



MERCK

Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: NUFLO[®]R Injectable Solution

SYNONYM(S): NUFLO[®]R Swine Injectable
NUFLO[®]R Cattle Injectable

MSDS NUMBER: SP000757

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/36) English Only

INFORMATION: Transportation Emergencies - CANUTEC:
(613) 996-6666 (Canada)

MERCK MSDS HELPLINE: Animal Health Technical Services:
(888) 306-0069 (Canada)
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SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Viscous solution
Clear, Light gold color
Odor unknown
May cause allergic reactions in susceptible individuals.
May be irritating to eyes.
May cause effects to:
gastrointestinal tract
male reproductive system
fetus

May cause impaired fertility.
May cause developmental effects.
Toxic to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

SECTION 2. HAZARDS IDENTIFICATION

No systemic toxicity, skin irritation, or skin sensitization was observed in acute animal studies using NUFLO[®] Injectable Solution. Slight eye irritation was observed in animals.

Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) is presented.

This product is not for use in humans. Clinical effects in humans have not been determined.

Florfenicol, the active ingredient in this product, is a broad-spectrum antibiotic used in veterinary products. Florfenicol may cause allergic reactions in susceptible individuals. Based on animal studies, florfenicol may cause slight eye irritation, constipation, changes in blood cell counts, changes in stool, or liver effects. It may also cause developmental effects or effects to male reproductive organs.

Acute exposure to polyethylene glycol may cause slight eye or skin irritation, abnormal taste, gas, nausea, vomiting, diarrhea, irregular heartbeat, low blood pressure, or fluid in the lungs. Repeated exposure of polyethylene glycol to damaged skin has been reported to cause kidney failure and necrosis. It may cause skin sensitization in sensitive individuals.

N-methyl-2-pyrrolidone (NMP) is a moderate to severe eye irritant in humans. Prolonged occupational exposure to low concentrations has caused chronic eye irritation and headache. Prolonged or repeated skin contact may cause dermatitis with blistering, edema, and erythema. In animal studies, fetotoxicity and teratogenicity was observed.

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 OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% 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	PERCENT
Florfenicol	73231-34-2	30
N-Methyl-2-Pyrrolidone	872-50-4	20-30
Polyethylene Glycol	25322-68-3	30-40
Propylene Glycol	57-55-6	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.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, 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. If irritation occurs or persists, consult a physician.

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SECTION 4. FIRST AID MEASURES

INGESTION:	Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.
NOTE TO PHYSICIAN:	This product contains florfenicol, a broad spectrum antibiotic which may cause allergic reactions in susceptible individuals.

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 toxic 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

HANDLING:

Avoid skin and eye contact. 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.

STORAGE:

Store in a cool, dry, well ventilated area.

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE BAND (OEB):

Florfenicol: OEB 2: 100-1000 mcg/m³. Materials in an OEB 2 category are considered to be slight 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.

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):

An Occupational Exposure Guideline (OEG) of 80 mcg/m³ (8-hr TWA) has been established for Florfenicol. Consult your site safety and industrial hygiene professional(s) for additional guidance.

HHC/OEG NOTATION(S):

Florfenicol: This material has a notation of "A" for its ability to cause immediate allergic hypersensitivity reactions or anaphylaxis.

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):

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.
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 may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
Body Protection:	<p>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.</p> <p>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.</p>

EXPOSURE LIMIT VALUES

See Occupational Exposure Guideline (OEG) listed above.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Viscous solution
COLOR:	Clear, Light gold color
ODOR:	Odor unknown
SOLUBILITY:	
Water:	Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY**STABILITY/ REACTIVITY:**

Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:

Open flames and high temperatures. Strong acids and bases. Oxidizers.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION
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The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA**INHALATION:**

Florfenicol: No mortality occurred in rats exposed to florfenicol for 4 hours at 0.28 mg/L (the maximum concentration tested). Clinical effects included dry rales, anogenital staining, secretory discharge, soft stool, and decreased body weights. These effects were seen immediately or up to one-week post exposure. Some effects did not resolve by study termination.

No mortalities were reported in rats (0/6) following a 4-hour exposure to polyethylene glycol vapors generated at 170 deg C; however, mortality was observed in all rats (6/6) following an 8-hour exposure to polyethylene glycol vapors generated at 170 deg C.

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

SKIN:

Dermal LD50 (rat): >2424 mg/kg

There were no deaths and no signs of systemic toxicity noted in an acute dermal toxicity study in rats.

