Meloxicam Solution for Injection

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Revision Date: 12/14/2015 Date of issue: 06/05/2015 Version: 3.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Meloxicam Solution for Injection

1.2. Intended Use of the Product

Use of the substance/mixture: Control of pain and inflammation associated with osteoarthritis in dogs. For professional use only. Federal law restricts this drug to be used by or on the order of a licensed veterinarian.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Putney, Inc.
One Monument Square, Suite 400
Portland, ME 04101
1-866-683-0660
www.putneyvet.com

1.4. Emergency Telephone Number

Emergency Number : 1-866-683-0660 (Monday-Friday: 8:00 AM–5:00 PM EST)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Flam. Liq. 3	H226
Skin Irrit. 2	H315
Eye Irrit. 2A	H319
Repr. 1B	H360

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

GHS02 GHS07 GHS08

Signal Word (GHS-US) : Danger

Hazard Statements (GHS-US) : H226 - Flammable liquid and vapor.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H360 - May damage fertility or the unborn child.

Precautionary Statements (GHS-US) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P210 - Keep away from extremely high or low temperatures, ignition sources, and incompatible materials. - No smoking.
P233 - Keep container tightly closed.
P240 - Ground/bond container and receiving equipment.
P241 - Use explosion-proof electrical, ventilating, and lighting equipment.
P242 - Use only non-sparking tools.
P243 - Take precautionary measures against static discharge.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352+P362 - IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash before reuse.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P370+P378 - In case of fire: Use appropriate media (see section 5) to extinguish.
P403+P235+P405 - Store in a well-ventilated place. Keep cool. Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national,

and international regulations.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No) Proprietary	Proprietary	Not classified
Proprietary alcohol	(CAS No) Proprietary	Proprietary	Flam. Liq. 2, H225 Eye Irrit. 2A, H319
Glycofurol	(CAS No) Proprietary	Proprietary	Not classified
Poloxamer 188	(CAS No) Proprietary	Proprietary	Aquatic Chronic 3, H412
Meloxicam	(CAS No) 71125-38-7	Proprietary	Acute Tox. 3 (Oral), H301 Repr. 1B, H360 Aquatic Chronic 3, H412
Meglumine	(CAS No) Proprietary	Proprietary	Not classified
Sodium chloride	(CAS No) Proprietary	Proprietary	Not classified
Glycine	(CAS No) Proprietary	Proprietary	Not classified
Sodium hydroxide	(CAS No) Proprietary	Proprietary	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Hydrogen chloride	(CAS No) Proprietary	Proprietary	Met. Corr. 1, H290 Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1C, H314 Eye Dam. 1, H318 STOT SE 3, H335

The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret [29 CFR 1910.1200].
Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Gently wash with plenty of soap and water followed by rinsing with water for at least 15 minutes. Call a POISON CENTER or doctor/physician if you feel unwell. Wash contaminated clothing before reuse.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation persists.

First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Causes skin irritation. Causes serious eye irritation. May damage fertility or the unborn child. Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: Causes skin irritation. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: May damage fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Flammable liquid and vapor.

Explosion Hazard: May form flammable/explosive vapor-air mixture.

Reactivity: Reacts with (strong) oxidizers: (increased) risk of fire.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all contact with skin, eyes, or clothing. Keep away from heat, sparks, open flames, hot surfaces. No smoking. Use special care to avoid static electric charges.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Absorb and/or contain spill with inert material, then place in suitable container. Clean up spills immediately and dispose of waste safely. Use only non-sparking tools.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Handle empty containers with care because residual vapors are flammable.

Precautions for Safe Handling: Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU. Keep away from heat, sparks, open flames, hot surfaces. No smoking. Provide good ventilation in process area to prevent formation of vapor. Take precautionary measures against static discharge. Use only non-sparking tools.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep in fireproof place. Keep only in the original container in a cool, well ventilated place away from: Sparks, heat, open flame and other sources of ignition. Keep container tightly closed.

Incompatible Products: Strong acids, strong bases, strong oxidizers.

Incompatible Materials: Sources of ignition. Direct sunlight. Heat sources.

