

SAFETY DATA SHEETS

This SDS packet was issued with item:

078390368

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

078483082



MATERIAL SAFETY DATA SHEET

| | | | |
|---|-------------------------------|--|---|
| IDENTITY | | | |
| Lepto Shield 5 – Bacterin | | Product # 125 | |
| Section I | | | |
| Manufacturer's Name Novartis Animal Health US, Inc. | | Emergency Telephone Number 800-454-3424 | |
| Address (Number, Street, City, State, and Zip Code) | | Telephone Number for Information 800-843-3386 | |
| 1447 140th Street | | Date Prepared November 18, 1992 | Revised Date: May 23, 2013 |
| Larchwood, IA 51241-9778 | | Signature of Preparer (optional) | |
| Section II - Hazardous Ingredients/Identity Information | | | |
| Hazardous Components (Specific Chemical Identity; Common Name(s)) | OSHA PEL | ACGIH TLV | Other limits Recommended % (optional) |
| Thimerosal (merthiolate) | 0.01 mg of Hg/ m ³ | | ≤ 0.01 |
| Thimerosal is an organomercury compound. | | | |
| Formaldehyde | 0.75 ppm | 0.3 ppm | ≤ 0.5 |
| Section III - Physical/Chemical Characteristics | | | |
| Boiling Point | NA | Specific Gravity (H ₂ O = 1) | NA |
| Vapor Pressure (mm Hg.) | NA | Melting Point | NA |
| Vapor Density (AIR = 1) | NA | Evaporation Rate (Butyl Acetate = 1) | NA |
| Solubility in Water Yes | | | |
| Appearance and Odor Opaque liquid | | | |
| Section IV - Fire and Explosion Hazard Data | | | |
| Flash Point (Method Used) NA | Flammable Limits NA | LEL NA | UEL NA |
| Extinguishing Media Dry chemical or carbon dioxide | | | |
| Special Fire Fighting Procedures Wear protective clothing and a self contained breathing apparatus as appropriate for the surrounding fire. | | | |
| Unusual Fire and Explosion Hazards None | | | |

| | | | |
|--|----------------------|---------------------------|--|
| Section V - Reactivity Data | | | |
| Stability | Unstable | | Conditions to Avoid Thimerosal will decompose with heat. |
| | Stable | X | |
| Incompatibility (Materials to Avoid) None | | | |
| Hazardous Decomposition or Byproducts Mercury, carbon monoxide, or carbon dioxide | | | |
| Hazardous Polymerization | May Occur | | Conditions to Avoid None |
| | Will Not Occur | X | |
| Section VI - Health Hazard Data | | | |
| Route(s) of Entry: | Inhalation? | Skin? | Ingestion? |
| | Yes | Yes | Yes |
| Health Hazards (Acute and Chronic) The product may be irritating in the case of skin or eye contact. Thimerosal is a toxic compound. | | | |
| | | | |
| | | | |
| Carcinogenicity: | NPT? | Yes | IARC Monographs? Yes OSHA Regulated? Yes |
| | | | |
| Emergency and First Aid Procedures In case of skin or eye contact, flush with plenty of water. If the product is ingested, wash the mouth out with water and call a physician. In case of accidental injection, wash the puncture site and see a physician immediately. | | | |
| | | | |
| | | | |
| Section VII - Precautions for Safe Handling and Use | | | |
| Steps to Be Taken in Case Material Is Released or Spilled | | | |
| Clean up the spill with absorbent material, and afterwards, wash the site thoroughly with water. | | | |
| | | | |
| Waste Disposal Method This product contains trace quantities of mercury. If discarded in its manufactured form, this product is a hazardous waste under RCRA (U.S.) and CEPA (Canada). It is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a solid or hazardous waste. Always dispose of this product in accordance with all applicable federal, state and local environmental regulations. | | | |
| | | | |
| Precautions to Be Taken in Handling and Storing | | | |
| Refrigerate the product (2° to 7° C) {35° to 45° F}. Keep the container closed when stored, and shake well before using. | | | |
| Other Precautions N/A | | | |
| | | | |
| Section VIII - Control Measures | | | |
| Respiratory Protection (Specify Type) An approved cartridge respirator for large spills | | | |
| Ventilation | Local Exhaust | No | Special NA |
| | Mechanical (General) | Yes | Other NA |
| Protective Gloves Vinyl or nitrile | | Eye Protection Goggles | |
| Other Protective Clothing or Equipment NA | | | |
| Work/Hygienic Practices Take precautions to prevent accidental injections. | | | |