Not irritating to the skin of rabbits.

EYE:

Nuflor Injectable Solution was slightly irritating to the eyes of rabbits. Conjunctival discharge and redness were observed 1-hour postinstillation. Effects were resolved by 24 hours.

ORAL:

Oral LD50 (rat): >2424 mg/kg

There were no deaths and no signs of systemic toxicity noted in an acute oral toxicity study in rats.

DERMAL AND RESPIRATORY SENSITIZATION:

Not a skin sensitizer in a dermal sensitization study in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:

Florfenicol was administered orally to dogs, rats, and mice at dosages as high as 100 to 400 mg/kg/day for up to 13 weeks. Effects including decreased body weight, changes in liver weight or liver enzyme levels, changes in testicular weight, testicular atrophy, decreased white blood cell counts, and decreased hemoglobin levels were observed at high dosages. Cellular changes in the liver or lymph nodes of rats and mice, and histopathologic changes in the brain and spinal cord of dogs were also noted at these high dosages. Although some effects were reversible after a 4-week withdrawal from treatment, testicular effects in rats persisted. Intramuscular injections of 45 mg/kg of florfenicol in swine produced diarrhea, injection site lesions, decreased body weight, decreased food and water consumption, changes in serum electrolytes and proteins, decreased red blood cell and white blood cell counts, decreased spleen weight, and decreased kidney weight.

In 52-week oral toxicity studies in dogs and rats, high dosages of florfenicol (12 and 48 mg/kg/day, respectively) increased liver weight and produced cellular changes in the gall bladder of dogs. In rats, florfenicol at the high dosage reduced body weight gain, reduced testicular weight, induced changes in hematologic and clinical chemistry parameters, and increased the incidence of testicular tubular atrophy. In two-year chronic studies in mice and rats, florfenicol caused similar effects as those observed in other long-term studies including reduced body weight gain, reduced red blood cell count, reduced hemoglobin levels, and testicular effects such as small testes, tubular atrophy and aspermatogenesis in both the high dosage rats (48 mg/kg/day) and mice (200 mg/kg/day).

Polyethylene glycol 400 produced no adverse effects in dogs and rats fed 2% in the diet for one or two years, respectively. Repeated dermal exposure to polyethylene glycol 300 for an eight-week period had no effect on mice. Repeated inhalation exposure to 1008 mg/m³ of a higher molecular weight polyethylene glycol increased lung weight, and also produced reversible increases in neutrophil counts in male rats.

Inhalation toxicity of N-methyl-2-pyrrolidone (NMP) was evaluated in male and female rats exposed to 0.1, 0.5, or 1.0 mg/L for four weeks. Mortality was seen in animals in the high-dosage group during the first nine days of exposure. Treatment-related effects noted in the high-dosage group included lethargy, irregular heartbeat, increased neutrophils, decreased lymphocytes, pulmonary edema and congestion, necrosis in hemopoietic cells, and atrophy or necrosis in lymphoid tissue. Surviving animals recovered following a two-week of recovery period.

Mice and rats were fed NMP dosages ranging from 2,000 to 30,000 ppm and 500 to 10,000 ppm for 28 days in rats and mice, respectively. Decreased body weight gains as well as clinical chemical changes, indicating possible alterations in lipid, protein, and carbohydrate metabolism, occurred in male rats dosed with 18,000 ppm and in both sexes dosed with 30,000 ppm. In mice, swelling of the epithelium of the distal parts of the renal tubules was observed at dosages of 7,500 ppm or higher. The NOAELs for these studies were 6,000 ppm for male rats, 18,000 ppm for female rats, and 2,500 ppm for mice. In a reproductive study, rats exposed to 116 ppm of NMP for 100 exposure days had a detectable decrease in response to sound.

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:

In a two-generation reproductive study, oral administration as high as 12 mg/kg/day of florfenicol reduced epididymal weights, decreased pup survival, and reduced lactation index in rats [NOAEL: 3 mg/kg/day].

There was no evidence of teratogenicity in rats administered florfenicol at dosages of 4, 12 or 40 mg/kg/day. Slight maternal toxicity, evidenced by decreased food and water consumption, was observed above 4 mg/kg/day. At 40 mg/kg/day, an increased incidence of delayed ossification and decreased fetal weight occurred. The NOAEL for maternal and fetal toxicity in rats was determined to be 4 mg florfenicol/kg/day.

