



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ventipulmin® Syrup
Product No.: NADA 140-973
GHS Product Identifier: Not applicable

Synonyms: Not available
Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: beta-2-adrenergic agonist

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

Emergency Telephone:
Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (800)530-5432

Intended Use: Oral bronchodilator for the management of horses affected with airway obstruction, such a chronic obstructive pulmonary disease (COPD).

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid, syrup
Color: Clear to light yellow
Odor: Alcohol-like



WARNING!
Harmful if swallowed
Equine use only.
Not for human use.

Precautionary Statements:

Keep away from heat, sparks and flame.

Do not use or store near heat or open flame.

Keep at a temperature not exceeding 30° C.

Keep only in original container.

Keep container closed.

Fire-fighting: Use water spray, dry chemical, carbon dioxide, foam

Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Use non-sparking equipment when picking up flammable spill. Remove ignition sources. 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.

In case of contact with eyes, directly, flush with gently flowing fresh water thoroughly.

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.

Acute effect:

Ventipulmin® Syrup was shown to be safe and effective for management of COPD in horses when used according to the recommended regimen of incremental dose titration to effect. Ventipulmin® Syrup relieves reversible bronchospasm arising from a variety of respiratory conditions. Ventipulmin® Syrup increases mucous secretions for improved airway resistance and improves mucociliary transport by decreasing thickness of mucous.

Precautions/Contraindications:

The reproduction effect in breeding stallions and brood mares has not been determined.

Ventipulmin® Syrup antagonizes the effects of prostaglandin F₂ alpha and oxytocin and should not be used in pregnant mares near term. Because tachycardia may occur, Ventipulmin® Syrup should not be used in horses suspected of having cardiovascular problems.

Overdosage:

Overdose can cause increased heart rate, nausea, tachycardia, sweating and other significant cardiovascular effects.

ADVERSE REACTIONS TO PRODUCT: Clenbuterol, like other beta adrenergic agonists, can product significant cardiovascular effects as evidenced by elevated pulse rate, blood pressure changes and/ or ECG changes. Mild sweating, muscle tremor, restlessness, urticaria and tachycardia may be observed in some horses during the first few days of treatment. May cause elevated creatine kinase (CK) serum levels. Ataxia was observed in 3 out of 239 horses (1.3%) in clinical studies.

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. Contact with eye may cause transient irritation.

Skin Contact: Can cause hypersensitive reactions.

Ingestion: Harmful. 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): Respiratory System, Cardiovascular System

Potential Physical Effects: Mild sweating, muscle tremor, restlessness, urticaria and tachycardia.

OSHA Regulatory Status: Exempt, FDA Regulated.

Environment: No data available.

3	COMPOSITION / INFORMATION ON INGREDIENTS
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Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Ethyl Alcohol	2005786	64-17-5	5.0	F, R11	----
Glycerin	2002895	56-81-5	4.5	----	----
Clenbuterol HCl	2533660	37148-27-9	.0723	R43	Denmark
Carbomer 934P, NF	----	57916-92-4	proprietary	----	----
Methylparaben	2027857	99-76-3	proprietary	----	----
Propylparaben	2023077	94-13-3	proprietary	----	----
Polyethylene glycol	76960	25322-68-3	proprietary	----	----
Sucrose	2003349	57-50-1	proprietary	----	----
Trolamine, N.F.	2030498	102-71-6	proprietary	R43	Denmark
Water	2317912	7732-18-5	proprietary	----	----

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

4	FIRST AID MEASURES
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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

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

Unusual Fire & Explosion Hazards: Combustible liquid and vapor

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, hydrochloric acid gas

Flammability Class: 2

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 LIQUID IS SPILLED: Eliminate all ignition sources. Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. 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 LIQUID: Avoid contact with eyes, skin or clothing. Absorb spilled liquid and collect for disposal. Wash hand thoroughly after handling.