| Section IX - Regulatory Information | |
|--|--|
| Transportation: | UN-Number: FREE (under all transportation regulations) Class: This product is <u>not regulated</u> as a <u>dangerous good</u> when offered for transportation according to US DOT, EUADR, ICAO/IATA, IMDG or ADR/RID regulations. |
| Note: This product contains <u>thimerosal</u> (< 0.01%) | <u>Thimerosal</u> is a mercury compound which is subject to CWA, SDWA, CAA, RCRA, CERCLA, SARA (Secs. 312 and 313), DOT and 29 CFR 1910.1200 regulations. |
| Note: This product contains Formaldehyde | Formaldehyde is subject to SARA (Secs. 312 and 313), CERCLA, and 29 CFR 1910.1048 regulations |

This Material Safety Data Sheet and the information it contains is offered to you in good faith as accurate. We have reviewed any information contained in this data sheet which we received from sources outside our company. We believe that information to be correct but cannot guarantee its accuracy or completeness. Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No statement made in this data sheet shall be construed as a permission or recommendation for the use of any product in a manner that might infringe existing patents. Accordingly, no guarantee expressed or implied is made by Novartis Animal Vaccines, Inc. as to the results to be obtained based upon your use of the information, nor does Novartis Animal Vaccines, Inc. assume any liability arising out of your use of the information.



SAFETY DATA SHEET

1. Identification

Product identifier Lepto Shield 5

Other means of identification

Item Code AV4235

Recommended use Veterinary Vaccine

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company Name Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)

Emergency Telephone: Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973

Email: elanco_sds@elanco.com

Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

| Chemical name | Common name and synonyms | CAS number | % |
|---------------|--------------------------|------------|----------|
| Formaldehyde | | 50-00-0 | <= 0.074 |
| Thimerosal | | 54-64-8 | <= 0.01 |

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

| | |
|---|---|
| Ingestion | Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Get medical attention. |
| Most important symptoms/effects, acute and delayed | None known. |
| General information | If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |

5. Fire-fighting measures

| | |
|--|---|
| Suitable extinguishing media | Use fire-extinguishing media appropriate for surrounding materials. |
| Unsuitable extinguishing media | Not available. |
| Specific hazards arising from the chemical | Not applicable. |
| Special protective equipment and precautions for firefighters | Wear suitable protective equipment. |
| General fire hazards | No unusual fire or explosion hazards noted. |

6. Accidental release measures

| | |
|--|---|
| Personal precautions, protective equipment and emergency procedures | Not available. |
| Methods and materials for containment and cleaning up | Prevent entry into waterways, sewer, basements or confined areas. Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

| | |
|---|---|
| Precautions for safe handling | Observe good industrial hygiene practices. |
| Conditions for safe storage, including any incompatibilities | Store in original tightly closed container. Keep refrigerated Keep refrigerated: ° to ° C (° to ° F). |

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

| Components | Type | Value |
|----------------------------|------|----------|
| Formaldehyde (CAS 50-00-0) | STEL | 2 ppm |
| | TWA | 0.75 ppm |

US. OSHA Table Z-2 (29 CFR 1910.1000)

| Components | Type | Value |
|--------------------------|---------|------------|
| Thimerosal (CAS 54-64-8) | Ceiling | 0.04 mg/m3 |
| | TWA | 0.01 mg/m3 |

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|----------------------------|---------|------------|
| Formaldehyde (CAS 50-00-0) | Ceiling | 0.3 ppm |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m3 |
| | TWA | 0.01 mg/m3 |

US. NIOSH: Pocket Guide to Chemical Hazards

| Components | Type | Value |
|----------------------------|---------|------------|
| Formaldehyde (CAS 50-00-0) | Ceiling | 0.1 ppm |
| | TWA | 0.016 ppm |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m3 |
| | TWA | 0.01 mg/m3 |

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines**US - California OELs: Skin designation**

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards Not available.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties**Appearance**

Physical state Liquid.

