MSD is a tradename of Merck & Co., Inc., with headquarters in Whitehouse Station, N.J., U.S.A.

SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. Merck urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

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

PRODUCT IDENTIFIER

SDS NAME: **Flunixin Meglumine Solution**

SYNONYM(S): Flunixin Meglumine Solution
Banamine Injectable Solution
Finadyne Injectable Solution
Finixin Solution
Bedozane Solution

SDS Number: SP000351

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Veterinary Product

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU SUPPLIER/MANUFACTURER: MSD Animal Health
Breakspear Road South
Harefield, Uxbridge
Middlesex, England UB9 6LS

INFORMATION: (0 11 44) 1895 62 6000 (MSD Animal Health- Harefield)

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

EU Transportation Emergencies - Carechem24:
+44 (0)208 762 8322 (24 hours/7 days/week)

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Acute Tox. 4 (H302), Eye Dam. 1 (H318), STOT Rep. 2 (H373)

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Xn;R22 Xi;R41 Xn;R48/22

COLOR: Clear, Colorless to light yellow
FORM: Solution
ODOR: Odor unknown

LABEL ELEMENTS

HAZARD STATEMENT(S):
Harmful if swallowed
Causes serious eye irritation
May cause damage to organs through prolonged or repeated exposure.

PRECAUTIONARY STATEMENT(S):
Wash hands and face thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Do not eat, drink or smoke when using this product. Do not breathe dust/fume/gas/mist/vapor/spray. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. Dispose of contents/container to an approved incineration plant.

OTHER HAZARDS

Health-Related Hazards:

TARGET ORGAN EFFECTS:
gastrointestinal tract
kidney
immune system
spleen

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) in this mixture.

Environmental-Related Hazards:

This substance has not been fully tested to meet the criteria for listing as a PBT or a vPvB.

Other Hazards:

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Flunixin Meglumine	42461-84-7	255-836-0	Not available	T+;R26 T;R25 T;R48/25 Xi;R41 Xi;R37 Xn:R68/22 N;R51-53	Acute Tox. 3 (H301) Eye Dam. 1 (H318) Acute Tox. 2 (H330) STOT SE 3 (H335) STOT Single 2 (H371) STOT RE 1 (H372) Aquatic Chronic 2 (H411)	8.5	Classified Active Pharmaceutical Ingredient
Propylene Glycol	57-55-6	200-338-0	x	Not Classified	Not Classified	10-20	Community workplace exposure limit

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

FIRST AID MEASURES

INHALATION: Remove to fresh air. Administer artificial respiration if breathing has ceased. IMMEDIATELY consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, IMMEDIATELY rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. Get IMMEDIATE medical attention.

INGESTION: Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture.

Flunixin meglumine is a potent non-narcotic, non-steroidal agent with pain killing, anti-inflammatory, and fever-reducing activity. Based on animal studies, flunixin meglumine may cause severe eye irritation or irreversible ocular effects. It may also cause irritation of the skin, mucous membranes, respiratory tract, and gastrointestinal tract. Repeated dermal contact to high concentrations may cause severe skin irritation. Prolonged inhalation may produce serious lung effects. Repeated ingestion or inhalation of high doses may cause internal bleeding, predominantly of the gastrointestinal tract.

Propylene glycol is considered to be relatively non-toxic. It is a mild irritant to the eyes and has been reported to irritate the skin. It may cause skin sensitization resulting in allergic contact dermatitis in susceptible individuals. Inhalation exposure to saturated and supersaturated atmospheres of propylene glycol for prolonged periods of time produced no adverse effects. Propylene glycol may cause nervous system depression, acidosis, stupor, and seizures after chronic ingestion.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: Flunixin meglumine is a potent Non-Steroidal Anti-inflammatory Drug (NSAID), and overexposure may cause gastrointestinal irritation and bleeding, kidney and central nervous system effects.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:
None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

SPECIAL FIRE HAZARDS:
None known.

ADVICE FOR FIREFIGHTERS

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

ENVIRONMENTAL PRECAUTIONS:

Do not allow product to reach ground water, water course, sewage or drainage systems.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Avoid contact with eyes. Avoid splashing or spraying. Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Store in a cool, dry, well ventilated area.

