

SAFETY DATA SHEETS

This SDS packet was issued with item:

078560714

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

078560722 078908970

1. Identification

| | |
|---|--|
| Product identifier | ReproSTAR L5 HB |
| Other means of identification | |
| Item Code | AV6280 |
| 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 | Aspiration hazard | Category 1 |
| OSHA defined hazards | Not classified. | |

Label elements



| | |
|--|---|
| Signal word | Danger |
| Hazard statement | |
| H304 | May be fatal if swallowed and enters airways. |
| Precautionary statement | |
| Prevention | Not available. |
| Response | |
| P301 + P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor. |
| P331 | Do NOT induce vomiting. |
| Storage | |
| P405 | Store locked up. |
| Disposal | |
| P501 | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Hazard(s) not otherwise classified (HNOC) | Accidental injection may cause local swelling, irritation or necrosis at the injection site. Get medical attention immediately. See also section 4. |
| Supplemental information | None. |

3. Composition/information on ingredients

Mixtures

| Chemical name | Common name and synonyms | CAS number | % |
|-------------------------------|--------------------------|------------|----|
| Mineral Oil Adjuvant SO 3-003 | | Mixture | 20 |

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

Composition comments * Mineral Oil Adjuvant contains up to 92% Light Mineral Oil (CAS 8042-47-5)
 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. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. 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 Aspiration may cause pulmonary edema and pneumonitis. Accidental injection may cause local swelling, irritation or necrosis at the injection site.

Indication of immediate medical attention and special treatment needed In case of accidental self-injection of oil emulsion vaccines, get medical attention immediately.

SEEK IMMEDIATE MEDICAL TREATMENT at nearest Hospital Emergency Room even if only a very small amount is injected, as failure to treat may result in the mineral oil adjuvant causing sterile abscess and/or loss of affected finger or thumb. If pain persists for more than 12 hours after medical examination, seek additional medical advice.

To the Doctor: This product contains mineral oil. Accidental injection with this oil-based product, even in small quantities, can cause intense swelling which may, for example, result in ischaemic necrosis and the loss of a digit. Expert PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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.

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 Use a needle guard to help prevent self-injection. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container.

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-1 Limits for Air Contaminants (29 CFR 1910.1000)

| Components | Type | Value | Form |
|-----------------------------------|------|---------------------|-------|
| Light Mineral Oil (CAS 8042-47-5) | PEL | 5 mg/m ³ | Mist. |

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

| Components | Type | Value |
|--------------------------|---------|------------------------|
| Thimerosal (CAS 54-64-8) | Ceiling | 0.04 mg/m ³ |
| | TWA | 0.01 mg/m ³ |

US. ACGIH Threshold Limit Values

| Components | Type | Value | Form |
|-----------------------------------|---------|------------------------|---------------------|
| Formaldehyde (CAS 50-00-0) | Ceiling | 0.3 ppm | |
| Light Mineral Oil (CAS 8042-47-5) | TWA | 5 mg/m ³ | Inhalable fraction. |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m ³ | |
| | TWA | 0.01 mg/m ³ | |

US. NIOSH: Pocket Guide to Chemical Hazards

| Components | Type | Value | Form |
|-----------------------------------|---------|------------------------|-------|
| Formaldehyde (CAS 50-00-0) | Ceiling | 0.1 ppm | |
| | TWA | 0.016 ppm | |
| Light Mineral Oil (CAS 8042-47-5) | STEL | 10 mg/m ³ | Mist. |
| | TWA | 5 mg/m ³ | Mist. |
| Thimerosal (CAS 54-64-8) | STEL | 0.03 mg/m ³ | |
| | TWA | 0.01 mg/m ³ | |

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 Use a needle guard to help prevent self-injection. 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 | Not available. |
| 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 | |
| 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 | < 20.5 mm ² /s at 40 C |
| 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 May be fatal if swallowed and enters airways.

| Components | Species | Test Results |
|-------------------|----------------|---------------------|
|-------------------|----------------|---------------------|

Formaldehyde (CAS 50-00-0)

Acute**Inhalation**

LC50

Rat

10500 mg/m³, 4 hours

| Components | Species | Test Results |
|---|--|--------------|
| Oral LD50 | Rat | 640 mg/kg |
| Thimerosal (CAS 54-64-8) | | |
| Acute | | |
| Oral LD50 | Rat | 75 mg/kg |
| Skin corrosion/irritation | Rabbit: Corrosive. (Formaldehyde) No skin irritation. (0.1% Thimerosal) Based on available data, the classification criteria are not met. | |
| Serious eye damage/eye irritation | Rabbit: Corrosive. (Formaldehyde) Slight irritation. (0.1% Thimerosal) 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) Risk of sensitization or allergic reactions among sensitive individuals. (Thimerosal) 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) Result in genetic toxicity assays (in vitro and in vivo): Negative (Thimerosal) 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) May damage fertility or the unborn child. (Thimerosal) 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) May cause damage to organs through prolonged or repeated exposure. (Thimerosal) Based on available data, the classification criteria are not met. | |
| Aspiration hazard | May be fatal if swallowed and enters airways. (Mineral oil) | |
| Further information | Accidental injection may cause local swelling, irritation or necrosis at the injection site. | |

12. Ecological information

Ecotoxicity

| Components | Species | Test Results |
|----------------------------|---------|--|
| Formaldehyde (CAS 50-00-0) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| Crustacea | EC50 | Water flea (Daphnia magna) 29 mg/l, 48 hours |
| Fish | LC50 | Fathead minnow (Pimephales promelas) 24.1 mg/l, 96 hours |
| <i>Chronic</i> | | |
| Fish | NOEC | Medaka, high-eyes (Oryzias latipes) > 48 mg/l, 28 days |

| Components | Species | Test Results |
|--------------------------|---------|--|
| Thimerosal (CAS 54-64-8) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| 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 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 09-12-2017

Revision date 04-01-2019

Version # 02

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 MERCHANTABILITY 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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