Form Liquid

Color Opaque

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

| | |
|--|----------------|
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Not available. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Explosive properties | Not explosive. |
| Oxidizing properties | Not oxidizing. |

10. Stability and reactivity

| | |
|------------------------------------|---|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | No hazardous decomposition products are known. |

11. Toxicological information

Information on toxicological effects

Acute toxicity

| Components | Species | Test Results |
|----------------------------|---------|-----------------------------------|
| Formaldehyde (CAS 50-00-0) | | |
| <u>Acute</u> | | |
| Inhalation | | |
| LC50 | Rat | 10500 mg/m ³ , 4 hours |
| Oral | | |
| LD50 | Rat | 640 mg/kg |
| Thimerosal (CAS 54-64-8) | | |
| <u>Acute</u> | | |
| Oral | | |
| LD50 | Rat | 75 mg/kg |

Skin corrosion/irritation Rabbit: Corrosive. (Formaldehyde)
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Rabbit: Corrosive. (Formaldehyde)
Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

ACGIH sensitization

FORMALDEHYDE (CAS 50-00-0)

Dermal sensitization
Respiratory sensitization

Respiratory sensitization Exposure to formaldehyde may cause respiratory sensitization in some individuals or aggravate pre-existing asthmatic conditions.
Based on available data, the classification criteria are not met.

Skin sensitization May cause an allergic skin reaction. (Formaldehyde)
Based on available data, the classification criteria are not met.

Germ cell mutagenicity Result in genetic toxicity assays (in vitro and in vivo): Mixed results (Formaldehyde)
Based on available data, the classification criteria are not met.

Carcinogenicity May cause cancer. (Formaldehyde)
Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Formaldehyde (CAS 50-00-0)

Cancer

US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0)

Known To Be Human Carcinogen.

Reproductive toxicity

No effects identified in animal studies. (Formaldehyde)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure

May cause respiratory irritation. (Formaldehyde)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure

No significant target organ toxicity reported. (Formaldehyde)
Based on available data, the classification criteria are not met.

Aspiration hazard

Not available.

12. Ecological information

Ecotoxicity

| Components | | Species | Test Results |
|----------------------------|------|--------------------------------------|---------------------|
| Formaldehyde (CAS 50-00-0) | | | |
| Aquatic | | | |
| Acute | | | |
| Crustacea | EC50 | Water flea (Daphnia magna) | 29 mg/l, 48 hours |
| Fish | LC50 | Fathead minnow (Pimephales promelas) | 24.1 mg/l, 96 hours |
| Chronic | | | |
| Fish | NOEC | Medaka, high-eyes (Oryzias latipes) | > 48 mg/l, 28 days |
| Thimerosal (CAS 54-64-8) | | | |
| Aquatic | | | |
| Acute | | | |
| Fish | LC50 | Bullhead, catfish (Ictalurus sp.) | 7.5 mg/l, 24 hours |

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Partition coefficient n-octanol / water (log Kow)

Formaldehyde 0.35

Mobility in soil

No data available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not established.

15. Regulatory information

US federal regulations

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Formaldehyde (CAS 50-00-0) Listed.

SARA 304 Emergency release notification

FORMALDEHYDE (CAS 50-00-0) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Formaldehyde (CAS 50-00-0) Cancer
Skin sensitization
Respiratory sensitization
Eye irritation
Skin irritation
respiratory tract irritation
Acute toxicity
Flammability

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Formaldehyde (CAS 50-00-0)
Thimerosal (CAS 54-64-8)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Formaldehyde (CAS 50-00-0)

US state regulations WARNING: This product contains a chemical known to the State of California to cause cancer.

California Proposition 65**California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Formaldehyde (CAS 50-00-0) Listed: January 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

Thimerosal (CAS 54-64-8) Listed: July 1, 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Formaldehyde (CAS 50-00-0)

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 09-07-2017

Revision date 03-15-2019

Version # 02

List of abbreviations TWA: Time Weighted Average

Disclaimer As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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