

Moxidectin 2mg Tablet

Preparation Date 28-Mar-2007

Revision Date 25-Jan-2010***

Revision Number 2***

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

Product Name Common Name Chemical Name Synonyms Product Use Classification Moxidectin 2mg Tablet Not available Not applicable Not available Pharmaceutical product Anthelmintic

Supplier

Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400

Contact E-Mail:

Emergency Telephone Number

pfizer-MSDS@pfizer.com*** Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

 Appearance Tablet
 Physical State
 Solid
 Odor
 Not available

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

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Potential Environmental Effects See

See Section 12

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Moxidectin	113507-06-05	N/A	2.0%	R2, R25, R50/53
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable

	4. FIRST AID MEASURES
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seel 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	
Suitable Extinguishing Media Unsuitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide. Do NOT use water jet.
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 eves skin, and clothing. When handling, use

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 70 µg/m^{3***} Pfizer OEL TWA-8 Hr: **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** Wear safety glasses or goggles if eye contact is possible. *** **Eye/face Protection** Skin Protection Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.*** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate **Respiratory Protection** respirator with a protection factor sufficient to control exposures to below the OEL. *** **General Hygiene** When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands Considerations 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 Color Odor Threshold	Tablet White to pale yellow Not available	Physical State Odor	Solid Not available
Molecular Formula	C37H53NO8	рН	Not applicable
Specific Gravity Solubility Partition Coefficient (n-octanol/water)	Not applicable Soluble in Organic Solvents 58300	Water Solubility Evaporation Rate Vapor Pressure	Slightly soluble in water Not applicable <3.2 v 10^8 torr
Boiling Point Flash Point Flammability Limits in Air Upper Not available	Not applicable Not applicable Upper Not available Lower Not available	Autoignition Temperature Melting Point Lower Not available	Not available 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

Moxidectin LD50 Oral Acute Dermal Irritation Primary Eye Irritation	106 mg/kg Rat, 84 mg/kg Mice >2000 mg/kg Rabbit Moderately irritating to the eyes.
Sensitization	Not a sensitizer
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.
Moxidectin No Toxicologic Effect Dose/Species/Study Length:	No data available
Maximum Tolerated Dose (MTD), Or	al
Moxidectin Carcinogenicity Genetic Toxicity Reproductive Toxicity Developmental Toxicity	Did not show carcinogenic effects in animal experiments. Negative in a battery of genotoxicity tests. Did show teratogenic effects in animal experiments. Animal studies did not show statistically significant developmental toxicological effects
Moxidectin Target Organ(s) of Toxicity	Central Nervous System, Gastrointestinal

12. ECOLOGICAL INFORMATION

Chemical Fate Information	Not available
Moxidectin Mobility Biodegradability	Adsorbs on soil Readily biodegradable.
Ecotoxicity	Not available
Moxidectin Algae Daphnia Fish	EC50/72h/algae > 87 ppb NOEC 11 ppt NOEC = < 0.15 ppb , LC50/96h/trout = < 0.15 ppb,

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. ***
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14. TRANSPORT INFORMATION

	This material is regulated for transportation as a hazardous material/dangerous goods.***	
Proper Shipping Name: Identification Number: Hazard Class: Packing Group:	Environmentally hazardous substances, solid, n.o.s. (Moxidectin)*** Marine Pollutant*** UN 3077*** 9*** 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 Associati		
UN-No	ID 8000	
Proper Shipping Name	Consumer Commodity	
Hazard Class International Maritime Dangerous Go	9 (MDC) ***	
Proper Shipping Name	Environmentally hazardous substances, solid, n.o.s. (Moxidectin), Ltd. Qty., Marine Pollutant***	
Hazard Class	9***	
UN-No	UN 3077***	
Packing Group	***	
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 Format Wyeth Department of Environment, Health & Safety This MSDS was prepared in accordance with Directive 2001/58/EC.

16. OTHER INFORMATION

List of References Revision Summary See Patient Package Insert for more information. Changes to Section 8, 14******

Disclaimer:

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End of MSDS