SAFETY DATA SHEETS

This SDS packet was issued with item:

078015787

N/A



MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Acarexx® (0.01% Ivermectin) Otic Suspension

Product No.: Not available

GHS Product Identifier: Not applicable

Synonyms: Ivermectin Otic Suspension Molecular Formula: Mixture, not applicable

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

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Highway St. Joseph, MO 64506

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: Treatment of adult ear mite infestations in cats and kittens four weeks of age or older.

2

HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid Suspension

Color: White to off-white **Odor:** Odorless to faint alcohol





WARNING!

Combustible liquid and vapor.

Feline 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.

Protect from freezing.

Protect from direct sunlight.

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:

Acarexx® (0.01% Ivermectin) Otic Suspension is indicated for the treatment of adult (Otodectes cynotis) infestations in cats and kittens four weeks or older. Effectiveness against eggs and immature stages has not been proven.

Overdosage: None known.

ADVERSE REACTIONS TO PRODUCT: May cause skin or membrane irritation in sensitive individuals or animals. In approximately 1% of 80 cats and kittens, pain associated with the pinna and vomiting was observed following treatment with Acarexx.

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. May cause slight eye irritation if exposed. Exposure may cause eye tearing, redness, and discomfort.

Skin Contact: Not expected to be a hazard to the skin. May cause slight skin irritation. Prolonged or repeated contact may cause itching, redness, and rash in some individuals or animals.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Exposure may cause vomiting, nausea, diarrhea or other systemic effects.

Chronic Health Effects: Repeated or prolonged exposure to Ivermectin may cause damage to the reproductive system, mucous membranes or blood.

Target Organ(s): Ear, skin, reproductive system, blood

Potential Physical Effects: Combustible liquid and vapor. (Flashpoint of 143 degrees F.)

OSHA Regulatory Status: Hazardous

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Ethyl Alcohol	2005786	64-17-5	proprietary	F, R11	
Ivermectin	2745360	70288-86-7	0.01%	T+, R28	

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. 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 feline use only. 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. Use water spray to keep fire-exposed containers cool.

Unusual Fire & Explosion Hazards: Combustible liquid and vapor.

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

Flammability Class: IIIA [OSHA 1910.106(a) (18) (ii) (a)]

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 breathing vapors. 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. Reseal containers immediately after use. Store at 0°-30° C (32°-86° F). Keep from freezing. Protect from direct sunlight. Store away from foodstuffs.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Ethyl alcohol	ACGIH	8-HR	1000 ppm	Irritation
		TWA		
Ethyl alcohol	OSHA Z-1	PEL	1000 ppm	

Where governmentally imposed exposure limites exist, suich limits should take prededence.

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 liquid 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.

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).

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hand Protection: Wear suitable gloves.

č

4/8

Hygiene Measures: Eye bath, washing facilities

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: White to off-white Odor: Odorless to faint alcohol Odor Threshold: No data available Physical State: Liquid Suspension

pH: 4 - 7

Melting Point: No data available Freezing Point: No data available Boiling Point: No data available

Flash Point: 143° F

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

Volatility: No data available **Specific Gravity:** 0.98 **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: High temperatures, freezing, direct sunlight

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Carbon dioxide, carbon monoxide, nitrogen oxides, hydrogen chloride.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results	
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	
Ivermectin	Oral LD ₅₀ (rat): 2 mg/kg	
	Oral LD ₅₀ (mouse): 25 mg/kg	

Listed Carcinogens:

Chemical Name	IARC	NTP	OSHA	ACGIH
Ethanol	1 – Carcinogenic to	Known carcinogen		
	humans as ethanol in	(alcoholic beverage		
	alcoholic beverages	consumption)		

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.

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.

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 listed on the DSL Inventory.

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 Ouantity
Ethyl alcohol (Generic RCRA Waste No. D001)	100lbs

State Regulations

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

Minnesota Hazardous Substances List: Ethanol New Jersey Right-To-Know List: Ethanol Pennsylvania Right-To-Know List: Ethanol Rhode Island Right-To-Know List: Ethanol

European Regulations

Austria MAK List (Annex I): Ethanol

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 (may harm fertility), Development Risk Category: 1 (may harm the

unborn child), Breastfeeding Risk: May be harmful through breast feeding.

Norway (List of Dangerous Substance): Ethanol

Switzerland Toxins List 1: Ethanol

16 OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	2	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	2	0	N/A

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

From Section 3

F – Highly flammable

T+ – Very toxic

R11 – Highly flammable.

R28 – Very toxic if swallowed.

Mixture -

Not classified as hazardous by EC Directives.

Handle in accordance with good industrial hygiene and safety practice.

ABBREVIATIONS:

BIV – Boehringer Ingelheim Vetmedica, Inc. AIHA – American Industrial Hygiene Association mppcf – million particles/cubic foot N/A – Not applicable.

N/A – Not applicable. N/E – Not established.

References:

- 1. Acarexx ® (0.01% Ivermectin) Otic Suspension Product Guide and MSDS. IDEXX Laboratories.
- 2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
- 3. RTECS No. KQ6300000 Ethyl alcohol
- 4. RTECS No. BO7175000 Ammonium, benzyldimethyl(2-(2-(p-(1,1,3,3-tetramethylbutyl)phenoxy)ethoxy)ethyl)-,chloride
- 5. RTECS No. IH7891500 22,23-Dihydroavermectin B1
- 6. GHS Manual

Revision Information: Revised 8/10/11.

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 8/10/2011

Disclaimer: The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIV") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIV, and which BIV has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIV") expressly disclaims all liability for reliance thereon. BIV EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIV's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIV EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIV neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America. © Copyright 2001 Boehringer Ingelheim Vetmedica, Inc. All rights reserved.

