMATION

<u>DOT</u>: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 **REGULATORY INFORMATION**

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Non-controlled, Exempt

Inventory Status

This material is **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, KECI, and NZIoC. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

Canada CEPA Schedule 1 – None listed

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

CERCLA Hazardous Substance List (40 CFR 302.4): None listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None listed.

SARA Title III

Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A): None listed.

Section 311/312 (40 CFR 370): Not Regulated.

Section 313 Toxic Release Inventory (40 CFR 372): None listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.

Massachusetts Right-To-Know List: None listed. Minnesota Hazardous Substances List: None listed. New Jersey Right-To-Know List: None listed. Pennsylvania Right-To-Know List: None listed. Rhode Island Right-To-Know List: None listed.

European Regulations

Austria MAK List (Annex I): None listed. Denmark (Annex 3.6): None listed. Germany (Dangerous Substances Ordinance 2004, Annex III): None listed. Norway (List of Dangerous Substance): None listed. Sweden (Annex 3): None listed. Switzerland (Toxins List 1): None listed.

16 OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	1	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	1	0	N/A
+ G1 1 1 1		1 011 1 0 1 (1		

* - Chronic health effect; 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

EU Symbol and R Phrase Definitions: None listed

ABBREVIATIONS:

- BIV Boehringer Ingelheim Vetmedica, Inc.
- N/A Not applicable
- N/E Not established
- pph parts per hour

References:

- 1. Lysigin[®] MSDS and Label
- 2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
- 3. GHS Manual

Prepared by: Boehringer Ingelheim Vetmedica, Inc. **Issue Date:** 10/12/2011 **Revision Information:** New

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