Storage: Keep only in the original container. Safety cap should be placed on the bottle when not in use. Store at a controlled room temperature 15°-30° C (59°-86° F). Keep from heat and flame. Keep from freezing. Store away from foodstuffs.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Carbomer 934P, N.F.	----	----	N/A	----
Clenbuterol HCl	Harmonized Exposure Limit	TWA	0.14 ug/m ³	----
Ethyl alcohol	ACGIH	8-HR TWA	1000 ppm	Irritation
Ethyl alcohol	OSHA Z-1	PEL	1000 ppm	----
Ethanol (Ethyl Alcohol)	Alberta	8-HR TWA	1000 ppm	Irritation
Ethanol	British Columbia	8-HR TWA	1000 ppm	----
Ethanol	Ontario	8-HR TWA	1000 ppm	----
Ethyl Alcohol	Quebec	8-HR TWA	1000 ppm	----
Ethanol	Austria MAK List	TWA	1000 ml/m ³	----
Ethyl alcohol	Belgium	8-HR TWA	1000 ppm	----
Ethanol	Denmark	TWA	1000 ppm	----
Ethanol	Finland	8-HR TWA	1000 ppm	----
Ethanol	France	TWA	5000 ppm	----
Ethanol	Germany	Limit Value	500 ml/m ³	Short term exposure classification category : II
Ethanol	Greece	8-HR TWA	1000 ppm	----
Ethanol	Iceland	8-HR TWA	1000 ppm	----
Ethanol	Italy	8-HR TWA	1000 ppm	----
Ethanol	Netherlands	MAC TWA	500 ppm	----
Ethanol	Portugal	8-hr Exposure Limit	1000 ppm	----
Ethanol	Spain	8-hr VLA-ED (Daily Exposure Limit)	1000 ppm	----
Ethanol	Sweden	NGV (Level Limit Value)	500 ppm	----
Ethanol	Switzerland	TWA	500 ppm	----
Ethanol	United Kingdom	TWA	1000 ppm	----
Glycerin Mist	ACGIH	8-HR TWA	10 mg/m ³	----
Glycerin Mist, Respirable Fraction	OSHA Z-1	PEL	5 mg/m ³	----
Glycerin Mist, Total Dust	OSHA Z-1	PEL	15 mg/m ³	----
Glycerin mist	Alberta	8-HR TWA	10 mg/m ³	----
Glycerin – mist	British Columbia	8-HR TWA	10 mg/m ³	----
Glycerin mist	Ontario	8-HR TWA	10 mg/m ³	----
Glycerin (mist)	Quebec	8-HR TWA	10 mg/m ³	----

Glycerina, niebla	Mexico	TWA	10 mg/m ³	----
Glycerin	Belgium	8-HR TWA	10 mg/m ³	----
Glycerin	Finland	8-HR Limit	20 mg/m ³	----
Glycerin	France	TWA	10 mg/m ³	----
Glycerin (anhydrous)	Greece	8-HR TWA	10 mg/m ³	----
Glycerol, Mist	Ireland	8-hour TWA	10 mg/m ³	----
Glycerin Mist	Italy	8-hour TWA	10 mg/m ³	----
Glycerol	Netherlands	MAC TWA	10 mg/m ³	----
Glycerin	Portugal	8-hr Exposure Limit	10 mg/m ³	----
Glycerin	Spain	8-hr VLA-ED (Daily Exposure Limit)	10 mg/m ³	----
Glycerol, Mist	United Kingdom	TWA	10 mg/m ³	----
Methylparaben	----	----	N/A	----
Propylparaben	----	----	N/A	----
Polyethylenglykole (mittlere molmassee 200- 400), einatembare fraction	Austria	8-HR TWA	1000 mg/m ³	----
Polyethyleneglycol (PEG) med middelmolvaeGT på	Denmark	8-HR	1000 mg/m ³	----
Polyethylenglydol 600 (PEG 600)	Germany	Limit Value	1000 mg/m ³	----
Polyethyleenglycol (Mol.Gew.200- 600)	Netherlands	MAC TWA (TGG)	1000 mg/m ³	----
Sucrose	ACGIH	8-HR TWA	10 mg/m ³	Lung
Sucrose, respirable fraction	OSHA Z-1	PEL	5 mg/m ³	----
Sucrose, total dust	OSHA Z-1	PEL	15 mg/m ³	----
Sucrose	Alberta	8-HR TWA	10 mg/m ³	----
Sucrose (respirable fraction)	British Columbia	8-HR TWA	3 mg/m ³	----
Sucrose (total dust)	British Columbia	8-HR TWA	10 mg/m ³	----
Sucrose (total dust)	Ontario	8-HR TWA	10 mg/m ³	----
Sucrose	Quebec	8-HR TWA	10 mg/m ³	----
Sucrose	Belgium	8-HR TWA	10 mg/m ³	----
Saacharose	France	VME	10 mg/m ³	----
Sucrose	Ireland	8-HR OEL	10 mg/m ³	----
Saccarosio	Italy	8-HR TWA	10 mg/m ³	----
Saccharose	Netherland	MAC TWA	10 mg/m ³	----
Sacarose	Portugal	8-HR TWA	10 mg/m ³	----

