

MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Sedivet[®] 1% Injection **Product No.:** NADA 141-229

MSDS ID#: P98RO658B

GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable

Molecular Weight: Not applicable CAS Number: Mixture, not applicable Chemical Family: Sedative/Analgesic

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: For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures, as well as a preanesthetic prior to the induction of general anesthesia, in adult horses.

HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid **Color:** Colorless

Odor: No data available



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WARNING!

May be harmful if swallowed. Allergic reactions can occur. For use in horses only. Not for human use.

Precautionary 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. May be harmful if swallowed. Exposure may cause vomiting, nausea, dizziness, drowsiness or other systemic effects. Sedatives cause respiratory depression which if not monitored, can cause death.

Injection: Swelling at injection site may occur.

Chronic Health Effects: Can produce prolonged sedation and muscle tremors when given in excessive amounts or when given to sensitive animals.

Target Organ(s): Central nervous system, skin

OSHA Regulatory Status: Hazardous (exempt)

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Romifidine		65896-14-2	1%	Xn; R22	
Hydrochloride					
Chlorocresol	200-431-6	59-50-7	0.2%	Xn, N;	
				R21/22, R41,	
				R43, R50	

Components not listed are not hazardous or are below reportable 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, hydrogen chloride, hydrogen fluoride, hydrogen bromide.

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.

7 HANDLING AND STORAGE

Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

Storage: Keep only in the original container. Store at 20° - 25° C (68° - 77° F). Store out of direct sunlight. Store away from foodstuffs.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: None Established.

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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

PHYSICAL AND CHEMICAL PROPERTIES

Color: Colorless

Odor: No data available

Odor Threshold: No data available

Physical State: Liquid **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: 1

Solubility: No data available

Partition Coefficient (n-Octanol/water): No data available

Autoignition Temperature: Not data available **Decomposition Temperature:** No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Excessive heat, freezing.

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Carbon oxides, nitrogen oxides, hydrogen chloride,

hydrogen fluoride, hydrogen bromide.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity:

Chemical Name	Test Results
Romifidine Hydrochloride	Oral (rat)LD50: 255 mg/kg
Chlorocresol	Oral (rat) LD50: 1830 mg/kg

Chronic Health Effects: Can produce prolonged sedation and muscle tremors when given in excessive amounts or when given to sensitive animals.

Listed Carcinogens:

Chemical Name	IARC	NTP	OSHA	ACGIH
Chlorocresol	2B: Possibly			
	carcinogenic to			
	humans.			

12 ECOLOGICAL INFORMATION

Ecotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available Other adverse effects: No data available

Germany WGK: Chlorocresol: ID No: 231; Class 2: Water-endangering.

13 DISPOSAL CONSIDERATIONS

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

14 TRANSPORT INFORMATION

<u>DOT</u>: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

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: Non-controlled

Inventory Status

This material is listed on the following inventory: NZIoC

This material is **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, and KECI. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

Canada CEPA Schedule 1 – None listed

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
Chlorocresol	5000 lbs.

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

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

SARA Title III

Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A): None listed.

Section	311	/312	(40	CFD	370).
Section	211	1314	(40	Urk	3/U);

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

Section 313 Toxic Release Inventory (40 CFR 372):

Component	CAS No.	Concentration
Chlorocresol	59-50-7	0.2 %

State Regulations

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

Massachusetts Right-To-Know List: Chlorocresol Minnesota Hazardous Substances List: None listed. New Jersey Right-To-Know List: Chlorocresol Pennsylvania Right-To-Know List: Chlorocresol Rhode Island Right-To-Know List: Chlorocresol

European Regulations

Austria MAK List (Annex I): None listed.

Denmark (Annex 3.6): None listed.

Germany (Dangerous Substances Ordinance 2004, Annex III): Chlorocresol

Norway (List of Dangerous Substance): Chlorocresol

Sweden (Annex 3): Chlorocresol

Switzerland (Toxins List 1): Chlorocresol

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:

Xn – Harmful

Xi – Irritant

N – Dangerous for the environment

R21/22 – Harmful in contact with skin and if swallowed.

R22 – Harmful if swallowed.

R41 – Risk of serious damage to eyes

R43 – May cause sensitization by skin contact

R50 – Very toxic to aquatic organisms

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

ppm – parts per million

References:

- 1. Sedivet[®] 1% Injection 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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