

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078573218

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

078573200



## MATERIAL SAFETY DATA SHEET

### 1 PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Citadel® L5  
**Product No.:** Not applicable  
**MSDS ID#:** B2665.00  
**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 the  
vaccination of healthy, susceptible cattle and  
swine as an aid in the reduction of  
leptospirosis caused by *Leptospira canicola*,  
*L. grippotyphosa*, *L. hardjo*, *L.*  
*icterohaemorrhagiae*, and *L. pomona*.  
Also recommended for the prevention of  
urinary shedding of *Leptospira*  
*borgpetersenii* serovar *hardjo* (type *hardjo-*  
*bovis*) in cattle.

### 2 HAZARDS IDENTIFICATION

#### **Emergency Overview**

**Physical State:** Deactivated bacterin in a liquid saline solution, packaged in 100mL bottle.  
**Color:** Tan to Light Yellow Opaque  
**Odor:** No data available

**DANGER!**

**Contains a component that may cause cancer and target organ damage.**

**Allergic reactions can occur.**

**In vaccines, chronic exposure potential is not expected.**

**For use in cattle and swine only.**

**Not for human use.**

**Precautionary Statements****Prevention:**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Use personal protective equipment as required.

Do not breathe fume/mist/vapors/spray.

**Response:**

If exposed or concerned: Get medical advice/attention.

**Storage:**

Store locked up.

**Disposal:**

Dispose of contents/container according to applicable federal and local regulations.

**Additional 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). Contains formaldehyde and thimerosal. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. Thimerosal is an organic mercury compound preservative found in vaccines. Long-term exposure to mercury compounds may cause damage to the nervous system. In vaccines, the chronic exposure potential is negligible.

**Target Organ(s):** Skin, nervous system

**OSHA Regulatory Status:** Hazardous (Exempt)

**Environment:** No data available

<b>3</b>	<b>COMPOSITION / INFORMATION ON INGREDIENTS</b>
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Chemical Name	EC No.	CAS-No.	Concentration	Classification	Notes
<i>Leptospira canicola</i> , bacterin - deactivated	----	----	proprietary	----	---
<i>Leptospira grippotyphosa</i> , bacterin - deactivated	----	----	proprietary	----	---
<i>Leptospira hardjo</i> , bacterin - deactivated	----	----	proprietary	----	---
<i>Leptospira icterohaemorrhagiae</i> , bacterin - deactivated	----	----	proprietary	----	---
<i>Leptospira pomona</i> , bacterin - deactivated	----	----	proprietary	----	---
Formaldehyde	200-001-8	50-00-0	0.2 %	T; C; C3 R23/24/25, R34, R40, R43	*
Thimerosal	200-210-4	54-64-8	0.1 %	T+; N R26/27/28, R33, R50/53	*

\* Used to inactivate bacterin and subsequently removed from solution. Concentration represents maximum remaining amount by percent weight which is below USDA allowable limits.

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, nitrogen oxides, mercury compounds

#### 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.

<b>7</b>	<b>HANDLING AND STORAGE</b>
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**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°-7° C (35°-45° F). Do not freeze. Store out of direct sunlight to protect product integrity. Shake well before using.

<b>8</b>	<b>EXPOSURE CONTROLS / PERSONAL PROTECTION</b>
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**Exposure Limits:**

Chemical Name	Source	Type	Exposure Limits	Notes
Formaldehyde	ACGIH	Ceiling Exposure Limit	0.3 ppm	Sensitizer, Suspected cancer hazard, Upper respiratory and eye irritation
Formaldehyde	OSHA	Action Level	0.5 ppm	Cancer-suspect agent
Formaldehyde	OSHA	TWA	0.75 ppm	----
Formaldehyde	OSHA	STEL	2 ppm	----
Thimerosal (as Mercury, alkyl compounds, as Hg)	ACGIH	TWA	0.01 mg/m <sup>3</sup>	CNS & PNS impairment, Kidney damage
Thimerosal (as Mercury, alkyl compounds, as Hg)	ACGIH	STEL	0.03 mg/m <sup>3</sup>	----
Thimerosal (organo (alkyl) mercury)	OSHA	TWA	0.01 mg/m <sup>3</sup>	----
Thimerosal (organo (alkyl) mercury)	OSHA	Ceiling Limit	0.04 mg/m <sup>3</sup>	----

Where lower governmentally imposed exposure limits exist, such limits should take precedence.

