This SDS packet was issued with item:

078905410

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

078036207

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078905411



Material Safety Data Sheet

Flunixamine

WW MSDS No. 305601

Section 1. Produc	t and Company Identification	
Manufactured/ Supplied by	Fort Dodge Animal Health 800 5th Street NW	Date of 11 August 2004 Preparation
	P.O. Box 518 Fort Dodge, IA 50501 Phone: 515-955-4600 Fax: 515-955-9149	Product No. 305601
Product Trade Name	Flunixamine	Formula No. Not available.
Common Name	Not applicable.	CAS No. Mixture.
Synonyms	Flunixin meglumine.	U.N. No. Not applicable.
Chemical Formula	Mixture.	EINECS No. Not applicable.
Chemical Family	Anti-inflammatory Agents.	
Material Uses	Pharmaceutical: Veterinary pharmaceutical.	<u>In Case of</u> 515-955-6033 <u>Emergency</u>
Packaging	Glass bottle/vial	
Formula Type	Injectable solution.	

Section 2. Composition - Information on Ingredients				
Name of Ingredients	CAS No.	Conc.	EU Symbol	R Phrase
Flunixin Meglumine Phenol	6284-40-8 108-95-2	5 0.5	Xn C Xn	R42/43 R34, R24/25
3) Sodium Formaldehyde Sulfoxylate4) Inert Ingredients	149-44-0	0.25 >90%	Xi Not controlled.	R37 Not controlled.

Section 3. Hazards Identification - Summary of Primary Effects and Critical Hazards				
Acute Health Effects	te Health Effects Severely irritating to eyes.			
Chronic Health Effects	MUTAGENIC EFFECTS: Mutagenic for mammalians [Propylene Glycol]. Mutagenic for mammalians Potential organ systems effected are: Central Nervous System (CNS), Gastrointestinal Tract.			
Environmental Hazards	No known significant effects or critical hazards.			

Section 4. First Aid Measures - (by medical responders using "Universal Precautions")			
Eye Contact	Flush eyes with plenty of water for 15 minutes, occasionally lifting upper and lower eyelids. (Check person for contact lenses and remove if present.) If redness or irritation persists have eyes examined by doctor immediately.		
Skin Contact	Flush skin with plenty of soap and water for at least 15 minutes (remove all contaminated clothing and shoes). Get medical attention if symptoms persist.		
Inhalation	No specific treatment, treat symptomaticaly. If breathing is difficult give oxygen, if respiratory arrest occurs provide artificial respiration and seek immediate medical assistance.		
Ingestion	No specific treatment, treat symptomatically. Call medical doctor or poison control center immediately if large quantities are ingested.		
Notes to Medical Doctor	Direct treatment at control of symptoms.		

Flunixamine Page number: 2 of 5				
Section 5. Fire-Fighting Measures				
Extinguishing Media and Instructions	Follow your company's procedures. Use an extinguishing agent suitable for the surrounding class of fire.			
Special Exposure Hazards	None. Dispose of fire debris and contaminated fire fighting water in accordance with regulations. Collect contaminated fire fighting water and prevent entry into drains and waterways.			
Special Fire Fighting Protective Equipment	Qualified persons wearing full fire-fighting suits and approved/certified self-contained breathing apparatus.			

Section 6. Accidental Release Measures			
Small Spill Guidelines	Follow your company's spill procedures. Keep people away from spill. Put on appropriate personal protective equipment (see Section 8). Use a tool to scoop up solid or absorbed material and put into appropriate labeled waste container.		
Large Spill Guidelines	Initiate company's spill response procedures immediately. Keep people out of area. Put on appropriate personal protective equipment (see Section 8). Absorb with an inert material and put the spilled material in an appropriate waste disposal.		
Environmental Precautions	Dike spill area and do not allow product to reach sewage system and surface or ground water. Provide notification of any reportable spill to authorities. (See Section 12 for environmental risks and 13 for disposal informations.) Clean spill area and tools used several times with inert absorbents and put in container for appropriate disposal.		