SPECIFIC END USE(S)

Refer to Section 1 for identified use(s).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

CONTROL PARAMETERS

OCCUPATIONAL EXPOSURE BAND (OEB):
Flunixin Meglumine: OEB 3: >=10<100 mcg/m^3. Materials in an OEB 3 category are considered moderate health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA):
30 mcg/m^3

Wipe Limit:
300 mcg/100 cm2

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Propylene Glycol	57-55-6		TWA 150 ppm TWA 470 mg/m^3 TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Propylene Glycol	57-55-6	STEL 37.5 ppm STEL 118.5 mg/m^3 TWA 25 ppm TWA 79 mg/m^3				STEL 450 ppm STEL 1422 mg/m^3 STEL 30 mg/m^3 TWA 150 ppm TWA 474 mg/m^3 TWA 10 mg/m^3

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Propylene Glycol				TWA 150 ppm TWA 474 mg/m^3 TWA 10 mg/m^3	

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Body Protection: In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

Skin Protection: Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Respiratory Protection: Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection is required if there is potential for contact with this material. Consult your site safety staff for guidance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Solution
COLOR:	Clear, Colorless to light yellow
ODOR:	Odor unknown
ODOR THRESHOLD:	Not determined
pH:	7.8 to 9.0
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	1.041 to 1.047 at 20 deg C
SOLUBILITY:	
Water:	Not determined
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	Not determined (liquids) or not applicable (solids).
Flammability (solid, gas):	Not determined
UEL:	Not determined
LEL:	Not determined
Autoignition Temperature:	Not determined

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon monoxide (CO). Carbon dioxide (CO2).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture. The information presented for the active ingredient in this formulation, flunixin meglumine, is either for flunixin (free acid) or the meglumine salt. The toxicity is considered equivalent, except for differences in mutagenicity, based on studies conducted using both forms of the drug.

LIKELY ROUTES OF EXPOSURE:
Skin, eye and inhalation.

ACUTE TOXICITY DATA

INHALATION:
Flunixin Meglumine: Inhalation LC50 (4hr): <0.52 mg/L (rat)
Mortality occurred in all rats (10/10) between days 3 and 6 following a single 4-hour exposure to an average analytical concentration of 0.52 mg/L (maximum attainable exposure). Signs exhibited following exposure included lacrimation, nasal discharge, dried red material around facial area, and yellow anogenital staining. Significant weight loss was noted following exposure in all animals.

Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

ORAL:
Flunixin Meglumine: Oral LD50: 53 to 157 mg/kg (rat), 176 to 249 mg/kg (male mouse, female estimated)
Flunixin (free acid): Oral LD50: 468.3 mg/kg (guinea pig)
Common effects observed in acute oral studies across species include gastrointestinal effects (perforation/ulceration and hemorrhage), hypoactivity, pallor, spleen enlargement, congestion of kidneys, lungs, or gastrointestinal tract, and respiratory distress. Necropsy of animals that died from flunixin meglumine revealed abnormalities of the brain, epididymides, abdominal cavity, thymus, liver, mesenteric lymph nodes, esophagus, mesentery, pancreas, and lungs. No signs of toxicity were observed following acute oral administration of 100 & 200 mg/kg to rhesus monkeys. However, 1 of 3 monkeys died following administration of 300 mg/kg. That monkey showed lethargy, prostration, and salivation prior to death, and signs of hyperemic mucosa in gastrointestinal tract and lungs at necropsy. Flunixin administered orally to mice at a dose of 300 mg/kg (100x the projected clinical dose) caused slight tremors and ataxia which resolved within 24 hours. Effects from acute oral and IV treatment of horses with 1.1 mg/kg flunixin were limited to sporadic incidence of fecal occult blood.

Propylene glycol: Oral LD50: 21 to 33.7 g/kg (rat), 10 to 20 g/kg (dog)
Propylene glycol caused dyspnea, cramps, loss of equilibrium, depression, analgesia, and death after prolonged moribund state in mice at doses ranging from 23.9 to 31.8 g/kg. In rabbits, 1 to 1.5 g/kg propylene glycol reduced intraocular pressure by raising the osmotic pressure of blood.

EYE:
Flunixin Meglumine: Severely irritating
All six animals exhibited severe conjunctival irritation including redness, swelling, discharge, and necrosis, as well as corneal opacity, ulceration and iridial damage. Severe ocular irritation was irreversible in most animals.

Propylene glycol was slightly irritating to the eyes of rabbits.

SKIN:
Flunixin meglumine: Slightly irritating
Flunixin meglumine produced mild, transient dermal irritation in rabbits. Dose-related skin irritation effects were observed in rabbits during a 21-day repeat skin application study (see below under Subchronic to Chronic Toxicity).

Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Propylene glycol was irritating in a human patch test. Propylene glycol was not irritating to the skin of rabbits, guinea pigs and swine.

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
Flunixin Meglumine was found not to be sensitizing in guinea pigs when tested by intradermal induction at 1% and topically at 100%.

