



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Citadel™ VL5
Product No. : Not applicable
MSDS ID# : Not applicable
GHS Product Identifier: Not applicable

Synonyms:

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

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc.
2621 North Belt Hwy
St. Joseph, MO 64506-2002

Emergency Telephone:

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (866) 638-2226

Intended Use: Recommended for the vaccination of healthy, susceptible cattle as an aid in the reduction of infertility, delayed conception, or abortion caused by *Campylobacter fetus* var *venerealis* and leptospirosis caused by *Leptospira canicola*, *L. grippotyphosa*, *L. hardjo*, *L. icterohaemorrhagiae*, and *L. pomona*.

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Inactivated Vaccine- Liquid, Vial of 10 doses / 20 mL and 50 doses / 100 mL
Color: Tan to light brown opaque
Odor: No data available



WARNING!

For use in cattle only.

Not for human use.**Allergic reactions can occur.****Precautionary Statements:**

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Keep at a temperature between 2 - 7° C.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

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.

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.

If swallowed, seek medical advice immediately and show this container or label.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Description:

Recommended for the vaccination of healthy, susceptible cattle against infertility, delayed conception or abortion caused by *Campylobacter fetus* and leptospirosis caused by *Leptospira canicola*, *L. grippityphosa*, *L. hardjo*, *L. icterohaemorrhagiae*, and *L. pomona*.

Vaccine is to be given 2 mL subcutaneously using aseptic technique. Repeat in 14 to 28 days. Calves revaccinated before 6 months of age should be revaccinated at 6 months or at weaning. A 2 mL booster dose is recommended annually.

Acute effect: Rarely, severe allergic reactions may occur that require immediate veterinary care. Antidote: Epinephrine.

Precautions/Contraindications: Do not vaccinate within 21 days before slaughter.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur but are rare.

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): Reproductive System

Potential Physical Effects: Can cause skin sensitization.

OSHA Regulatory Status: Nonhazardous, exempt

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
<i>Campylobacter Fetus- Leptospira Canicola- Grippytyphosa-Hardjo- Icterhaemorrhagiae- Pomona Bacterin (Inactivated Vaccine)</i>	----	----	proprietary	----	---
Neomycin	2157663	1404-04-2	proprietary	----	*

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

*Preservative

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 use in cattle only.

Antidote: Epinephrine is indicated for anaphylactoid reactions.

5	FIRE-FIGHTING MEASURES
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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

Flammability Class: 0

6	ACCIDENTAL RELEASE MEASURES
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Personal Precautions: Wear appropriate personal protective equipment. (See Section 8)

Spill Cleanup Methods: Small liquid spill: Use a non-combustible material like vermiculite, earth or sand to soak up the product and place into container for later disposal. Incinerate. For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers. Incinerate.

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

7	HANDLING AND STORAGE
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Handling: Avoid contact with eyes, skin and clothing. Avoid accidental injection. Wash thoroughly with soap and water after handling. Use only with adequate ventilation.

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. Use entire contents when first opened.

8	EXPOSURE CONTROLS / PERSONAL PROTECTION
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For Industrial Exposures:

Exposure Limits: None

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 active ingredient or mixture is likely wear:

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

Hand Protection: Wear suitable gloves.

Skin Protection: Wear protective clothing appropriate for the risk of exposure.

Hygiene Measures: Eye bath, washing facilities, shower

9	PHYSICAL AND CHEMICAL PROPERTIES
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Color: Tan to light brown opaque

Odor: No data available

Odor Threshold: No data available

Physical State: Inactivated Vaccine - Liquid, Vial of 10 doses / 20 mL and 50 doses / 100 mL

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
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Stability: Stable

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

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Will not occur.

11	TOXICOLOGICAL INFORMATION
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Specified Substances

Campylobacter fetus is an opportunistic pathogen that can cause infections such as bacteremia and phlebitis. Human infection is uncommon and is usually limited to debilitated individuals. The virulence mechanisms are unknown.

Acute Toxicity:

Neomycin	Skin Sensitization TCL _o (humans) : 20 pph : dermatitis, allergic Oral LD ₅₀ (rat): 2750 mg/kg
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Listed Carcinogens: None

12	ECOLOGICAL INFORMATION
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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: Not applicable

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

Disposal Methods: Incinerate containers and unused contents. 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
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DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15	REGULATORY INFORMATION
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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: Noncontrolled, 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. In the United States, this product is regulated by the FDA (Food and Drug Administration).

Canada CEPA Schedule 1 - None

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): None

SARA Title III

Section 302Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 311/312 (40 CFR 370): None

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

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

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

State Regulations

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

Massachusetts Right-To-Know List: None

Minnesota Hazardous Substances List: None

New Jersey Right-To-Know List: None

Pennsylvania Right-To-Know List: None

Rhode Island Right-To-Know List: None

European Regulations

Austria MAK List (Annex I): None

Denmark (Annex 3.6, April 2005): None

Germany (Dangerous Substances Ordinance 2004, Annex III): None

Norway (List of Dangerous Substance): None

Sweden (Sensitizers- Annex 3): None

Switzerland (Toxins List 1): None

16	OTHER INFORMATION
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	0	0	N/A

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

R43 - May cause sensitization by skin contact.

S24 - Avoid contact with skin.

S37 – Wear suitable gloves.

ABBREVIATIONS:

BIV - Boehringer Ingelheim Vetmedica, Inc.

N/A - Not applicable

N/E - Not established

pph – parts per hour

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
2. GHS Manual
3. RTECS – Neomycin, QP3850000, Review Date, RTECS No. 200608
4. Citadel™ VL5 Label

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

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