Section 7. Handling and Storage		
Handling (ventilation and fire prevention)	Avoid contact with eyes. Wash thoroughly after handling.	
Storage (conditions and limitations)	Keep container tightly closed. Keep in a well-ventilated place. Store between 15 to 30°C (59 to 86°F)	

Section 8. Exposu	re Controls and Perso	nal Protectio	n - (normal and	intended use)	
Exposure Guidelines					
Component		REG. Limit	OSHA (PEL)	ACGIH (TLV®)	Company Guideline
1) Phenol	TWA:	19 mg/m³ SKIN	19 mg/m³ SKIN	19 mg/m³ SKIN	
2) Propylene Gly	col TWA:	156 mg/m ³			
Engineering Design and Control Measures	General ventilation is typically sufficient to keep airborne levels below established values. Provide eye wash and quick drench shower close to work station. Clean, appropriately launder, or dispose of all potentially contaminated work clothing, foot wear, and protective equipment after use.				
Protective Clothing					
Eyes	Safety glasses. Goggles, fa aerosols or splashes.	ace shield, or ot	her full-face protection	on where if the potentia	l exists for direct exposure to
Skin	Lab coat.				
Hands	Gloves, Chemical resistant.	Gloves, Nitrile.			
Respiratory	Respirator selection must be the selected respirator. A re				and the safe working limits of as of product use.

Flunixamine	Page Number: 3 of 5				
Section 9. Physical and Chemical Properties					
Physical State and Appearance	Liquid. Odo		Slight.		
Molecular Weight	Mixture.	Clear			
Boiling Point	Not available.	8.3 [Basic.]			
Melting/Freezing Point	0°C (32°F) based on data for: Water For Injection.				
Density/Bulk Density	Weighted average: 1.01 (Water = 1)				
Vapor Pressure	18 mm of Hg (@ 20°C) (Water For Injection.).				
Vapor Density	2.62 (Air = 1) (Propylene Glycol).				
Viscosity	Not available.				
Partition Coefficient	The product is more soluble in oil.				
Solubility	Flunixin Injection: Partially soluble in cold water, hot water.				
Flash Point	Not applicable.				
Autoignition Point	Not applicable.				
Explosion Limits	Not applicable.				
Dust Explosivity	Not applicable.				

Section 10. Stability and Reactivity				
Conditions to Avoid and Incompatibility	Highly reactive with oxidizing agents. Reactive with acids, alkalis.			
Decomposition Products	These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2), sulfur oxides (SO2, SO3).			

omponent		Test	Result	Route	Species
) Dhanal		I DEO	247 //		Det
1) Phenol		LD50 LD50	317 mg/kg	oral oral	Rat Mouse
		LD50 LD50	270 mg/kg	dermal	Rabbit
		LD50 LD50	630 mg/kg 669 mg/kg	dermal	Rabbit
2) Propylene Gly	col	LD50	20000 mg/kg	oral	Rat
z) i Topylette Giyt	201	LD50	22000 mg/kg 22000 mg/kg	oral	Mouse
		LD50	20800 mg/kg	dermal	Rabbit
3) Sodium Forma	ldehyde	LD50	>2000 mg/kg	oral	Rat
Sulfoxylate		LD50	4000 mg/kg	oral	Mouse
4) Water For Inje	ction.	LD50	90000 mg/kg	oral	Rat
Eye Contact	Severely in	ritating (USA).	Irritating (EU).		
Skin Contact	Moderately	y irritating (USA)). Irritating (EU).		
Inhalation	Slightly irri	tating to the resp	piratory system.		
Ingestion	Practically	non-toxic if swa	llowed.		

Flunixamine	Page Number: 4 of 5
Target Organs	Potential organ systems effected are: Central Nervous System (CNS), Gastrointestinal Tract.
Adverse Effects Statements	Adverse affects could include uncoordination, motor and sensory paralysis discomfort (gastrointestinal)
Sensitization	Not available.
Carcinogenic Effects	Classified (ACGIH-A4-Not Classifiable as a Human Carcinogen), 3 (Not classifiable for human.) by IARC [Phenol].
Mutagenic Effects	Mutagenic for mammalians [Propylene Glycol].
Teratogenic Effects	No known human teratogenic effect
Reproductive Effects	No evidence of human reproductive effects.
Other Effects	FDA C - Risk cannot be ruled out.

Section 12. Ecolog	ical Informa	tion			
Environmental Fate	Not available.				
Environmental Hazards	No known sig	nificant effects or critica	ıl hazards.		
Ecotoxicity					
Component		Species	Period	Result	
1) Phenol		Trout EC50 (daphnia)	48 hour(s) 48 hour(s)	9.4 10	mg/l mg/l
Other	Not available.				

Section 13. Disposal Considerations			
Waste Handling and Disposal	Medical waste Avoid disposal, make attempts to use product completely in accordance with intended use. Incinerate unwanted products and waste materials.		
Note: The waste generator must be informed of and follow all applicable rules and regulations for the handling and disposal of waste.			