Two teratogenicity studies were performed in mice. In the first study, the mice were administered florfenicol at dosages of 40, 120, or 400 mg/kg by gavage on days 6-15 of gestation. Florfenicol produced embryoletality at the 400 mg/kg/day dose level, which was evidenced by the high incidence of intrauterine deaths. Significant decreases in mean fetal body weight, soft tissue defects, and retarded skeletal ossification were also observed at 400 mg/kg/day. Skeletal ossification was less pronounced, in a dose-related fashion, at the lower doses tested (40 and 120 mg/kg/day). A developmental NOAEL could not be determined for these data [NOAEL for maternal: 120 mg/kg]. In the second teratogenicity study, florfenicol was retested at lower administered dosages of 1, 3, or 60 mg/kg/day. Maternal effects were limited to a slight increase in water consumption at the 60 mg/kg/day dose. There was no evidence of any adverse effects on the embryo/fetus at doses as high as 60 mg/kg/day in this study. However, based upon the retarded skeletal ossification effects observed in the first study at 40 mg/kg/day the NOAEL for the two studies combined was determined to be between 3 and 40 mg/kg/day.

Polyethylene glycol 200 was developmentally toxic in mice, causing malformations and other fetotoxicity, but elicited no similar response in rats at higher doses.

N-methyl-2-pyrrolidone (NMP) was not teratogenic to the offspring of rats exposed to 0.1 or 0.36 mg/L by inhalation from days 6 to 15 of gestation. No adverse reproductive effects were found in male or female rats exposed to airborne concentrations up to 116 ppm (6hr/day x 100 days) in a two-generation reproductive study. NMP was fetotoxic and teratogenic to the offspring of mice and rats following dermal, oral, or intraperitoneal exposure during gestation [NOEL: 1154 mg/kg/day (oral; mice); 237 mg/kg/day (oral and dermal; rats); LOEL: 166 mg/kg/day (IP; mice)]. Maternal toxicity was also observed 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:

Florfenicol was negative in a bacterial mutagenicity study (Ames), a mammalian mutagenicity study (mouse lymphoma), a bone marrow micronucleus assay, an in vitro chromosomal aberration assay in CHO cells, a cytogenetics assay in bone marrow, and an unscheduled DNA synthesis assay in rat hepatocytes.

Polyethylene glycol was negative in a bacterial mutagenicity study (Ames), results were inconclusive in a bacterial DNA repair study.

N-methyl-2-pyrrolidone (NMP) induced aneuploidy in *Saccharomyces*. NMP was negative in a bacterial (*Salmonella*) mutagenicity assay, an in vitro mouse micronucleus assay, and in an in vitro chromosomal aberration assay in CHO cells.

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

CARCINOGENICITY:

Florfenicol was not carcinogenic in a 2-year study in rats administered dosages up to 48 mg/kg/day for 5 days a week or in mice at dosages up to 200 mg/kg/day for 5 days per week.

N-methyl-2-pyrrolidone was not carcinogenic in rats exposed, by inhalation, to 0.04 to 0.4 mg/L for six hours/day for two years.

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

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA**INGREDIENT ECOTOXICITY**

Florfenicol: 96-hr LC50 (bluegill): >830 mg/L
Florfenicol: 96-hr LC50 (trout): >780 mg/L
Florfenicol: 48-hr EC50 (daphnid): >330 mg/L
Florfenicol: Algae maximum cell density: MIC = 1.5 mg/L
Florfenicol: Algae maximum growth rate: MIC >2.9 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:**

Florfenicol: log Pow (log octanol/water partition coefficient): 2.36
Florfenicol: Solubility 1.32 mg/ml at pH 7
Florfenicol: Biodegradability: Not readily biodegradable but there is evidence of inherent biodegradability.

Propylene glycol is expected to be readily biodegradable.

ENVIRONMENTAL FATE AND EFFECTS:

Photolytic half-life of Florfenicol in synthetic humic water (SHW) or pure water (PW) was 196 days in SHW and 171 days in PW.

SECTION 13. DISPOSAL CONSIDERATIONS**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:

This product contains materials that are harmful to the environment. 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

WHMIS CLASSIFICATIONS:

The final packaged product is not subject to WHMIS classification. The following classification applies to the bulk formulation handled in the workplace.

This product has been classified in accordance with the hazard criteria on the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

Controlled Product Class: D2A: Very Toxic



TSCA LISTING

INGREDIENT	TSCA
N-Methyl-2-Pyrrolidone	X
Polyethylene Glycol	X
Propylene Glycol	X

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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