

SAFETY DATA SHEET



Revision date: 24-Apr-2015

Version: 3.0

Page 1 of 14

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

Product Identifier

Material Name: Flunixinamine (flunixin meglumine) Injectable Solution (U.S. only)

Trade Name: FLUNIXAMINE
Synonyms: MEFLOSYL
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as Non-steroidal, anti-inflammatory drug (NSAID)
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4
Acute Toxicity - Dusts and Mists: Category 5
Skin Corrosion/Irritation: Category 2
Serious Eye Damage/Eye Irritation: Category 1
Carcinogenicity: Category 2
Specific target organ systemic toxicity (repeated exposure): Category 2
Acute aquatic toxicity: Category 3
Chronic aquatic toxicity: Category 3

EU Classification:

EU Indication of danger: Toxic
Dangerous for the Environment

EU Symbol: T N
EU Risk Phrases:

R23 - Toxic by inhalation.
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R38 - Irritating to skin.

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 2 of 14

Version: 3.0

2. HAZARDS IDENTIFICATION

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label Elements

Signal Word: Danger
Hazard Statements: H318 - Causes serious eye damage
H315 - Causes skin irritation
H302 - Harmful if swallowed
H333 - May be harmful if inhaled
H373 - May cause damage to organs through prolonged or repeated exposure (gastrointestinal system , kidneys)
H351 - Suspected of causing cancer
H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements: 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/eye protection/face protection
P271 - Use only outdoors or in a well-ventilated area
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P270 - Do not eat, drink or smoke when using this product
P264 - Wash hands thoroughly after handling
P273 - Avoid release to the environment
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTRE or doctor/physician
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P403 - Store in a well-ventilated place
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term: In the event of accidental injection, an allergic reaction may occur.
Long Term: May cause damage to organs through prolonged or repeat exposure.
Known Clinical Effects: Drugs of this class may cause gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable Solution (U.S. only)
Revision date: 24-Apr-2015

Page 3 of 14

Version: 3.0

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	20
Flunixin meglumine	42461-84-7	255-836-0	T+;R26 T;R25 Xi;R41 Xn;R48/22 ;R51/53	Acute Tox. 1 (H330) Acute Tox. 2 (H300) Eye Dam. 1 (H318) STOT RE 2 (H373) Aquatic Tox. 2 (H401 and H411)	5
PHENOL	108-95-2	203-632-7	T; R23/24/25 C; R34 Xn; R48/20/21/22 Muta. Cat. 3; R68	Acute Tox. 3 (H301) STOT RE 2 (H373) Muta. 2 (341) Skin Corr. 1B (H314) Acute Tox. 3 (H331)	<1
2,2 IMINODIETHANOL	111-42-2	203-868-0	Xn; R22-48/22 Xi; R38-41	Acute Tox. 4 (H302) STOT RE 2 (H373) Skin Irrit. 2 (H315) Eye Dam. 1 (H318)	<1
HYDROCHLORIC ACID	7647-01-0	231-595-7	T; R23 C; R35	Skin Corr.1B (H314) STOT SE 3 (H335)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium formaldehyde sulfoxylate dihydrate	6035-47-8	Not Listed	Not Listed	Not Listed	*
Disodium EDTA (dihydrate)	6381-92-6	Not Listed	Not Listed	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

Additional Information: * Proprietary
 ** to adjust pH
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 4 of 14

Version: 3.0

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 5 of 14

Version: 3.0

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Keep away from heat, sparks, and flame. Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Avoid accidental injection. Wash thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging. Keep containers tightly closed in a cool, well-ventilated place

Storage Temperature: 15-30°C (59-86°F)

Incompatible Materials: Acids, bases, and oxidizers

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Propylene glycol

Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³

PHENOL

ACGIH Threshold Limit Value (TWA)	5 ppm
ACGIH - Biological Exposure Limit:	250 mg/g creatinine
Australia TWA	1 ppm 4 mg/m ³
Austria OEL - MAKs	2 ppm 8 mg/m ³
Belgium OEL - TWA	2 ppm 8 mg/m ³
Bulgaria OEL - TWA	8 mg/m ³ 2 ppm
Bulgaria - Biological Exposure Limit:	200 mg/L
Cyprus OEL - TWA	8 mg/m ³ 2 ppm
Czech Republic OEL - TWA	7.5 mg/m ³
Denmark OEL - TWA	1 ppm 4 mg/m ³