Propylene glycol did not cause sensitization in a human patch test.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Repeat oral dosing studies have been performed with flunixin across multiple species. The most common adverse effect seen in these studies is gastrointestinal irritation/ulceration and bleeding as indicated by blood in the stools. Other common adverse effects observed across species from oral, IV or IM routes of exposure include nephrotoxicity, emesis, anorexia, and bleeding. Blood cell count changes, blood coagulation effects, and immune organ effects were observed secondary to gastrointestinal erosion and bleeding. Liver, nervous system and behavioral effects were also noted in mice. In addition to ulceration and bleeding, significant mortality was observed in rats at 8 and 16 mg/kg dosed for six weeks. [6-week oral toxicity NOAEL: 2 mg/kg (rats); 90-day oral toxicity NOAEL: 5 mg/kg (monkeys), 3.0 mg/kg (rats); one year oral toxicity NOEL: 1 mg flunixin/kg (rats)]

In several 21-day repeat skin application studies in rabbits using up to 80 mg/kg flunixin meglumine or the free acid in spray or cream formulations, no conclusive treatment-related toxicity could be established. The incidence and severity of dermal irritation increased in a dose-related manner with severe irritation seen at 80 mg/kg/day.

Propylene glycol caused no adverse effects in monkeys or rats exposed to saturated vapor concentrations for 12 to 18 months. Rats exposed to 25 or 50% (7.7 and 13.2 g/kg/day) propylene glycol in water died within 69 days in a 140 day study. In a separate study, a diet of 30% propylene glycol was not well tolerated in young rats, and dams could not bring their young to weaning; diets containing 40, 50, or 60% propylene glycol were lethal after a few days.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Reproductive and teratology studies in rats, mice and rabbits were performed with flunixin. Although significant maternal toxicity, including mortality, was reported, these studies indicate that flunixin does not affect offspring development, male or female fertility, or mating behavior. A slight increase in the length of gestation and difficult labor with an increase in stillbirths were observed. No evidence of any drug-related teratogenic effects were observed. Maternal toxicity observed in these studies was consistent with those findings in acute and repeated dose oral toxicity studies with the addition of pale eyes, ears and extremities. [Reproductive or developmental NOELs ranged from 2-21 mg/kg in studies with multiple species. Maternal toxicity NOELs ranged from 3-9 mg/kg in these studies].

Propylene glycol caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. Propylene glycol was not teratogenic in rabbits, monkeys or chickens.

MUTAGENICITY / GENOTOXICITY:
Flunixin meglumine was negative in the Ames and mouse micronucleus assays. It was positive in mouse lymphoma L5178Y cells, both in the absence and presence of S-9 metabolic activation and in the chromosomal abberation assay in CHO cells in vitro both in the absence and presence of S-9 metabolic activation. It has been reported to alter cellular DNA and caused primary DNA damage in E. coli. Flunixin free acid yielded the same results as flunixin meglumine. However, it was inconclusive in the bacterial repair assay in E.coli whereas flunixin meglumine was strongly positive. The meglumine moiety (N-methyl-D glucamine) was negative in all studies performed except the micronucleus study in which it was positive in one study and negative in a second.

Propylene glycol was negative in a bacterial mutagenicity study (Ames).

CARCINOGENICITY:
Flunixin meglumine had no carcinogenic effects or increase in tumor incidence relative to controls in either a 104-week study in rats administered 2, 4 and 8 mg flunixin meglumine/kg/day in the diet, or in mice administered 0.6, 2.0 and 6.0 mg flunixin meglumine/kg/day in the diet for 97 weeks. Significant toxicity observed in rats and mice included decreased body weights, increased mortality (high dose groups) and dose-related increases in gastrointestinal lesions in all treated groups. Compound-related lesions observed at necropsy included dose-related gastrointestinal ulcers, ulcer perforation with secondary peritonitis and adhesion formation, and large or edematous lymph nodes. Dose-related nonproliferative lesions were present in the gastrointestinal tract and mesenteric lymph node. Necrosis and ulceration of the mucosa, transmural necrosis, mucosal and mural inflammation, lymphoid hyperplasia, peritonitis and abscess formation were present. Inflammatory lesions and necrosis secondary to the peritonitis were present in other abdominal organs. Splenomegaly (enlarged spleens) were observed at necropsy in mice and were significant in the high dose group only. [Rat NOEL for tumor formation = 8 mg flunixin meglumine/kg/day and the LOEL = 2 mg flunixin meglumine/kg/day based on GI lesions. Mouse NOEL for tumor formation = 6.0 mg flunixin meglumine/kg/day; Toxicity NOEL = 0.6 mg flunixin meglumine/kg/day].

Propylene glycol was not carcinogenic when applied to the skin, or when given orally in mice and rats.

Classification according to EC Directive 1272/2008:
Acute Tox. 4 (H302). Eye Dam. 1 (H318). STOT Rep. 2 (H373).

