SAFETY DATA SHEET

1. Identification

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

Other means of identification: None.

Recommended use: Treatment 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 hazards: Flammable liquids Category 4

Health hazards: Serious eye damage/eye irritation Category 2A

OSHA defined hazards: Not classified.

Label elements

Signal word: Warning

Hazard statement: Combustible liquid. Causes serious eye irritation.


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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>proprietary</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Acarexx® (0.01% Ivermectin) Otic Suspension

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

SDS US

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 occurs, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

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 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
Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
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.

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

General fire hazards
Combustible liquid.

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

7. Handling and storage

Precautions for safe handling
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.
8. Exposure controls/personal protection

Occupational exposure limits

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol (CAS 64-17-5)</td>
<td>PEL</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

**US. ACGIH Threshold Limit Values**

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol (CAS 64-17-5)</td>
<td>STEL</td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

**US. NIOSH: Pocket Guide to Chemical Hazards**

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol (CAS 64-17-5)</td>
<td>TWA</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

**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.

**Odor**

Odorless to faint alcohol.

**Odor threshold**

Not available.

**pH**

4 - 7

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**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.
Explosive limit - upper (%)  Not available.
Vapor pressure  Not available.
Vapor density  Not available.
Relative density  0.98
Solubility(ies)  
Solubility (water)  Not available.
Partition coefficient (n-octanol/water)  Not available.
Auto-ignition temperature  Not available.
Decomposition temperature  Not available.
Viscosity  Not available.
Other information  
Flammability class  IIIA

10. Stability and reactivity
Reactivity  The 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 contact  No 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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol (CAS 64-17-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>20000 ppm, 10 Hours</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>6.2 g/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td></td>
<td>Prolonged skin contact may cause temporary irritation.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td></td>
<td>Causes serious eye irritation.</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitization  
Respiratory sensitization  Not a respiratory sensitizer.
Skin sensitization  This product is not expected to cause skin sensitization.
Germ cell mutagenicity  No 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.
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.

Components

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol (CAS 64-17-5)</td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
</tr>
<tr>
<td>Water flea (Daphnia obtusa)</td>
<td>10100 - 11200 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
</tr>
<tr>
<td>Fathead minnow (Pimephales promelas)</td>
<td>13480 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential

<table>
<thead>
<tr>
<th>Partition coefficient n-octanol / water (log Kow)</th>
<th>Ethanol (CAS 64-17-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-0.31</td>
</tr>
</tbody>
</table>

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

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

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. 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 Annex II of MARPOL 73/78 and the IBC Code
Not established.

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.
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 chemical
Yes

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

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

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

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