Boehringer Ingelheim

SAFETY DATA SHEET

1. Identification

Product identifier Acarexx® (0.01% Ivermectin) Otic Suspension

Other means of identification None.

Recommended useTreatment of adult ear mite infestations in cats and kittens four weeks of age or older.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer Boehringer Ingelheim Vetmedica, Inc.

Address 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 calls: (800) 821-7467

2. Hazard(s) identification

Physical hazardsFlammable liquidsCategory 4Health hazardsSerious eye damage/eye irritationCategory 2A

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Combustible liquid. Causes serious eye irritation.

Precautionary statement

Prevention Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Wash thoroughly after

handling. Wear protective gloves/eye protection/face protection.

Response If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. In case of fire:

Use appropriate media to extinguish.

Storage Store in a well-ventilated place. Keep cool.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Ethanol	64-17-5	proprietary
Ivermectin	70288-86-7	0.01

Acarexx® (0.01% Ivermectin) Otic Suspension

SDS US

925363 Version #: 01 Revision date: - Issue date: 27-April-2015

1 / 7

4. First-aid measures

Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact

Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred

Most important symptoms/effects, acute and

symptoms/effects, acute and delayed

Indication of immediate medical attention and special treatment needed

Not for human use. For use in felines only. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Persons developing anaphylactic (life threatening) reactions, such a as difficulty in breathing or unconsciousness, must receive immediate medical attention.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Unsuitable extinguishing media Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

The product is combustible, and heating may generate vapors which may form explosive vapor/air mixtures. During fire, gases hazardous to health may be formed. Combustion products may include: carbon oxides, nitrogen oxides, hydrogen chloride.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

ment/instructions so without ris

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

Specific methods

Combustible liquid.

vision.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil, etc.) away from spilled material.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

7. Handling and storage Precautions for safe handling

Avoid discharge into drains, water courses or onto the ground.

Keep away from open flames, hot surfaces and sources of ignition. When using do not smoke. Avoid contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Use care in handling/storage.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. Store away from incompatible materials (see Section 10 of the SDS). Store material between 0°C (32°F) and 30°C (86°F). Store away from foodstuffs.

Acarexx® (0.01% Ivermectin) Otic Suspension

SDS US

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Туре	Value	
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3	
		1000 ppm	

US. ACGIH Threshold Limit Values

 Components
 Type
 Value

 Ethanol (CAS 64-17-5)
 STEL
 1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

 Components
 Type
 Value

 Ethanol (CAS 64-17-5)
 TWA
 1900 mg/m3 1000 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general 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. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

Respiratory protection 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. Respirator type: NIOSH approved

organic vapor respirator.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work

clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid suspension
Color White to off-white.

Odorless to faint alcohol.

Odor threshold Not available.

pH 4 - 7

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point 143.0 °F (61.7 °C)
Evaporation rate Not available.
Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper Not available.

(%)

Explosive limit - lower (%) Not available.

Acarexx® (0.01% Ivermectin) Otic Suspension

SDS US

Explosive limit - upper (%)Not available.Vapor pressureNot available.Vapor densityNot available.

Relative density 0.98

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Flammability class IIIA

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the

flash point. Contact with incompatible materials. Keep from freezing.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Prolonged inhalation may be harmful.

Skin contactNo adverse effects due to skin contact are expected.

Eye contact Causes serious eye irritation.

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and

toxicological characteristics

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred

vision

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Components Species Test Results

Ethanol (CAS 64-17-5)

Acute

Inhalation

LC50 Rat 20000 ppm, 10 Hours

Oral

LD50 Rat 6.2 g/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye

irritation

Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Acarexx® (0.01% Ivermectin) Otic Suspension

SDS US

925363 Version #: 01 Revision date: - Issue date: 27-April-2015

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Species Components **Test Results**

Ethanol (CAS 64-17-5)

Aquatic

Crustacea EC50 Water flea (Daphnia obtusa) 10100 - 11200 mg/l, 48 hours

Fish LC50 Fathead minnow (Pimephales promelas) 13480 mg/l, 96 hours

Persistence and degradability

Bioaccumulative potential

No data is available on the degradability of this product.

Partition coefficient n-octanol / water (log Kow)

Ethanol (CAS 64-17-5) -0.31

Mobility in soil No data available.

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation Other adverse effects

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of **Disposal instructions**

contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Empty containers should be taken to an approved waste handling site for recycling or disposal. Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Not established.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED

VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Acarexx® (0.01% Ivermectin) Otic Suspension

SDS US

925363 Version #: 01 Revision date: -Issue date: 27-April-2015

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Ethanol (CAS 64-17-5) LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Ethanol (CAS 64-17-5)

US. New Jersey Worker and Community Right-to-Know Act

Ethanol (CAS 64-17-5)

US. Pennsylvania Worker and Community Right-to-Know Law

Ethanol (CAS 64-17-5)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Ethanol (CAS 64-17-5)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

Acarexx® (0.01% Ivermectin) Otic Suspension

SDS US

925363 Version #: 01 Revision date: - Issue date: 27-April-2015

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 27-April-2015

Revision date - Version # 01

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA).

HMIS® ratings Health: 1

Flammability: 2 Physical hazard: 0

NFPA ratings



Disclaimer

The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIVI") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIVI, and which BIVI has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIVI") expressly disclaims all liability for reliance thereon. BIVI EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIVI's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIVI EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIVI neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

Acarexx® (0.01% Ivermectin) Otic Suspension

925363 Version #: 01 Revision date: - Issue date: 27-April-2015