Sacrosa	Spain	8-hr VLA-ED (Daily Exposure Limit)	10 mg/m ³	----
Sucrose	United Kingdom	TWA	10 mg/m ³	----
Triethanolamine	ACGIH	8-HR TWA	5 mg/m ³	Irritation; liver; kidney
Triethanolamine	Alberta	8-HR TWA	5 mg/m ³	Irritation effect
Triethanolamine	British Columbia	8-HR TWA	5 mg/m ³	----
Triethanolamine	Ontario	8-HR TWA	3.1 mg/m ³	----
Triethanolamine	Quebec	8-HR TWA	5 mg/m ³	----
Triethanolamin, einatembare fraction	Austria	TWA	5 mg/m ³	Sensitizer
Tri-ethanolamine	Belgium	8-HR TWA	5 mg/m ³	----
Triethanolamin	Denmark	TWA	3.1 mg/m ³	----
Triethanolamine	Iceland	8-HR TWA	5 mg/m ³	Allergenic substance
Triethanolamine	Ireland	8-HR TWA	5 mg/m ³	----
Triethanolamine	Italy	8-HR TWA	5 mg/m ³	----
Triethanolamine	Netherlands	MAC TWA (TGG)	5 mg/m ³	----
Triethanolamina	Portugal	8-HR TWA	5 mg/m ³	----
Triethanolamina	Spain	8-hr VLA-ED (Daily Exposure Limit)	5 mg/m ³	----
Triethanolamin	Sweden	NGV (Level Limit Value)	5 mg/m ³	----

Engineering Controls: Not generally required when handling containers or liquid. (See exposure limits). Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions.

Respiratory Protection: Not generally required when handling containers or liquid. 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 air-purifying respirator with an appropriate, government approved (where applicable), air-purifying filter, cartridge, or canister.

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: It is a good industrial hygiene practice to minimize skin contact.

Hygiene Measures: Eye bath, washing facilities

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear to light yellow

Odor: Alcohol-like

Odor Threshold: 100 ppm (ethyl alcohol)

Physical State: Liquid, syrup

pH: No data available

Melting Point: 17.9° C (64.2° F) (glycerin)

Freezing Point: No data available

Boiling Point: 78.5° C (173.3° F) (ethyl alcohol)

Flash Point: 43.3° C (110° F)

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: 43 mmHg (ethyl alcohol)

Vapor Density (Air=1): 3.17 (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: Heat

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, hydrochloric acid gas

Possibility of Hazardous Reactions: Hazardous polymerization will not occur

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Clenbuterol HCl	Intravenous LD ₅₀ (mouse): 27,600 µg/kg Oral LD ₅₀ (rat): 315 mg/kg

	Oral LD ₅₀ (dog): 67 mg/kg
Ethyl Alcohol	Eye Irritation (rabbit): 500 mg – severe irritation Skin Irritation (rabbit): 20 mg/24H – moderate irritation Inhalation (rat) LC ₅₀ : 20000 ppm/10H Oral LD ₅₀ (guinea pig) : 5560 mg/kg
Glycerol	Eye Irritation (rabbit): 126 mg – mild irritation Skin Irritation (rabbit): 500 mg/24H – mild irritation Oral LD ₅₀ (rat) : 12,600 mg/kg Oral LD ₅₀ (mouse) : 4090 mg/kg Dermal LD ₅₀ (rabbit): > 10 gm/kg