**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

<b>9</b>	<b>PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Color:** Tan to Light Yellow Opaque

**Odor:** No data available

**Odor Threshold:** No data available

**Physical State:** Deactivated bacterin in a liquid saline solution, packaged in 100mL 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

<b>10</b>	<b>STABILITY AND REACTIVITY</b>
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**Stability:** Stable

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

**Incompatible Materials:** Strong oxidizing agents

**Hazardous Decomposition Products:** Nitrogen oxides, mercury compounds

**Possibility of Hazardous Reactions:** Will not occur.

<b>11</b>	<b>TOXICOLOGICAL INFORMATION</b>
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Citadel® L5 is considered non-toxic.

**Specified Substances**

**Acute Toxicity**

Chemical Name	Test Results
Formaldehyde	Administration into the eye (rabbit): 750 ug, Severe Irritant Administration onto the skin (rabbit): 2 mg/24 h, Severe Irritant Oral LD50 (rat): 800 mg/kg Dermal LD50 (rabbit): 630 mg/kg Inhalation LC50 (rat): 0.48 mg/l/4 hours
Thimerosal	Oral LD50 (rat): 75 mg/kg

**Chronic Toxicity** – Possible hypersensitization (development of abnormal sensitivity). Contains formaldehyde and thimerosal. Formaldehyde has a carcinogenic potential and is a known skin and respiratory sensitizer. Thimerosal is an organic mercury compound preservative found in vaccines. Long-term exposure to mercury compounds may cause damage to the nervous system. In vaccines, the chronic exposure potential is negligible.

**Listed Carcinogens:**

Chemical Name	IARC	NTP	OSHA	ACGIH
Formaldehyde	1: Carcinogenic to humans	Known carcinogen	Cancer suspect agent	A2: Suspected Human Carcinogen

<b>12</b>	<b>ECOLOGICAL INFORMATION</b>
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**Ecotoxicity:** No data available

**Persistence and degradability:** No data available

**Mobility in soil:** No data available

**Other adverse effects:** No data available

**Germany WGK:** Formaldehyde ID No: 112; Class 2: water-endangering. Thimerosal: ID No: 872; Class 3: severely water-endangering.

<b>13</b>	<b>DISPOSAL CONSIDERATIONS</b>
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**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



<b>14</b>	<b>TRANSPORT INFORMATION</b>
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**DOT:** Not regulated

**TDG:** Not regulated

**ADR/RID:** Not regulated

**IATA:** Not regulated

**IMDG:** Not regulated

<b>15</b>	<b>REGULATORY INFORMATION</b>
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**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:** D/2/A, 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 –** Formaldehyde; Mercury

**US Regulations**

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

**CERCLA Hazardous Substance List (40 CFR 302.4):**

Component	Reportable Quantity
Formaldehyde	100lbs

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

Formaldehyde

**Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**

Component	Reportable Quantity Code	Reportable Quantity
Formaldehyde	B	100lbs

**SARA Title III**

**Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):**

Component	Reportable Quantity
Formaldehyde	100lbs

**Section 311/312 (40 CFR 370):**

Acute (Immediate)     Chronic (Delayed)     Fire     Reactive     Pressure Generating

**Section 313 Toxic Release Inventory (40 CFR 372):**

Component	CAS No	Weight %
Formaldehyde	50-00-0	0.2

**State Regulations****California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**

Formaldehyde (gas); Thimerosal – Developmental toxin

**Massachusetts Right-To-Know List:** Formaldehyde; Organo(alkyl) mercury**Minnesota Hazardous Substances List:** Formaldehyde; Organo(alkyl) mercury**New Jersey Right-To-Know List:** Formaldehyde; Mercury, alkyl compounds**Pennsylvania Right-To-Know List:** Formaldehyde**Rhode Island Right-To-Know List:** Formaldehyde; Mercury, alkyl compounds**European Regulations****Austria MAK List (Annex I):** Formaldehyde; Mercury, alkyl compounds**Denmark (Annex 3.6):** Formaldehyde**Germany (Dangerous Substances Ordinance 2004, Annex III):** Formaldehyde; Mercury Compounds**Norway (List of Dangerous Substance):** Formaldehyde; Organo(alkyl) mercury**Sweden (Annex 3):** Formaldehyde**Switzerland (Toxins List 1):** Formaldehyde**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

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

**EU Symbol and R Phrase Definitions**

T+ – Very toxic.

T – Toxic

C – Corrosive

C3 – Carcinogen category 3

N – Dangerous for the environment

R26/27/28 – Very toxic by inhalation, in contact with skin and if swallowed

R23/24/25 – Toxic by inhalation, in contact with skin and if swallowed.

R33 – Danger of cumulative effects.

R34 – Causes burns.

R40 – Limited evidence of a carcinogenic effect.

R43 – May cause sensitization by skin contact.

R50/53 – Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

**ABBREVIATIONS:**

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

ppm – parts per million

**References:**

1. Citadel® L5 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.

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