Proper Shipping Name,	Not controlled	
Primary Class, UNNA Number, Pakaging Group		
ADR/RID Classification (Road and Rail Transport)	Not controlled.	
ADNR Classification (Inland Waterways)	Not controlled.	
IMO/IMDG Class (Maritime Transport)	Not controlled.	
ICAO/IATA (Air Transport)	Not controlled.	
CEFIC Tremcard	Not available.	HI Kemler Not available.

Flunixamine			Page Number: 5 of 5
U.S.A. DOT Class	Not controlled.	NFPA Health	Flammability Reactivity
RQ	Not applicable.		Specific hazard
Packaging Intructions	Not available.		

(S) Safety Phrases S41. In case of fire and/or explosion do not breathe fumes		R36/38- Irritating to eyes and skin.	
Of 1- in case of the analor explosion do not breathe funes.		S41- In case of fire and/or explosion do not breathe fumes.	(S) Safety Phrases

Section 16. Other Key Information

Other Considerations See product label and package insert for additional information.

11 August 2004 Responsible for MSDS: FDAH Environmental, Health, and Safety Department

Fort Dodge Animal Health -- A Division of Wyeth Corporation

Notice to Reader

* This symbol indicates information which has changed from the previous MSDS.

The information provided in this MSDS is based on current knowledge, however, this does not constitute a warranty by the Company for that information. The product user is responsible for the appropriate and intended handling, use, and disposal of this product in accordance with label or package precautions and this information. All materials may present unknown hazards and should be used with caution.

Attn: SAFETY DIRECTOR

EMERGENCY PHONE⁻ 573-443-5363 DATE-11/14/2012

MATERIAL SAFETY DATA SHEET

IDENTIFICATION- Product Code: 7910.00

Name: ENDOVAC-EQUI® Salmonella Typhimurium Bacterin Toxoid

TOXICITY HAZARDS -No toxicity data available

HEALTH HAZARDS DATA-

ACUTE EFFECTS:

-May be harmful if swallowed as the toxicological properties have not been thoroughly investigated.

FIRSTAID- In case of skin contact, wash thoroughly with soap and water. If swallowed, call a physician.

F|RE AND EXPLOSION HAZARD DATA- No fire or explosion hazard exists

-PHYS|CAL DATA- Appearance and Odor: Opaque liquid

REACTIVITY and STABILITY DATA -Stable

SPILL OR LEAK PROCEDURES- No special requirements are necessary

PRECAUTIONS TO BE TAKEN REGARDING HANDLING & STORAGE-

- Store at 2° - 7° C.

The above information is believed to be correct, but does not purport to be all inclusive and shall only be used as a guide.

IMMVAC INC. shall not be held liable for any damage resulting from handling or from contact with the above product.

#



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

Product Identifier

Material Name: Flunixamine (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

Zoetis Belgium S.A.

Mercuriusstraat 20
1930 Zaventem

Belgium

Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number: Emergency telephone number:

Contact E-Mail: VMIPSrecords@zoetis.com

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.

Material Name: Flunixamine (flunixin meglumine) Injectable Page 2 of 14

Solution (U.S. only)

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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

P280 - Wear protective gloves/protective clothing/eye protection/face protect P271 - Use only outdoors or in a well-ventilated area

P271 - Ose only outdoors of in a well-vertilated 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.

Material Name: Flunixamine (flunixin meglumine) Injectable

Solution (U.S. only)

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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.

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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)	<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

Material Name: Flunixamine (flunixin meglumine) Injectable Page 4 of 14

Solution (U.S. only)

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4. FIRST AID MEASURES

Description of First Aid Measures

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention **Eye Contact:**

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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information. **Exposure:**

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

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 / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

Collecting: area thoroughly.

Additional Consideration for

Non-essential personnel should be evacuated from affected area. Report emergency Large Spills:

situations immediately. Clean up operations should only be undertaken by trained personnel.

