



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ventipulmin Gel
Product No.: P140-973EUR
GHS Product Identifier: Not applicable
Synonyms: No data available

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: Bronchodilator veterinary
drug

2 HAZARDS IDENTIFICATION

US GHS Classification

Physical Hazards

| Hazard Classification | Hazard Category |
|-----------------------|-----------------|
| Flammable Liquids | Category 3 |

Health Hazards: Not classified as hazardous.

US GHS Label Elements

Signal Word: WARNING!

Symbol(s):

Hazard Statements: Flammable liquid and vapor.

Precautionary Statement(s):**General:**

If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read label before use.

Prevention:

Keep away from heat/sparks/open flames/hot surfaces – No smoking.
Keep container tightly closed.
Ground/bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Wear protective gloves/protective clothing/eye protection/face protection.

Response:

In case of fire: Use water spray, carbon dioxide, dry chemical or alcohol foam to extinguish.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Storage:

Store in a well-ventilated place. Keep cool.

Disposal:

Dispose of contents/container to in accordance with applicable local authority requirements.

OSHA Regulatory Status: Hazardous (exempt)

Environment: Not classified as hazardous.

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| 3 | COMPOSITION / INFORMATION ON INGREDIENTS |
|----------|---|

| Chemical Name | EC No. | CAS- No. | Concentration | Classification | Notes |
|---------------------------|-----------|------------|---------------|----------------|-------|
| Ethyl alcohol | 200-578-6 | 64-17-5 | 5 % | F; R11 | ---- |
| Glycerin | 200-289-5 | 56-81-5 | 4.5455 % | ---- | ---- |
| Clenbuterol hydrochloride | 244-643-7 | 21898-19-1 | 0.0023% | T; R25 | ---- |

Components not listed are not hazardous or are below reportable limits.

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

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.

Skin Contact: Wash with soap and water. If skin irritation or rash occurs, get medical attention. 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.

Note to Physician: Not for human use.

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. Fight fire from a protected location. Use water spray to keep fire-exposed containers cool.

Unusual Fire & Explosion Hazards: Vapors may cause a flash fire or ignite explosively. Vapors may travel to a source of ignition and flashback. Prevent build-up of vapors or gases to explosive concentrations.

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

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: Eliminate all ignition sources. 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.

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| 7 | HANDLING AND STORAGE |
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Handling: HANDLING SIGNIFICANT QUANTITIES OF LIQUID: Avoid contact with eyes, skin or clothing. 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.

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| 8 | EXPOSURE CONTROLS / PERSONAL PROTECTION |
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Exposure Limits:

| Chemical Name | Source | Type | Exposure Limits | Notes |
|------------------------------------|--------|------|----------------------|------------------------------|
| Glycerin Mist | ACGIH | TWA | 10 mg/m ³ | Upper respiratory irritation |
| Glycerin Mist, Respirable fraction | OSHA | PEL | 5 mg/m ³ | ---- |
| Glycerin Mist, Total dust | OSHA | PEL | 15 mg/m ³ | ---- |
| Ethyl alcohol | ACGIH | STEL | 1000 ppm | Upper respiratory irritation |
| Ethyl alcohol | OSHA | PEL | 1000 ppm | ---- |

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°C (> 100°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: Elevated temperatures, sparks, flame and ignition sources

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Carbon dioxide, carbon monoxide, 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:

| Chemical Name | IARC | NTP | OSHA | ACGIH |
|--------------------------------|----------------------------------|----------------------|------|---|
| Ethanol in alcoholic beverages | Group 1 – Carcinogenic to humans | NTP Known carcinogen | ---- | ---- |
| Ethanol | ---- | ---- | ---- | A3 – Confirmed animal carcinogen with unknown relevance 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: 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: Incinerate the material under controlled conditions in an approved incinerator. 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. If discarded, this product is considered a RCRA ignitable waste.

RCRA Information: Not applicable.

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| 14 TRANSPORT INFORMATION |
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DOT: Not regulated according to the 49 CFR 173.150 (e).

TDG: Not regulated according to the TDG Regulation Special Provision 144.

ADR/RID: Not regulated according to the ADR Special Provision 144.

IATA: Not regulated according to the IATA Special Provision A58.

IMDG: Not regulated according to the IMDG Special Provision 144.

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| 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: B/3, D/2/B

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 KECL. 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):

| | | | | |
|--|---|--|-----------------------------------|---|
| <input checked="" type="checkbox"/> Acute (Immediate) | <input type="checkbox"/> Chronic (Delayed) | <input checked="" type="checkbox"/> Fire | <input type="checkbox"/> Reactive | <input type="checkbox"/> Pressure 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

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

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

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| 16 | OTHER INFORMATION |
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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.

AIHA – American Industrial Hygiene Association

mppcf – million particles/cubic foot

N/A – Not applicable.

N/E – Not established.

References:

1. Ventipulmin Gel MSDS and Label.
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

Revision Information: New MSDS

Prepared by: Boehringer Ingelheim Vetmedica, Inc.
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