Listed Carcinogens

Chemical Name	IARC	NTP	OSHA	ACGIH
Ethanol	I (Inadequate data - animals; Sufficient data – humans)	Known carcinogen (alcoholic beverage consumption)	Not listed	Not listed

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: Ethanol: ID No: 96; Class 1: slightly water-endangering; Glycerin: ID No: 116; Class 1: slightly water-endangering; Triethanolamine: ID No: 201; Class 1: slightly water-endangering; Methylparaben: ID No: 3413; Class 1: slightly water-endangering; Propylparaben: ID No: 6054; Class 1: slightly water-endangering; Polyethylene Glykol: ID No: 279; Class 1: slightly water-endangering

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state and federal 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 storage disposal.

RCRA Information: EPA Hazardous: D001 (ethyl alcohol)

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14 TRANSPORT INFORMATION

DOT: Not regulated

Special provision 49 CFR 173.150 (e) - Aqueous solution containing greater than 50% water and less than 24% alcohol.

TDG: Not regulated

Alcohol/water solutions exempt if the ethanol range is 0-50%.

ADR/RID: Not regulated

Aqueous solutions of ethyl alcohol and alcoholic beverages containing not more than 24% alcohol by volume are not subject to the provisions of the ADR.

IATA: Not regulated

Special provision A58. Ethanol aqueous solutions containing 24% or less alcohol by volume.

IMDG: Not regulated

Special provision 144. Aqueous solutions containing 24% or less ethanol by volume.

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: Noncontrolled, exempt

Inventory Status

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

This material is **not** listed on the DSL Inventory.

US Regulations

FEDERAL LAW PROHIBITS EXTRA LABEL USE OF THIS DRUG IN FOOD ANIMALS.

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
Ethyl alcohol (Generic RCRA Waste No. D001)	100

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Ethyl alcohol in alcoholic beverages

Massachusetts Right-To-Know List: Denatured alcohol, ethanol, ethyl alcohol; Glycerin mist

Minnesota Hazardous Substances List: Ethanol; Glycerin mist

New Jersey Right-To-Know List: Ethanol

Pennsylvania Right-To-Know List: Ethanol; 1,2,3-Propanetriol

Rhode Island Right-To-Know List: Ethanol; Glycerin mist; Glycerol

European Regulations

Denmark: The MAL-factor Ethanol - 7 m3 air/10g substance. (The MAL-factor applies to concentrations > 0% by weight)

Netherlands: Ethanol: Fertility Risk Category: 1

Switzerland Toxins List 1: 1, 2,3-Propantriol

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

Mixture -

R10 – Flammable

R43- Irritant

S24 - Avoid Contact with skin.

S37 – Wear suitable gloves.

From Section 3

F- Flammable

R11-Highly Flammable

R43- Irritant

S24 - Avoid Contact with skin.

S37 - Wear suitable gloves.

ABBREVIATIONS:

BIV - Boehringer Ingelheim Vetmedica, Inc.

AIHA- American Industrial Hygiene Association

mppcf – million particles/cubic foot

N/A - Not applicable

N/E - Not established

References:

1. Freedom of Information Summary. NADA 140-973. VENTIPULMIN® Syrup Boehringer Ingelheim Vetmedica, Inc. May 11, 1998. www.fda.gov
2. VENTIPULMIN® Syrup. Product Reference Information. Boehringer Ingelheim Vetmedica, Inc. www.bi-vetmedica.com
3. Federal Register. Vol 63, No. 149, Tuesday, August 4, 1998/ Rules and Regulations
4. FDA Veterinarian. July/August 1998. Vol. III, No. IV
5. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
6. RTECS – Benzenemethanol, 4-amino-3,5-dichloro-alpha-(((1,1-dimethylethyl)amino)methyl)-
7. RTECS – Ethyl alcohol. RTECS No. KQ6300000.

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8. RTECS – Glycerol. RTECS No.MA8050000.
 9. GHS Manual

Revision Information: Updated all sections of the MSDS for ANSI, GHS and OSHA Compliance.

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 07/05/06

Supersedes Date: 5/31/05

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