Material Name: Flunixamine (flunixin meglumine) Injectable Page 5 of 14

Solution (U.S. only)

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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/m³ 10 mg/m³

150 ppm **Ireland OEL - TWAs**

> 470 mg/m³ 10 mg/m³

Latvia OEL - TWA 7 mg/m^3

 7 mg/m^3 Lithuania OEL - TWA

PHENOL

ACGIH Threshold Limit Value (TWA) 5 ppm

ACGIH - Biological Exposure Limit: 250 mg/g creatinine

Australia TWA 1 ppm 4 mg/m^3

2 ppm **Austria OEL - MAKs**

8 mg/m³ 2 ppm **Belgium OEL - TWA**

8 mg/m³ **Bulgaria OEL - TWA** 8 ma/m³

Bulgaria - Biological Exposure Limit: 200 mg/L 8 mg/m³ Cyprus OEL - TWA

2 ppm 7.5 mg/m³ Czech Republic OEL - TWA **Denmark OEL - TWA** 1 ppm 4 mg/m³

2,2 IMINODIETHANOL

PZ01728

ACGIH Threshold Limit Value (TWA) 1 mg/m^3

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the

2 ppm

cutaneous route

Material Name: Flunixamine (flunixin meglumine) Injectable Page 6 of 14

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

		S/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/m³
	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/m³
	Poland OEL - TWA	9 mg/m ³
	Portugal OEL - TWA	2 mg/m ³
	Slovenia OEL - TWA	15 mg/m³
	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
LIVE	DOCUL ODIO ACID	
нти	ROCHLORIC ACID	2
	ACGIH Ceiling Threshold Limit:	2 ppm
	Australia PEAK	5 ppm 7.5 mg/m ³
	Austria OEL MAKa	5 ppm
	Austria OEL - MAKs	8 mg/m ³
	Belgium OEL - TWA	5 ppm
	Beigium OLL - TWA	8 mg/m ³
	Bulgaria OEL - TWA	5 ppm
	Daigana OLL TVIA	8.0 mg/m ³
	Cyprus OEL - TWA	5 ppm
	O)p. 10 0	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

Material Name: Flunixamine (flunixin meglumine) Injectable Page 7 of 14

Solution (U.S. only)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA 8 mg/m³ **Ireland OEL - TWAs** 5 ppm 8 mg/m³ **Italy OEL - TWA** 5 ppm 8 mg/m³ 5 ppm Japan - OELs - Ceilings 7.5 mg/m^{3} Latvia OEL - TWA 5 ppm 8 mg/m³ Lithuania OEL - TWA 5 ppm 8 ma/m³ **Luxembourg OEL - TWA** 5 ppm 8 mg/m³ 5 ppm Malta OEL - TWA 8 mg/m³ 8 mg/m³ **Netherlands OEL - TWA Vietnam OEL - TWAs** 5 mg/m³ 5 mg/m³ **Poland OEL - TWA** Portugal OEL - TWA 5 ppm 8 mg/m³ 5 ppm Romania OEL - TWA 8 mg/m³ 5 ppm Slovakia OEL - TWA 8.0 mg/m³ Slovenia OEL - TWA 5 ppm 8 mg/m³ Spain OEL - TWA 5 ppm 7.6 mg/m³ **Switzerland OEL -TWAs** 2 ppm 3.0 mg/m³

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

Personal Protective

Refer to applicable national standards and regulations in the selection and use of personal **Equipment:**

protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk

processing operations.

Eves: Wear safety glasses or goggles if eye contact is possible.

Impervious protective clothing is recommended if skin contact with drug product is possible and Skin:

for bulk processing operations.

Material Name: Flunixamine (flunixin meglumine) Injectable Page 8 of 14

Solution (U.S. only)

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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:LiquidColor:Clear, colorlessOdor:SlightOdor Threshold:No data available.

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: Soluble pH: Soluble

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

Flammablity:

Autoignition Temperature (Solid) (°C):No data availableFlammability (Solids):No data availableFlash Point (Liquid) (°C):No data availableUpper Explosive Limits (Liquid) (% by Vol.):No data availableLower 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

Material Name: Flunixamine (flunixin meglumine) Injectable Page 9 of 14

Solution (U.S. only)

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11. TOXICOLOGICAL INFORMATION

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

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Flunixin meglumine

 $\begin{array}{lll} \text{Rat} & \text{Inhalation} & \text{LC50} & < 0.52 \text{ mg/L} \\ \text{Rat} & \text{Oral} & \text{LD50} & 53\text{-}157\text{mg/kg} \end{array}$

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 / SensitizationMay cause skin irritation.