7.3. Specific End Use(s)

Control of pain and inflammation associated with osteoarthritis in dogs. For professional use only. Federal law restricts this drug to be used by or on the order of a licensed veterinarian.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Proprietary alcohol (Proprietary)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA ACGIH	ACGIH chemical category	Confirmed Animal Carcinogen with Unknown Relevance to Humans
USA NIOSH	NIOSH REL (TWA) (mg/m³)	1900 mg/m³
USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m³)	1900 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

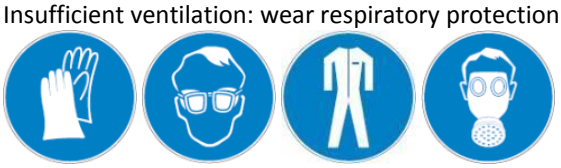
Sodium hydroxide (Proprietary)		
USA ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	2 mg/m³
USA IDLH	US IDLH (mg/m³)	10 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³

Hydrogen chloride (Proprietary)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	7 mg/m³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m³)	7 mg/m³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Gas detectors should be used when flammable gases/vapors may be released. Proper grounding procedures to avoid static electricity should be followed.

Personal Protective Equipment : Avoid all unnecessary exposure. Gloves. Safety glasses. Protective clothing. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection : In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Yellow colored, clear solution

Odor : No data available

Odor Threshold : No data available

pH : 8.2 - 9.2

Evaporation Rate : No data available

Melting Point : No data available

Freezing Point : No data available

Boiling Point : No data available

Flash Point	: ≈ 36 °C (96.8 °F) 20% solution of ethanol
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Reacts with (strong) oxidizers: (increased) risk of fire.

10.2. Chemical Stability: Stable at standard temperature and pressure.

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Ignition sources. Direct sunlight. Extremely high or low temperatures. Open flame. Sparks.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: Carbon oxides (CO, CO_2). Nitrogen oxides. Sulfur oxides. Hydrogen chloride. Chlorine. May release flammable gases.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Meloxicam (71125-38-7)	
ATE (Oral)	100.00 mg/kg body weight

Proprietary alcohol (Proprietary)	
LD50 Oral Rat	10470 mg/kg
LD50 Dermal Rat	20 ml/kg
LC50 Inhalation Rat	124.7 mg/l/4h

Poloxamer 188 (Proprietary)	
LC50 Inhalation Rat	320 mg/m³ (Exposure time: 4 h)

Meglumine (Proprietary)	
LD50 Oral Rat	5000 mg/kg

Sodium chloride (Proprietary)	
LD50 Oral Rat	3 g/kg
LC50 Inhalation Rat	> 42 g/m³ (Exposure time: 1 h)

Hydrogen chloride (Proprietary)	
LD50 Oral Rat	238 (238 - 277) mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
ATE (Gases)	700.00 ppmV/4h
ATE (Dust/Mist)	0.42 mg/l/4h

Skin Corrosion/Irritation: Causes skin irritation

pH: 8.2 - 9.2

Serious Eye Damage/Irritation: Causes serious eye irritation

pH: 8.2 - 9.2

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Proprietary alcohol (Proprietary)	
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: May damage fertility or the unborn child

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause respiratory irritation

Symptoms/Injuries After Skin Contact: Causes skin irritation. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects

Chronic Symptoms: May damage fertility or the unborn child

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Proprietary alcohol (Proprietary)	
LC50 Fish 1	12.0 - 16.0 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

Meglumine (Proprietary)	
LC50 Fish 1	> 1000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
EC50 Daphnia 1	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)

Sodium chloride (Proprietary)	
LC50 Fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Sodium hydroxide (Proprietary)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

12.2. Persistence and Degradability

Proprietary alcohol (Proprietary)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Proprietary alcohol (Proprietary)	
Log Pow	-0.32
Bioaccumulative Potential	Not established.

Sodium chloride (Proprietary)	
BCF fish 1	(no bioaccumulation)

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

Additional Information: Handle empty containers with care because residual vapors are flammable. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with EC Directive 2010/32/EU.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Meloxicam Solution for Injection	
SARA Section 311/312 Hazard Classes	Fire hazard Immediate (acute) health hazard Delayed (chronic) health hazard

Water (Proprietary)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Proprietary alcohol (Proprietary)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Poloxamer 188 (Proprietary)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Meglumine (Proprietary)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium chloride (Proprietary)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Glycine (Proprietary)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (Proprietary)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard

Hydrogen chloride (Proprietary)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Listed on United States SARA Section 313	
SARA Section 302 Threshold Planning Quantity (TPQ)	500 (gas only)
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2 US State Regulations

Proprietary alcohol (Proprietary)	
U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer.
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.

Proprietary alcohol (Proprietary)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (Proprietary)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

Hydrogen chloride (Proprietary)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 12/14/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1C	Skin corrosion/irritation Category 1C
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)