1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name: Moxidectin 2mg Tablet
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Not available
Product Use: Pharmaceutical product
Classification: Anthelmintic
Supplier: Wyeth
  P.O. Box 8299
  Philadelphia, PA 19101 USA.
  Telephone: 1-610-688-4400

Contact E-Mail: pfizer-MSDS@pfizer.com***
Emergency Telephone Number:
  Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
  Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Potential Physical Hazards: Powders and solids are presumed to be combustible.

Potential Health Effects:
- Eyes: May cause irritation
- Skin: Not irritating
- Inhalation: Not available
- Ingestion: Please see Patient Package Insert for further information.
- Therapeutic Target Organ(s): Gastrointestinal system and Nervous system

Potential Environmental Effects: See Section 12

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>EC No.</th>
<th>Composition</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxidectin</td>
<td>113507-06-05</td>
<td>N/A</td>
<td>2.0%</td>
<td>R2, R25, R50/53</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Remainder</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Preparation Date: 28-Mar-2007
Revision Date: 25-Jan-2010***
Revision Number: 2***
4. FIRST AID MEASURES

**Eye Contact**
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

**Skin Contact**
Wash off with soap and plenty of water & Consult a physician if necessary

**Inhalation**
Artificial respiration and/or oxygen may be necessary

**Ingestion**
Consult a physician if necessary

5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Not flammable

**Extinguishing Media**

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Unsuitable Extinguishing Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use water spray, foam, dry chemical or carbon dioxide.</td>
<td>Do NOT use water jet.</td>
</tr>
</tbody>
</table>

**Fire Fighting**
Evacuate area and fight fire from a safe distance

**Hazardous Combustion Products**
Carbon oxides, nitrogen oxides.

**Protective Equipment and Precautions for Firefighters**
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions**
Avoid contact with skin, eyes and clothing and Refer to protective measures listed in Sections 7 and 8.

**Environmental Precautions**
Dangerous for the environment

**Methods for Containment**
Keep away from heat and sources of ignition.

**Methods for Cleaning up**
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

**Handling**
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.***

**Storage**
Keep containers tightly closed in a dry, cool and well-ventilated place
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.***

**Moxidectin**

**Pfizer OEL TWA-8 Hr:** 70 µg/m³***

**Engineering Controls**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.***

**Personal Protective Equipment**

**Eye/face Protection**
Wear safety glasses or goggles if eye contact is possible. ***

**Skin Protection**
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.***

**Respiratory Protection**
If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. ***

**General Hygiene Considerations**
When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

**Other**
Limit access to only personnel trained in the safe handling of this material

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**
Tablet

**Physical State**
Solid

**Color**
White to pale yellow

**Odor Threshold**
Not available

**Molecular Formula**
C₃₇H₅₃NO₈

**pH**
Not applicable

**Specific Gravity**
Not applicable

**Solubility**
Soluble in Organic Solvents

**Partition Coefficient (n-octanol/water)**
58300

**Boiling Point**
Not applicable

**Flash Point**
Not applicable

**Flammability Limits in Air**
Upper Not available  
Lower Not available

**Water Solubility**
Slightly soluble in water

**Evaporation Rate**
Not applicable

**Vapor Pressure**
<3.2 x 10⁻⁸ torr

**Molecular Weight**
Not applicable

**Autoignition Temperature**
Not available

**Melting Point**
Not available

**Physical State**
Solid

**Odor**
Not available

**Color**
White to pale yellow

**Evaporation Rate**
Not applicable

**Autoignition Temperature**
Not available

**Melting Point**
Not available

**Physical State**
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**Odor**
Not available

**Color**
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**Evaporation Rate**
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**Melting Point**
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**Physical State**
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**Odor**
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**Color**
White to pale yellow

**Evaporation Rate**
Not applicable

**Autoignition Temperature**
Not available

**Melting Point**
Not available

10. STABILITY AND REACTIVITY

**Chemical Stability**
Stable at room temperature.

**Conditions to Avoid**
Keep away from heat and sources of ignition

**Materials to Avoid**
Incompatible with strong acids and bases

**Hazardous Decomposition Products**
None under normal use.

**Possibility of Hazardous Reactions**
None under normal use.

11. TOXICOLOGICAL INFORMATION
**Multiple Dose Toxicity**

Results of repeat-dose toxicity evaluated in oral (diet) studies of mice (4-weeks), rats (4 and 13 weeks), and dogs (4, 13, and 52 weeks) indicate Moxidectin was well tolerated with no toxic effects at calculated dosages up to 6.9 mg/kg/day for 4 weeks in mice, 3.9 mg/kg/day for 13 weeks in rats, or 1.1 mg/kg/day for 1 year in dogs.

**Maximum Tolerated Dose (MTD), Oral**

Moxidectin

- **No Toxicologic Effect**
- **Dose/Species/Study Length:** No data available

**Target Organ(s) of Toxicity**

- Central Nervous System
- Gastrointestinal

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**12. ECOLOGICAL INFORMATION**

**Chemical Fate Information**

- Not available

**Mobility**

- Adsorbs on soil

**Biodegradability**

- Readily biodegradable

**Ecotoxicity**

- Not available

**Algae**

- EC50/72h/algae > 87 ppb

**Daphnia**

- NOEC 11 ppt

**Fish**

- NOEC = < 0.15 ppb , LC50/96h/trout = < 0.15 ppb

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**13. DISPOSAL CONSIDERATIONS**

**Waste Disposal Method**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. ***
14. TRANSPORT INFORMATION

Proper Shipping Name: Environmentally hazardous substances, solid, n.o.s. (Moxidectin)*** Marine Pollutant***
Identification Number: UN 3077***
Hazard Class: 9***
Packing Group: III***

Exceptions: For small quantities packed in combination packaging [limited to inner packaging <= 5.0 kg (11 lb)*** and outer packaging <= 30 kg (66 lb.) gross weight], the following will apply. In addition, see "excepted quantity" provisions if applicable.***

Note: If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may be considered a Consumer Commodity and excepted from additional requirements as applicable.***

U.S. Department of Transport (DOT) ***
Proper Shipping Name Consumer Commodity***
UN-No ORM-D***

International Air Transport Association (IATA)***
UN-No ID 8000
Proper Shipping Name Consumer Commodity
Hazard Class 9

International Maritime Dangerous Goods (IMDG) ***
Proper Shipping Name Environmentally hazardous substances, solid, n.o.s. (Moxidectin), Ltd. Qty., Marine Pollutant***
Hazard Class 9***
UN-No UN 3077***
Packing Group III***

Transport of Dangerous Goods by Road (ADR) ***
Proper Shipping Name Environmentally hazardous substances, solid, n.o.s. (Moxidectin), Ltd. Qty., Marine Pollutant******
Hazard Class 9***
UN-No UN 3077***
Packing Group III***

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

Symbol(s) N - Dangerous for the environment

R -phrase(s) R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S -phrase(s) S20 - When using do not eat or drink
S22 - Do not breathe dust
S25 - Avoid contact with eyes
S36 - Wear suitable protective clothing
S38 - In case of insufficient ventilation, wear suitable respiratory equipment
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S61 - Avoid release to the environment. Refer to special instructions/safety data sheets

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with Directive 2001/58/EC.
16. OTHER INFORMATION

List of References

See Patient Package Insert for more information.

Revision Summary

Changes to Section 8, 14******

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End of MSDS