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

Flunixin meglumine

PZ01728

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

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

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

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

PHENOL

103 Week(s) Oral 5,000 ppm NOAEL Not carcinogenic Rat 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), 1000 mg/kg

Acute Toxicity Estimate (ATE),

10 mg/l

inhalation (dust/mist)

Acute Toxicity Estimate (ATE), >5000 mg/kg

dermal

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Solution (U.S. only)

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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) 96 Hours 150 ma/L EC50 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 23.88 mg/L 96 Hours

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

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

HYDROCHLORIC ACID

CERCLA/SARA Hazardous Substances 5000 lb and their Reportable Quantities: 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

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not

Flunixin meglumine

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Present

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 255-836-0

PHENOL

PZ01728

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed
203-632-7

2,2 IMINODIETHANOL

CERCLA/SARA 313 Emission reporting 1.0 % CERCLA/SARA Hazardous Substances 100 lb and their Reportable Quantities: 45.4 kg

California Proposition 65 carcinogen initial date 6/22/12

Inventory - United States TSCA - Sect. 8(b) Present

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15. REGULATORY INFORMATION

Australia (AICS): Present
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 6
EU EINECS/ELINCS List 203-868-0

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances 5000 lb and their Reportable Quantities: 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous 500 lb

TPQs

CERCLA/SARA - Section 302 Extremely Hazardous 5000 lb

Substances EPCRA RQs

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Standard for the Uniform Scheduling
for Drugs and Poisons:
Schedule 6
EU EINECS/ELINCS List
Not Listed
Present
Schedule 5
Schedule 6
231-595-7

Sodium formaldehyde sulfoxylate dihydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Disodium EDTA (dihydrate)

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Water for Injection

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed

Present

obligations of Register:

EU EINECS/ELINCS List 231-791-2

16. OTHER INFORMATION

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

Material Name: Flunixamine (flunixin meglumine) Injectable Page 14 of 14

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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.

Prepared by: Toxicology and Hazard Communication

Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



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

Product Identifier

Material Name: Flunixamine (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.

Zoetis Belgium S.A.

100 Campus Drive, P.O. Box 651

Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896

Belgium

Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number: Emergency telephone number:

Contact E-Mail: VMIPSrecords@zoetis.com

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.

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Solution (U.S. only)

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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.

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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.

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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

Material Name: Flunixamine (flunixin meglumine) Injectable Page 4 of 14

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4. FIRST AID MEASURES

Description of First Aid Measures

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention **Eye Contact:**

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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information. **Exposure:**

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

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 / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

Collecting: area thoroughly.

Additional Consideration for

Non-essential personnel should be evacuated from affected area. Report emergency Large Spills:

situations immediately. Clean up operations should only be undertaken by trained personnel.

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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/m³ 10 mg/m³

Ireland OEL - TWAs 150 ppm

470 mg/m³ 10 mg/m³

Latvia OEL - TWA 7 mg/m³ Lithuania OEL - TWA 7 mg/m³

PHENOL

ACGIH Threshold Limit Value (TWA) 5 ppm

ACGIH - Biological Exposure Limit: 250 mg/g creatinine

Australia TWA 1 ppm 4 mg/m³

Austria OEL - MAKs 2 ppm 8 mg/m³

Belgium OEL - TWA 2 ppm 8 mg/m³ 8 mg/m³ 8 mg/m³

Bulgaria OEL - TWA 8 mg/m³ 2 ppm

Bulgaria - Biological Exposure Limit: 200 mg/L
Cyprus OEL - TWA 8 mg/m³
2 ppm

 Czech Republic OEL - TWA
 7.5 mg/m³

 Denmark OEL - TWA
 1 ppm

 4 mg/m³
 4 mg/m³

2,2 IMINODIETHANOL

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ACGIH Threshold Limit Value (TWA) 1 mg/m³

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the

cutaneous route

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Greece OEL - TWA

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	RE CONTROLS / PERSONAL PROTECTION
Australia TWA	3 ppm 13 mg/m³
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/m³
Denmark OEL - TWA	0.46 ppm 2 mg/m³
Estonia OEL - TWA	3 ppm 5 mg/m³
Finland OEL - TWA	0.46 ppm 2 mg/m ³
France OEL - TWA	3 ppm 15 mg/m³
Germany (DFG) - MAK	1 mg/m³
Greece OEL - TWA	3 ppm 15 mg/m ³
Ireland OEL - TWAs	1 mg/m³
Lithuania OEL - TWA	3 ppm 15 mg/m³
Poland OEL - TWA	9 mg/m³
Portugal OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	15 mg/m³
Spain OEL - TWA	0.46 ppm 2 mg/m ³
Sweden OEL - TWAs	3 ppm 15 mg/m³
Switzerland OEL -TWAs	1 mg/m³
HYDROCHLORIC ACID	
ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m³
Austria OEL - MAKs	5 ppm 8 mg/m³
Belgium OEL - TWA	5 ppm 8 mg/m³
Bulgaria OEL - TWA	5 ppm 8.0 mg/m³
Cyprus OEL - TWA	5 ppm 8 mg/m³
Czech Republic OEL - TWA	8 mg/m³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³