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):
Skin sensitization. Skin corrosion or irritation. Respiratory sensitization. Mutagenicity. Carcinogenicity. Reproductive toxicity. Specific target organ toxicity (STOT) - Single Exposure. Aspiration hazard. Inhalation toxicity. Dermal toxicity.

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Flunixin meglumine: 96-hr LC50 (trout): 9.2 mg/L
Flunixin meglumine: 96-hr LC50 (bluegill): 46 mg/L
Flunixin meglumine: 48-hr EC50 (Daphnia): 25 mg/L
Flunixin meglumine: 72 hr IC50 (Algae): 36-120 mg/L

Propylene glycol: 96-hr LC50 (sheepshead minnow): 23,800 mg/L
Propylene glycol: 48-hr EC50 (daphnid): >43,500 mg/L
Propylene glycol: 72-hr EC50 (green algae): >19,000 mg/L

Banamine solution: 96-hr LC 50 (trout): >100mg/L
48-hr EC 50 (daphnia): >100 mg/L
72-hr EC 50 (algae); >100mg/L
72-hr NOEC (algae): 32 mg/L

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: No data available.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results: No data available.

MOBILITY IN SOIL

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

This substance has not been assessed.

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

OTHER INGREDIENT ENVIRONMENTAL DATA: Flunixin Meglumine: log Pow (log octanol/water partition coefficient): 1.34

Propylene glycol is expected to be readily biodegradable.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:
Do not allow product to reach ground water, water courses, sewage or drainage systems.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

This product is classifed in Germany - Substances Hazardous to Water: WGK 1

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Flunixin Meglumine	Not listed.	Not listed.	3
Propylene Glycol	Not listed.	280	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Flunixin Meglumine	Not listed.
Propylene Glycol	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Flunixin Meglumine	Not listed.
Propylene Glycol	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Flunixin Meglumine	Not listed.	Not listed.	Not listed.
Propylene Glycol	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Flunixin Meglumine	Not listed.
Propylene Glycol	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Flunixin Meglumine	Not listed.	Not listed.	Not listed.	Not listed.
Propylene Glycol	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING SDS: Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SUPERSEDES DATE: 07-May-2010

SECTIONS CHANGED (EU SUBFORMAT): 2, 11, 15
SIGNIFICANT CHANGES (EU SUBFORMAT): Hazard classification, Risk and safety phrases, OEB (Occupational Exposure Band), New regional format, Ecotox data

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Acute Tox. 4 (H302) • Eye Dam. 1 (H318) • STOT Rep. 2 (H373) • Acute Tox. 3 (H301) - Toxic if swallowed. • Acute Tox. 2 (H330) - Fatal if inhaled. • STOT Single 3 (H335) - May cause respiratory irritation. • STOT Single 2 (H371) - May cause damage to organs. • STOT Rep. 1 (H372) - Causes damage to organs through prolonged or repeated exposure. • Aquatic Chronic 2 (H411) - Toxic to aquatic life with long lasting effects.	• Harmful if swallowed • Causes serious eye irritation • May cause damage to organs through prolonged or repeated exposure.
Risk Phrases:	• R22 - Harmful if swallowed. • R25 - Toxic if swallowed. • R26 - Very toxic by inhalation. • R37 - Irritating to respiratory system. • R41 - Risk of serious damage to eyes. • R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed. • R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed. • R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. • R68/22 - Harmful: possible risk of irreversible effects if swallowed.	

GLOSSARY:
IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
NTP - National Toxicology Program
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - International Carriage of Dangerous Goods by Road
API - Active Pharmaceutical Ingredient
CAS - Chemical Abstract Service
CLP - Classification, Labeling and Packaging
DOT - Department of Transportation
EC - European Council
ETAC - Estimated Target Airborne Concentration
GHS - Globally Harmonized System
HEPA - High Efficiency Particulate Arresting
HHC - Health Hazard Category
HPA - Hypothalamic Pituitary Adrenal
IATA - International Air Transport Association
IMO - International Maritime Organization
IP - Intraperitoneal Injection
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
LOEL - Lowest Observed Effect Level
NEL - No Effect Level
NOAEL - No Adverse Effect Level
NOEL - No Observe Effect Level
OEG - Occupational Exposure Guideline
PBT - Persistent BioaccumulativeToxic
PG - Packing Group
PIC - Prior Informed Consent
PPE - Personal Protective Equipment
REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
RPE - Respiratory Protective Equipment
SCBA - Self Contained Breathing Apparatus
STOT - Specific Target Organ Toxicity
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
UN - United Nations
vPvB - Very Persistent andVery Bioaccumulative
WGK - Water Hazard Class (Germany)