



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

SAFETY DATA SHEET

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: Salix (Furosemide) Injection 5%

SYNONYM(S): Salix (Furosemide) Injection

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

IDENTIFIED USE(S): Veterinary Product; A diurectic-saluretic for relief of edema.

USE(S) ADVISED AGAINST: See warnings indicated on the product label or package insert.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

US SUPPLIER: Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK SDS HELPLINE: (800) 770-8878 (US and Canada) (908)
473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): Rocky Mountain Poison Center (For Human Exposure): (303)
595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals: (800) 224-5318
For Animal Adverse Events: Equine: (866) 349-3497
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

(908) 423-6000 (24/7/365)

SECTION 2. HAZARDS IDENTIFICATION

Classification

This chemical has been classified as hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200):

Toxic to Reproduction Category 2 H361
Specific Target Organ Toxicity (STOT) – Repeated exposure (RE) Category 2 H373

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word

Warning



Hazard Statements

H361 Suspected of damaging the unborn child.

H373 May cause damage to organs (Kidney) through prolonged or repeated exposure.

COLOR: Yellow

FORM: Liquid

ODOR: Odor unknown

Precautionary Statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container to an approved waste disposal plant

Other information

May cause effects to:

kidney

blood electrolytes

cardiovascular system

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

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. Non-hazardous ingredients include water.

CHEMICAL COMPOSITION

INGREDIENTS	CAS NUMBER	PERCENT
Furosemide	54-31-9	5
Water	7732-18-5	94

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 SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

MSDS NAME: Salix (Furosemide) Injection 5%

Latest Revision Date: 01-Feb-2016

SECTION 4. FIRST AID MEASURES

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.
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.
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 toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s).

This product contains furosemide, a diuretic. In animals, signs of acute toxicity include lethargy, prostration, diuresis, and weight loss. In humans, diuresis should be the first sign of exposure. Excessive diuresis may result in dehydration, hypokalemia, hypocalcemia, and orthostatic hypotension. Other symptoms include weakness, fatigue, and malaise. Furosemide may cause effects to the kidneys, and inhibits the absorption of sodium and chlorine in the proximal and distal tubules and in the loop of Henle.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symptomatically.

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 CHEMICAL

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard.

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.

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 SDS. 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 proper absorbent cleaning methods as appropriate. For large liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, 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:

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 INCOMPATIBILITIES

STORAGE:

Store between 15 and 30 deg C. Protect from freezing. Protect from light. Store in adequately sealed container.

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

OCCUPATIONAL EXPOSURE BAND (OEB):

Furosemide: OEB 2: $\geq 100 < 1000$ 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.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA) for Furosemide:

200 mcg/m³

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 internal Occupational Exposure Limit above.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Liquid aqueous solution
COLOR:	Yellow
ODOR:	Odor unknown
ODOR THRESHOLD:	Not determined
pH:	Not determined
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Soluble
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 normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

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

LIKELY ROUTES OF EXPOSURE:

Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

INHALATION: No data available for the finished product. None expected under normal use conditions. Avoid inhalation of mists.

SKIN: No data available for the finished product. None expected under normal use conditions. Avoid skin contact.

EYE: No data available. Avoid eye contact.

ORAL:

Furosemide: Oral LD50: 2600 mg/kg (rat)
Oral LD50: 2000 mg/kg (mouse)
Oral LD50: 2000 mg/kg (dog)

OTHER:

Furosemide: Intravenous LD50: 800 mg/kg (rat)
Intravenous LD50: 308 mg/kg (mouse)
Intravenous LD50: >400 mg/kg (dog)

DERMAL AND RESPIRATORY SENSITIZATION: No data available for the active ingredient or finished product.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:

Furosemide: A six-month study in dogs revealed calcification and scarring of the renal parenchyma at all doses above 10 mg/kg. In a one-year study in rats, renal tubular degeneration occurred with all doses higher than 50 mg/kg.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Furosemide: Reproductive studies were conducted in mice, rats and rabbits. Rats and mice given dietary doses of furosemide up to 200 mg/kg/day prior to and during mating or through pregnancy (females only) showed no adverse effects on health, fertility, pregnancy and postnatal development. Additional studies in mice administered 50 mg/kg/day at gestation days 6 to 8, 9 to 11 or 12 to 14 resulted in increased incidences of hydronephrosis and/or skeletal irregularities in treated groups. In rabbits administered furosemide at 50 mg/kg/day on gestation days 6 to 8, 9 to 11 or 12 to 14 resulted in increased incidences of abortion and material death.

MUTAGENICITY / GENOTOXICITY:

Furosemide (*in vitro*): Ames assay: negative
V-79 mammalian cell mutagenicity assay: negative
UDS assay: negative
Chromosomal aberration assay (Chinese hamster ovary cells (CHO)): positive
Mouse lymphoma assay: positive

Furosemide (*in vitro*): Mouse micronucleus assay: negative
Bone marrow chromosomal aberration assay (chinese hamster): negative

CARCINOGENICITY:

This product has not been evaluated for carcinogenicity.

Furosemide: Furosemide was tested for carcinogenicity by oral administration in one strain of mice and one strain of rats. A small increase in the incidence of mammary gland carcinomas was observed in female mice. No increase in the incidence of tumors was seen in rats.

LISTED CARCINOGENS

LISTED CARCINOGEN NOTE:

Furosemide is not classified as to its carcinogenicity to humans (Group 3) by IARC. No other carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

ASPIRATION:

None anticipated from normal handling of this product.

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Latest Revision Date: 01-Feb-2016

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

There are no ecotoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

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.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

All ingredients of this formulation are either on the TSCA inventory or exempt from listing.

U.S. STATE REGULATIONS

Check state requirements for ingredient listing

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 MSDS:

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One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:

(800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SIGNIFICANT CHANGES (US SUBFORMAT):

New regional format