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5 ppm 7 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA 8 mg/m³ **Ireland OEL - TWAs** 5 ppm 8 mg/m³ **Italy OEL - TWA** 5 ppm 8 mg/m³ 5 ppm Japan - OELs - Ceilings 7.5 mg/m^{3} Latvia OEL - TWA 5 ppm 8 mg/m³ Lithuania OEL - TWA 5 ppm 8 ma/m³ **Luxembourg OEL - TWA** 5 ppm 8 mg/m³ 5 ppm Malta OEL - TWA 8 mg/m^3 8 mg/m³ **Netherlands OEL - TWA Vietnam OEL - TWAs** 5 mg/m³ 5 mg/m³ **Poland OEL - TWA** Portugal OEL - TWA 5 ppm 8 mg/m³ 5 ppm Romania OEL - TWA 8 mg/m³ 5 ppm Slovakia OEL - TWA 8.0 mg/m³ Slovenia OEL - TWA 5 ppm 8 mg/m³ Spain OEL - TWA 5 ppm 7.6 mg/m³ **Switzerland OEL -TWAs** 2 ppm 3.0 mg/m³

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

Personal Protective

Refer to applicable national standards and regulations in the selection and use of personal **Equipment:**

protective equipment (PPE).

Impervious gloves are recommended if skin contact with drug product is possible and for bulk Hands:

processing operations.

Eves: Wear safety glasses or goggles if eye contact is possible.

Impervious protective clothing is recommended if skin contact with drug product is possible and Skin:

for bulk processing operations.

Material Name: Flunixamine (flunixin meglumine) Injectable Page 8 of 14

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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:LiquidColor:Clear, colorlessOdor:SlightOdor Threshold:No data available.

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: Soluble pH: Soluble

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

Flammablity:

Autoignition Temperature (Solid) (°C):No data availableFlammability (Solids):No data availableFlash Point (Liquid) (°C):No data availableUpper Explosive Limits (Liquid) (% by Vol.):No data availableLower 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

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11. TOXICOLOGICAL INFORMATION

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

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

Flunixin meglumine

 $\begin{array}{lll} \mbox{Rat} & \mbox{Inhalation} & \mbox{LC50} & < 0.52 \mbox{ mg/L} \\ \mbox{Rat} & \mbox{Oral} & \mbox{LD50} & 53\text{-}157\mbox{mg/kg} \end{array}$

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

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

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

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

PHENOL

103 Week(s) Oral 5,000 ppm NOAEL Not carcinogenic Rat 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), 1000 mg/kg

Acute Toxicity Estimate (ATE),

10 mg/l

inhalation (dust/mist)

Acute Toxicity Estimate (ATE), >5000 mg/kg

dermal

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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) 96 Hours 150 ma/L EC50 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 23.88 mg/L 96 Hours

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

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

HYDROCHLORIC ACID

CERCLA/SARA Hazardous Substances 5000 lb and their Reportable Quantities: 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

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not

Flunixin meglumine

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Not Listed

Present

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 255-836-0

PHENOL

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed
203-632-7

2,2 IMINODIETHANOL

CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances 100 lb and their Reportable Quantities: 45.4 kg

California Proposition 65 carcinogen initial date 6/22/12

Inventory - United States TSCA - Sect. 8(b) Present

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15. REGULATORY INFORMATION

Australia (AICS): Present
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 6
EU EINECS/ELINCS List 203-868-0

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances 5000 lb and their Reportable Quantities: 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous 500 lb

TPQs

CERCLA/SARA - Section 302 Extremely Hazardous 5000 lb

Substances EPCRA RQs

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Standard for the Uniform Scheduling
for Drugs and Poisons:
Schedule 6
EU EINECS/ELINCS List
Not Listed
Present
Schedule 5
Schedule 6
231-595-7

Sodium formaldehyde sulfoxylate dihydrate

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Disodium EDTA (dihydrate)

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Water for Injection

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex IV - Exemptions from the

Not Listed

Present

obligations of Register:

EU EINECS/ELINCS List 231-791-2

16. OTHER INFORMATION

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

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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.

Prepared by: Toxicology and Hazard Communication

Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

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