

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Loxicom 1.5 mg/ml Oral Suspension For Dogs

Product Code: ANADA 200-497

1.2. Intended Use of the Product

Use of the substance/mixture: Non-steroidal anti-inflammatory drug for use in dogs only. Loxicom Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

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

Supplier

Norbrook, Inc.

9401 Indian Creek Parkway – Ste. 680

Overland Park, KS 66210

Phone: 913 599 5777

Fax: 913 599 5766

Manufacturer

Norbrook Laboratories Ltd,

Station Works, Newry, Co.Down,

N.Ireland, BT35 6JP.

Telephone No. +44 (0)28 3026 4435

Fax No. +44 (0)28 3026 1721

E-Mail: enquiries@norbrook.co.uk

1.4. Emergency Telephone Number

Emergency Number : 913 599 5777

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Repr. 1B H360

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: 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.

P280 - Wear protective gloves, protective clothing, and eye protection.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

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	%	GHS-US classification
Glycerin	(CAS No) 56-81-5	Proprietary	Not classified
Meloxicam	(CAS No) 71125-38-7	Proprietary	Acute Tox. 3 (Oral), H301 Repr. 1B, H360 Aquatic Chronic 3, H412

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

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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: 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: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may 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: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed. Avoid all contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or spray.

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: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Use only non-sparking tools. Do not take up in combustible material such as: saw dust or cellulosic material.

6.4. Reference to Other Sections

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

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

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: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Store locked up. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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

Storage Temperature: 25 °C Max

7.3. Specific End Use(s)

Non-steroidal anti-inflammatory drug for use in dogs only. Loxicom Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

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), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Glycerin (56-81-5)		
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (mist, total particulate)
		5 mg/m ³ (mist, respirable fraction)

8.2. Exposure Controls

Appropriate Engineering Controls

: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Avoid all unnecessary exposure. Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical goggles or safety glasses.

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	: Clear solution
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available

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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:** Hazardous reactions will not occur under normal conditions.
- 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:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂). Sodium oxides. Phosphorus oxides.

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
Glycerin (56-81-5)	
LD50 Oral Rat	23000 mg/kg
LD50 Dermal Rabbit	> 10 g/kg
LC50 Inhalation Rat	> 570 mg/m ³ (Exposure time: 1 h)

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: May damage fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Glycerin (56-81-5)	
LC50 Fish 1	54000 (51000 - 57000) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

Glycerin (56-81-5)	
BCF fish 1	(no bioaccumulation)
Log Pow	-1.76

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

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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.

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

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SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard
Glycerin (56-81-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule

15.2 US State Regulations

Glycerin (56-81-5)
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

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

Revision Date : 03/08/2016

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 (Oral)	Acute toxicity (oral) Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Repr. 1B	Reproductive toxicity Category 1B
H301	Toxic if swallowed
H360	May damage fertility or the unborn child
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)