2,2 IMINODIETHANOL

ACGIH Threshold Limit Value (TWA)	1 mg/m ³
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 6 of 14

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	3 ppm 13 mg/m ³
Austria OEL - MAKs	0.46 ppm 2 mg/m ³
Belgium OEL - TWA	0.46 ppm 2 mg/m ³
Bulgaria OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	5 mg/m ³
Denmark OEL - TWA	0.46 ppm 2 mg/m ³
Estonia OEL - TWA	3 ppm 5 mg/m ³
Finland OEL - TWA	0.46 ppm 2 mg/m ³
France OEL - TWA	3 ppm 15 mg/m ³
Germany (DFG) - MAK	1 mg/m ³
Greece OEL - TWA	3 ppm 15 mg/m ³
Ireland OEL - TWAs	1 mg/m ³
Lithuania OEL - TWA	3 ppm 15 mg/m ³
Poland OEL - TWA	9 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	15 mg/m ³
Spain OEL - TWA	0.46 ppm 2 mg/m ³
Sweden OEL - TWAs	3 ppm 15 mg/m ³
Switzerland OEL - TWAs	1 mg/m ³
HYDROCHLORIC ACID	
ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m ³
Austria OEL - MAKs	5 ppm 8 mg/m ³
Belgium OEL - TWA	5 ppm 8 mg/m ³
Bulgaria OEL - TWA	5 ppm 8.0 mg/m ³
Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
 Solution (U.S. only)
 Revision date: 24-Apr-2015

Page 7 of 14

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm
	8 mg/m ³
Italy OEL - TWA	5 ppm
	8 mg/m ³
Japan - OELs - Ceilings	5 ppm
	7.5 mg/m ³
Latvia OEL - TWA	5 ppm
	8 mg/m ³
Lithuania OEL - TWA	5 ppm
	8 mg/m ³
Luxembourg OEL - TWA	5 ppm
	8 mg/m ³
Malta OEL - TWA	5 ppm
	8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm
	8 mg/m ³
Romania OEL - TWA	5 ppm
	8 mg/m ³
Slovakia OEL - TWA	5 ppm
	8.0 mg/m ³
Slovenia OEL - TWA	5 ppm
	8 mg/m ³
Spain OEL - TWA	5 ppm
	7.6 mg/m ³
Switzerland OEL -TWAs	2 ppm
	3.0 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Flunixin meglumine

Zoetis OEB

OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Exposure Controls

Engineering Controls:

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

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

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

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 8 of 14

Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear, colorless
Odor:	Slight	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	8.3
Melting/Freezing Point (°C):	0°C (32°F) based on water
Boiling Point (°C):	100°C (212°F) based on water
Partition Coefficient: (Method, pH, Endpoint, Value)	No data available
Decomposition Temperature (°C):	No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	18 mm of Hg (@ 20°C) based on water
Vapor Density (g/ml):	>1
Relative Density:	No data available
Specific Gravity:	1.01
Viscosity:	No data available

Flammability:	
Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	Acids, bases, and oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact

SAFETY DATA SHEET

Material Name: Flunixin meglumine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 9 of 14

Version: 3.0

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Flunixin meglumine

Rat Inhalation LC50 < 0.52 mg/L

Rat Oral LD50 53-157mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg

Mouse Oral LD 50 24,900mg/kg

Rabbit Dermal LD 50 20,800mg/kg

PHENOL

Rat Oral LD50 317 mg/kg

Rat Dermal LD50 525mg/kg

Rabbit Dermal LD50 630mg/kg

Mouse Oral LD50 270mg/kg

2,2 IMINODIETHANOL

Rat Oral LD50 710 mg/kg

Rabbit Dermal LD50 11.9ml/kg

Inhalation Acute Toxicity

May be harmful if inhaled. May cause respiratory tract and mucous membrane irritation.

Ingestion Acute Toxicity

Harmful if swallowed.

Irritation / Sensitization: (Study Type, Species, Severity)

Flunixin meglumine

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Severe

Skin Sensitization - GPMT Negative

Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

2,2 IMINODIETHANOL

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Irritation / Sensitization Comments: May cause irreversible eye damage.

