

MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ventipulmin[®] Syrup

Product No.: Not applicable **MSDS ID#:** Not Available

GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable Molecular Weight: Mixture, not applicable CAS Number: Mixture, not applicable Chemical Family: Adrenergic amine

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 the management of horses affected with airway obstruction, such as chronic obstructive pulmonary disease (COPD).

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid Color: Light yellow Odor: Alcohol like







WARNING! Combustible liquid.

For use in horses only.

Not for human use.

Precautionary Statements:

Prevention:

Keep away from heat/sparks/flames/hot surfaces – No smoking.

Wear protective gloves/eye protection/face protection.

Response:

In case of fire: Use water spray/dry chemical/carbon dioxide/foam to extinguish.

Storage:

Store in a well-ventilated place. Keep cool.

Disposal:

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

Additional statements:

Keep only in original container.

Keep at a temperature between 15°-30°C.

Keep from freezing.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

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.

Spills: Absorb spilled substance with inert material and sweep into appropriate waste containers.

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 eye irritation.

Skin Contact: Not expected to be a hazard to the skin with prescribed use. May cause skin irritation. May cause skin sensitization by contact.

Ingestion: Ingestion may cause cardiovascular effects such as elevated pulse rate, blood pressure changes and/or ECG changes and other systemic effects.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Central nervous system, cardio vascular system.

OSHA Regulatory Status: Hazardous (Exempt)

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical Name | EC No. | CAS- No. | Concentration | Classification | Notes |
|----------------------|-----------|------------|---------------|----------------|-------|
| Polyethylene Glycol | 500-038-2 | 25322-68-3 | 9.1 % | | |
| 400 (PEG 400) | | | | | |
| Ethyl alcohol | 200-578-6 | 64-17-5 | 5 % | F; R11 | |
| Glycerin | 200-289-5 | 56-81-5 | 4.5455 % | | |
| Clenbuterol | 244-643-7 | 21898-19-1 | 0.0023% | T; R25 | |
| hydrochloride | | | | | |

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: Wash with soap and water. Get medical attention if symptoms occur.

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

Note to Physician: For animal use only. Not for human use. Treatment for Clenbuterol HCl overdose should be symptomatic and supportive.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with water spray, dry chemical, carbon dioxide, foam.

Unsuitable Extinguishing Media: None known

Protective Equipment for Firefighters: Wear self-contained breathing apparatus (SCBA) and full protective gear including helmet with face shield, coat, pants, boots, and gloves.

Special Fire Fighting Procedures: In the event of a fire, do not breathe fumes. Use water spray to cool unopened containers. Move exposed containers from fire area if you can do so without risk.

Unusual Fire & Explosion Hazards: Combustible liquid and vapor.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, hydrogen chloride.

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Eliminate all sources of ignition. No smoking. 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: Do not use near fire, sparks, or any other open flame. Avoid contact with eyes, skin or clothing. Use with adequate ventilation. Wash hand thoroughly after handling.

Storage: Keep only in the original container. Store at 15°-30° C (59°-86° F). Store out of direct sunlight. Keep from freezing. Store away from foodstuffs.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

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| Chemical Name | Source | Type | Exposure Limits | Notes |
|----------------------|--------|-------------|------------------------|-------------|
| Glycerin Mist | ACGIH | TWA | 10 mg/m3 | Upper |
| | | | | respiratory |
| | | | | irritation |
| Glycerin Mist, | OSHA | PEL | 5 mg/m3 | |
| Respirable fraction | | | | |
| Glycerin Mist, Total | OSHA | PEL | 15 mg/m3 | |
| dust | | | | |
| Ethyl alcohol | ACGIH | STEL | 1000 ppm | Upper |
| | | | | respiratory |
| | | | | irritation |
| Ethyl alcohol | OSHA | PEL | 1000 ppm | |
| Polyethylene Glycol | AIHA | WEELs | 10 mg/m3 | |
| (as a particulate) | | | | |
| Clenbuterol | BIEL* | TWA | $1 \mu g/m^3$ | Category: |
| hydrochloride | | | | 3B |
| Clenbuterol | BIEL* | STEL | $8 \mu g/m^3$ | |
| hydrochloride | | (15 minute) | | |
| Clenbuterol | BIEL* | STEL | $4 \mu g/m^3$ | |
| hydrochloride | | (1 hour) | | |

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.

