

SAFETY DATA SHEETS

This SDS packet was issued with item:

078908970

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

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SAFETY DATA SHEET

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/m3	Mist.

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	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm	
Light Mineral Oil (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
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	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm	
	TWA	0.016 ppm	
Light Mineral Oil (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
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 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.
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Decomposition temperature	Not available.
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Viscosity	< 20.5 mm ² /s at 40 C
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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.
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Chemical stability	Material is stable under normal conditions.
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Possibility of hazardous reactions	Hazardous polymerization does not occur.
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Conditions to avoid	Contact with incompatible materials.
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Incompatible materials	Strong oxidizing agents.
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Hazardous decomposition products	No hazardous decomposition products are known.
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11. Toxicological information**Information on toxicological effects**

Acute toxicity	May be fatal if swallowed and enters airways.
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Components	Species	Test Results
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Formaldehyde (CAS 50-00-0)

Acute**Inhalation**

LC50	Rat	10500 mg/m ³ , 4 hours
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Components	Species	Test Results
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) 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			
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 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 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.

For additional information contact:

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