Skin Irritation / Sensitization May cause skin irritation.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Flunixin meglumine

1 Year(s) Rat Oral 1 mg/kg/day NOEL Gastrointestinal System, Kidney

SAFETY DATA SHEET

Material Name: Flunixin meglumine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 10 of 14

Version: 3.0

11. TOXICOLOGICAL INFORMATION

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Flunixin meglumine

Fertility and Embryonic Development Rat Oral 2-12 mg/kg NOEL Not teratogenic
Reproductive & Fertility Rat Oral 3-9 mg/kg NOEL Maternal Toxicity

PHENOL

2 Generation Reproductive Toxicity Rat Oral 1000 ppm NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 120 mg/kg LOAEL Fetotoxicity, Not Teratogenic
Fertility and Embryonic Development Rat Oral 53 mg/kg LOAEL Maternal Toxicity, Fetotoxicity, Not Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 200 mg/kg NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Flunixin meglumine

Bacterial Mutagenicity (Ames) Bacteria Negative
Micronucleus Mouse Negative
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
Mammalian Cell Mutagenicity Mouse Lymphoma Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Flunixin meglumine

104 Week(s) Rat Oral, in feed 8 mg/kg/day NOEL Not carcinogenic
97 Week(s) Mouse Oral, in feed 6 mg/kg/day NOEL Not carcinogenic

PHENOL

103 Week(s) Rat Oral 5,000 ppm NOAEL Not carcinogenic
103 Week(s) Mouse Oral 5,000 ppm NOAEL Not carcinogenic

Carcinogen Status: See below

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

2,2 IMINODIETHANOL

IARC: Group 2B (Possibly Carcinogenic to Humans)

Product Level Toxicity Data

Acute Toxicity Estimate (ATE), oral 1000 mg/kg
Acute Toxicity Estimate (ATE), inhalation (dust/mist) 10 mg/l
Acute Toxicity Estimate (ATE), dermal >5000 mg/kg

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 11 of 14

Version: 3.0

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. may be harmful to aquatic organisms. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Flunixin meglumine

Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 46 mg/L
Salmo gairdneri (Trout) LC50 96 Hours 9.2 mg/L
Daphnia Magna (Water Flea) EC50 48 Hours 25 mg/L
Algae IC50 72 Hours 36-120 mg/L

PHENOL

Selenastrum capricornutum (Green Alga) EC50 96 Hours 150 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 Hours 24 mg/L
Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 8.9 mg/L
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 23.88 mg/L
Daphnia magna (Water Flea) LC50 48 Hours 13 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

2,2 IMINODIETHANOL

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 12 of 14

Version: 3.0

CERCLA/SARA Hazardous Substances
and their Reportable Quantities: 100 lb
45.4 kg

HYDROCHLORIC ACID
CERCLA/SARA Hazardous Substances
and their Reportable Quantities: 5000 lb
2270 kg

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Flunixin meglumine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	255-836-0

PHENOL

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	203-632-7

2,2 IMINODIETHANOL

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb 45.4 kg
California Proposition 65	carcinogen initial date 6/22/12
Inventory - United States TSCA - Sect. 8(b)	Present

SAFETY DATA SHEET

Material Name: Flunixamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015

Page 13 of 14

Version: 3.0

15. REGULATORY INFORMATION

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	203-868-0
HYDROCHLORIC ACID	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7
Sodium formaldehyde sulfoxylate dihydrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Disodium EDTA (dihydrate)	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Water for Injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

SAFETY DATA SHEET

**Material Name: Flunixinamine (flunixin meglumine) Injectable
Solution (U.S. only)
Revision date: 24-Apr-2015**

Page 14 of 14

Version: 3.0

H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure
H315 - Causes skin irritation
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H300 - Fatal if swallowed
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects
H314 - Causes severe skin burns and eye damage
H335 - May cause respiratory irritation
H301 - Toxic if swallowed
H341 - Suspected of causing genetic defects
H331 - Toxic if inhaled

R22 - Harmful if swallowed.
R26 - Very toxic by inhalation.
R34 - Causes burns.
R35 - Causes severe burns.
R38 - Irritating to skin.
R41 - Risk of serious damage to eyes.
R68 - Possible risks of irreversible effects.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R48/20/21/22 - Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.
Updated Section 15 - Regulatory Information. Updated Section 10 - Stability and Reactivity.
Updated Section 9 - Physical and Chemical Properties.

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Zoetis Global Risk Management

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End of Safety Data Sheet