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Light yellow Odor: Alcohol like

Odor Threshold: 100 ppm; highest known value (Ethyl alcohol)

Physical State: Liquid pH: No data available

Melting Point: May solidify at 17.9°C (64.2°F) based on data for Glycerin **Freezing Point:** May solidify at 17.9°C (64.2°F) based on data for Glycerin **Boiling Point:** 78.5°C (173.3°F); lowest known value (Ethyl alcohol)

Flash Point: $> 37.8^{\circ}\text{C} (> 100^{\circ}\text{F})$

Flammability Limit – Upper (%): No data available Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: 43 mm of Hg @ 20°C; highest known value (Ethyl alcohol)

Vapor Density (Air=1): 3.17; highest known value (Glycerin)

Specific Gravity: 1.09 **Solubility:** No data available

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

Autoignition Temperature: No 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

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity:

| Chemical Name | Test Results | |
|---------------------------|--|--|
| Clenbuterol hydrochloride | Oral (rat) LD50: 159 mg/kg | |
| Glycerin | Administration into eye, rabbit; 500 mg/24H; Mild irritant | |
| | Administration onto skin, rabbit; 500 mg/24H; Mild irritant | |
| | Oral (rat) LD50: 12600 mg/kg | |
| Ethyl alcohol | Administration into eye, rabbit; 100 uL; Moderate irritant | |
| | Administration onto skin, rabbit; 20 mg/24H; Moderate irritant | |
| | Oral (rat) LD50: 7000 mg/kg | |
| | Dermal (rabbit) LD50: 20000 mg/kg | |
| | Inhalation (rat) LC50: 5900 mg/m ³ /6H | |
| Polyethylene glycol 400 | Administration into the eye, rabbit; 500 mg; mild irritant | |
| | Oral LD50 (rat): > 30 gm/kg | |
| | Dermal LD50 (rabbit): > 20 gm/kg | |

Chronic Toxicity: Possible hypersensitization (development of abnormal sensitivity).

Listed Carcinogens: Ethanol used in alcoholic beverages is an IARC carcinogen.

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: Glycerin ID No: 116; Class 1: slightly water-endangering. Ethyl alcohol ID

No: 96; Class 1: slightly 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

DOT: 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: B/3, D/2/B, Exempt

Inventory Status

This material is listed on the following inventories: AICS, EINECS, DSL, and NZIoC.

This material is **not** listed on the following inventories: TSCA, 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): None listed.

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 CFR 370):

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

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

State Regulations

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

Massachusetts Right-To-Know List: Glycerin; Ethyl alcohol

Minnesota Hazardous Substances List: Glycerin; Ethyl alcohol; Polyethylene glycol.

New Jersey Right-To-Know List: Glycerin; Ethyl alcohol Pennsylvania Right-To-Know List: Glycerin; Ethyl alcohol Rhode Island Right-To-Know List: Glycerin; Ethyl alcohol

European Regulations

Austria MAK List (Annex I): Ethyl alcohol; Polyethylene glycol

Denmark (Annex 3.6): None listed.

Germany (Dangerous Substances Ordinance 2004, Annex III): Ethyl alcohol

Norway (List of Dangerous Substance): Ethyl alcohol.

Sweden (Annex 3): None listed.

Switzerland (Toxins List 1): Glycerin; Ethyl alcohol; Polyethylene glycol

16 OTHER INFORMATION

Hazard Ratings

| | Health Hazard | Fire Hazard | Reactivity Hazard |
|------|---------------|-------------|-------------------|
| HMIS | 2 | 2 | 0 |

| | Health Hazard | Fire Hazard | Reactivity Hazard | Special Hazard |
|------|---------------|-------------|-------------------|----------------|
| NFPA | 2 | 2 | 0 | N/A |

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

EU Symbol and R Phrase Definitions:

F – Highly flammable

T-Toxic

R11 – Highly flammable

R25 – Toxic if swallowed

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E - Not established

pph – parts per hour

ppm - parts per million

References:

1. Ventipulmin[®] Syrup 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.

Issue Date: 4/30/2012

Revision Information: 11/1/2011

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