

SAFETY DATA SHEETS

This SDS packet was issued with item:

078908178

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

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PRODUCT SAFETY DATA SHEET

FLUNIXIN INJECTION - S (50mg/mL)

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

Product Name Flunixin Injection - S

Manufacturer Norbrook Laboratories Ltd,
Station Works, Newry, Co.Down,
N.Ireland, BT35 6JP.

Supplier Norbrook, Inc.
9733 Loiret Blvd
Lenexa, KS 66219
Phone: 913 599 5777
Fax: 913 599 5766

2. HAZARDS IDENTIFICATION

Physical and Chemical Hazards : Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC.

Environmental Hazards : None known

Adverse Human Health Effects : There are no known adverse effects of exposure to Flunixin Injection -S.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation : Preparation

Active Ingredients : Flunixin Meglumine

Description : Non-narcotic, non-steroidal analgesic

Chemical Family : Flunixin - non-steroidal, anti-inflammatory drug (NSAID)

4. FIRST AID MEASURES

Inhalation : Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.

Skin Contact : Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.

Eyes Contact : Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Ingestion : Do not induce vomiting. Seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours.

Fire and explosion hazards: None.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.
Environmental Precautions : Keep away from drains, surface-water, ground-water and soil.
Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.

Storage : Store in closed containers in a cool, dry, well-ventilated area, between 2°C and 30°C and away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.

Keep container closed when not in use. Do not transfer contents to unlabelled containers. Use only with adequate ventilation. Keep out of reach of children. Should any discolouration occur, the product should be discarded.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Flunixin

Not Established

For pure flunixin meglumine :

LD50 (Oral, rat) : 120 mg/kg

Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Liquid
Colour : Clear, colourless
Odour : None.

10. STABILITY AND REACTIVITY

Stability : Stable under normal temperatures and pressures.
Conditions to avoid : None known
Materials to avoid : None known

11. TOXICOLOGICAL INFORMATION

Exposure Effects (Acute)

Eye Contact : Direct contact of the solution with eyes can cause irritation.
Skin Contact : Prolonged or repeated contact with Flunixin Injection - S may cause irritation and/or drying and cracking of the skin.

Inhalation	:	None known.
Ingestion	:	Oral toxicity of the Flunixin Injection - S solution is low.

Exposure Effects (Chronic)

Unknown for the product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Both its mutagenicity and its teratogenicity are not known.

12. ECOLOGICAL INFORMATION

Data on the ecological implications for Flunixin Injection - S is not yet available.

13. DISPOSAL CONSIDERATIONS

Product/Residues	:	Do not discharge the product material into surface or waste water. For disposal, use an incinerator licensed for chemical waste.
Package	:	Dispose of waste containers using regular disposal methods in accordance with local and national environmental regulations.

14. TRANSPORT INFORMATION

Land, Sea & Air Transport

ADR/RID, IMO/IMDG, IATA/ICAO, UN No. : Not applicable

15. REGULATORY INFORMATION

Labelling Information	:	None
Safety phrases	:	S2 Keep out of reach of children
	:	S7 Keep container tightly closed

16. OTHER INFORMATION

For Animal Treatment Only Injectable solution 50mg/mL

ANADA 200-476, approved by FDA

Revision Date : 07/08/09
Revision No : 01
Printing Date : 09/08/2009

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories Limited will not be held liable for any damage resulting from the handling of or contact with the above product.



Flunixin S

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 04/13/2016 Date of issue: 04/13/2016

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Flunixin S

Product Code: ANADA 200-308

1.2. Intended Use of the Product

Use of the substance/mixture: For intravenous or intramuscular use in horses and for intravenous use in beef and dairy cattle. Flunixin Meglumine is a potent, non-narcotic, non-steroidal, analgesic drug with anti-inflammatory and anti-pyretic activity.

Horse: Flunixin S is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic.

Cattle: Flunixin S is indicated for the control of pyrexia associated with bovine respiratory disease and endotoxemia and acute bovine mastitis.

