MSD Animal Health
Breakspear Road South
Harefield, Uxbridge
Middlesex, England UB9 6LS

SAFETY DATA SHEET

MSD Animal Health 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 SUBSTANCE AND CONTACT INFORMATION

SDS NAME: **Flunixin Meglumine Paste**

SYNONYM(S): Banamine Paste
Finadyne Paste

SDS Number: SP000350

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

MSD Security Control Center (908) 820-6921 (24 Hours)

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

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: spmsds@spcorp.com

SECTION 2. HAZARDS IDENTIFICATION

EU CLASSIFICATION(S): Xn;R22 Xi;R36 R52 R53 Xn;R48/22

EMERGENCY OVERVIEW

White to off-white
Paste
Odor unknown
May be severely irritating to the eyes.
Harmful if swallowed.
Prolonged exposure may cause serious health effects.
Harmful to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

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. Inhalation hazard of Flunixin Meglumine is not expected due to the physical form of the paste.

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.

LISTED CARCINOGENS

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

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

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	EU CLASSIFICATION	PERCENT
Flunixin Meglumine	42461-84-7	255-836-0	T+;R26 T;R25 T;R48/25 Xi;R41 Xi;R37 N;R51-53	8.3
Propylene Glycol	57-55-6	200-338-0		10-20

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 15 for EU hazard classification symbols and risk and safety phrases.

SECTION 4. 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.

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

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

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

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

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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.

ENVIRONMENTAL PRECAUTIONS:
This product is harmful to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

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

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Ensure adequate ventilation. Handle in essentially closed systems, or in a laboratory fume hood. Cover containers during material transfer or transportation.

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.

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
An Occupational Exposure Guideline (OEG) of 18 mcg/m^3 (8-hr TWA) has been established for flunixin. Consult your site safety and industrial hygiene professional(s) for additional guidance.

EXPOSURE CONTROLS
For laboratories and small-scale operations, essentially no open handling. Open handling of small quantities may be performed if there is no potential for dust or aerosol generation. For larger quantities or materials that may become airborne, materials should be handled in a properly functioning chemical fume hood, ventilated enclosure or controlled by local exhaust ventilation.

For manufacturing and large-scale operations, essentially no open handling. Open handling is limited to small quantities in appropriately ventilated, enclosed environments. For larger quantities or materials that may become airborne, enclosed processes and the use of containment technology are preferred. Recirculation of general ventilation or local exhaust ventilation is not permitted unless appropriate scrubbing or filtration of incoming recirculated air is controlled.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	In laboratories and small-scale operations, appropriate respiratory protection is required in situations where exposure (e.g. spills, process upsets, or non-routine maintenance) may exceed any available recommended exposure limit. Consult your site safety staff for additional guidance. In manufacturing and large-scale operations, powered air purifying respirators (PAPRs) or positive-pressure air supplied respirators with full-face coverage are required. Consult your site safety staff for additional 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.
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.
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.

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

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Paste
COLOR: White to off-white
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

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 oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. 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.

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.

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.

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.

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.

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:
This material or product has not been evaluated for 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.

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

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA: 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 ECG or OEG.

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

The following classification is based on available data and is in accordance with European Union criteria.

EUROPEAN UNION REGULATIONS:

Indication of Danger: Xn - Harmful.
N - Dangerous For The Environment.

Risk Phrases:
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R52 - Harmful to aquatic organisms.
R53 - May cause long-term adverse effects in the aquatic environment.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Safety Phrases:
S46 - If swallowed, seek medical advice immediately and show this container or label.
S29 - Do not empty into drains.
S 1/2 - Keep locked-up and out of the reach of children.

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).

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SIGNIFICANT CHANGES (EU SUBFORMAT):	Hazard classification, Risk and safety phrases, OEB