



## MATERIAL SAFETY DATA SHEET

### 1 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:**

AAI Development Services

4221 Faber Place Drive

Charleston, SC 29405

**Emergency Telephone:**

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (866) 638-2226

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

**Non-emergency Telephone:** (800) 821-7467

### 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.

**Precautions/Contraindications:**

The active ingredient (Ivermectin) has shown reduced weight gain and other post-partum effects in rats along with multi-generational reproductive effects. Little, if any, effects from this product exposure are expected.

**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. This product has a flash point at 60.56° C (141° 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 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 <sup>3</sup>	----
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 <sup>3</sup>	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	----

**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).

**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:** 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 <sub>50</sub> : 20000 ppm/10H Oral LD <sub>50</sub> (guinea pig) : 5560 mg/kg
Ivermectin	Oral LD <sub>50</sub> (rat): 2 mg/kg Oral LD <sub>50</sub> (mouse): 25 mg/kg

**Listed Carcinogens:**

Chemical Name	IARC	NTP	OSHA	ACGIH
Ethanol	1 – Carcinogenic to humans as ethanol in alcoholic beverages	Known carcinogen (alcoholic beverage 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 Quantity
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 m<sup>3</sup> 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



<b>16</b>	<b>OTHER INFORMATION</b>
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**Hazard Ratings**

	Health Hazard	Fire Hazard	Reactivity Hazard
<b>HMIS</b>	1	2	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
<b>NFPA</b>	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/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-Dihydroivermectin B1
6. GHS Manual

**Revision Information:** New MSDS

**Prepared by:** Boehringer Ingelheim Vetmedica, Inc.

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