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

Aquatic Chronic 3 H412

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

2.2. Label Elements

GHS-US Labeling

Hazard Statements (GHS-US) : H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US) : P273 - Avoid release to the environment.
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
1,2-Propylene glycol	(CAS No) 57-55-6	Proprietary	Not classified
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	(CAS No) 42461-84-7	Proprietary	Comb. Dust Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation:dust,mist), H331 Eye Irrit. 2A, H319 Aquatic Chronic 2, H411

Flunixin S

Safety Data Sheet

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

Phenol	(CAS No) 108-95-2	Proprietary	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Muta. 2, H341 STOT RE 2, H373 Aquatic Acute 3, H402
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Full text of H-phrases: see section 16

The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret [29 CFR 1910.1200].

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. Rinse affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

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: Suspected of causing cancer. 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: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

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 contact with skin, eyes and clothing. Avoid breathing (vapor, mist, 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.

Flunixin S

Safety Data Sheet

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

6.2. Environmental Precautions

Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

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.

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

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.

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: 30 °C Max

7.3. Specific End Use(s)

For intravenous or intramuscular use in horses and for intravenous use in beef and dairy cattle. Flunixin Meglumine is a potent, non-narcotic, non-steroidal, analgesic drug with anti-inflammatory and anti-pyretic activity.

Horse: Flunixin S is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic.

Cattle: Flunixin S is indicated for the control of pyrexia associated with bovine respiratory disease and endotoxemia and acute bovine mastitis.

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).

1,2-Propylene glycol (57-55-6)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³
Phenol (108-95-2)		
USA ACGIH	ACGIH TWA (ppm)	5 ppm
USA ACGIH	ACGIH chemical category	Skin - potential significant contribution to overall exposure by the cutaneous route, Not Classifiable as a Human Carcinogen
USA ACGIH	Biological Exposure Indices (BEI)	250 mg/g Kreatinin (Medium: urine - Time: end of shift - Parameter: Phenol with hydrolysis (background, nonspecific))
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	19 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	5 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	60 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	15.6 ppm
USA IDLH	US IDLH (ppm)	250 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	19 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	5 ppm
USA OSHA	Limit value category (OSHA)	prevent or reduce skin absorption

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.

Flunixin S

Safety Data Sheet

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

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
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:** Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

1,2-Propylene glycol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg
Phenol (108-95-2)	
LD50 Oral Rat	340 mg/kg
LD50 Dermal Rabbit	630 mg/kg
LC50 Inhalation Rat	0.316 mg/l/4h (reported as 316 mg/m3/4h)
ATE (Oral)	100.00 mg/kg body weight

Flunixin S

Safety Data Sheet

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

ATE (Gases)	700.00 ppmV/4h
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate (42461-84-7)	
LD50 Oral Rat	157 mg/kg
LC50 Inhalation Rat	< 0.52 mg/l/4h
ATE (Dust/Mist)	0.50 mg/l/4h

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

Phenol (108-95-2)	
IARC group	3
National Toxicology Program (NTP) Status	Twelfth Report - Items under consideration.

Reproductive Toxicity: Not classified

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: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Harmful to aquatic life with long lasting effects.

1,2-Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC 50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Phenol (108-95-2)	
LC50 Fish 1	11.9 - 50.5 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	4.24 - 10.7 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC 50 Fish 2	20.5 - 25.6 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	10.2 - 15.5 mg/l (Exposure time: 48 h - Species: Daphnia magna)

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1
Log Pow	-0.92
Phenol (108-95-2)	
BCF fish 1	(no significant bioaccumulation)
Log Pow	1.47

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

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

Flunixin S

Safety Data Sheet

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

Additional Information: 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.

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

1,2-Propylene glycol (57-55-6)

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

Phenol (108-95-2)

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

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

EPA TSCA Regulatory Flag

T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA

SARA Section 302 Threshold Planning Quantity (TPQ)

≤ 10000

SARA Section 313 - Emission Reporting

1.0 %

15.2 US State Regulations

1,2-Propylene glycol (57-55-6)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Phenol (108-95-2)

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 : 04/13/2016

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 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) 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 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Muta. 2	Germ cell mutagenicity Category 2
Skin Corr. 1B	Skin corrosion/irritation Category 1B
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
	May form combustible dust concentrations in air
H301	Toxic if swallowed
H311	Toxic in contact with skin

Flunixin S

Safety Data Sheet

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

H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H341	Suspected of causing genetic defects
H373	May cause damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects
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)