



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

MATERIAL SAFETY DATA SHEET

Merck 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: SALIX TABLETS 50 mg

SYNONYM(S): SALIX TABLETS 50 mg

MSDS NUMBER: SP002216

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

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

(908) 423-6000 (24/7/365) English Only
Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

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

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

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Tablets
Yellow
Odor unknown
May be irritating to eyes, skin or respiratory tract.
May cause effects to:
kidney
blood electrolytes
cardiovascular system

POTENTIAL HEALTH EFFECTS:

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.

Corn starch is a mild skin irritant and may cause dermatitis with chronic skin exposure. Inhalation of corn starch may aggravate pre-existing lung conditions. Corn starch may cause mechanical irritation to the eye and respiratory tract.

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 |
|----------------------------|------------|---------|
| Furosemide | 54-31-9 | 17.9 |
| Starch | 9005-25-8 | 50-60 |
| Microcrystalline cellulose | 9004-34-6 | <10 |

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.

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.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

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

EXPLOSION HAZARDS:

Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

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SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

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| SECTION 6. ACCIDENTAL RELEASE MEASURES |
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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.

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

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| SECTION 7. HANDLING AND STORAGE |
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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.

STORAGE:

Store below 25 deg C. Store in a cool, dry, well ventilated area. Store in adequately sealed container.

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

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| SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION |
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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):

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| 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: | 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 | ACGIH TLV (TWA) | OSHA PEL (TWA) |
|----------------------------|------------|----------------------|----------------------|
| Starch | 9005-25-8 | 10 mg/m ³ | 15 mg/m ³ |
| Microcrystalline cellulose | 9004-34-6 | 10 mg/m ³ | 15 mg/m ³ |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Tablets
COLOR: Yellow
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:
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).

ACUTE TOXICITY DATA

INHALATION:
Microcrystalline cellulose: Inhalation LC50 (4hr): >5.05 mg/L (rat)

SKIN:
Corn starch was practically not irritating to rabbits and rats.

Microcrystalline cellulose: Dermal LD50: >2000 mg/kg (rabbit)
Microcrystalline cellulose was not irritating to the skin of rabbits.

EYE:
Microcrystalline cellulose: Not irritating to the eyes

ORAL:
Furosemide: Oral LD50: 2600 mg/kg (rat)

Microcrystalline cellulose: Oral LD50: >5000 mg/kg (rat)

DERMAL AND RESPIRATORY SENSITIZATION:
Microcrystalline cellulose was not a skin sensitizer in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
No data available.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Corn starch had no effect on reproduction in rats given 10% to 62% in the diet.

MUTAGENICITY / GENOTOXICITY:
No data available.

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CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

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| SECTION 12. ECOLOGICAL INFORMATION |
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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**

Microcrystalline cellulose: 96-hr LC50 (trout): >100% saturate solution
 Microcrystalline cellulose: 48-hr LC50 (daphnid): >100% saturate solution
 Microcrystalline cellulose: 96-hr EC50 (algae): >100% saturate solution

ENVIRONMENTAL DATA

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

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| SECTION 13. DISPOSAL CONSIDERATIONS |
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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.

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| SECTION 14. TRANSPORT INFORMATION |
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This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

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| SECTION 15. REGULATORY INFORMATION |
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TSCA LISTING

| INGREDIENT | TSCA |
|----------------------------|------|
| Starch | X |
| Microcrystalline cellulose | X |

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

| INGREDIENT | California Proposition 65 | CARTK | NJRTK | CTRTK | MARTK |
|----------------------------|------------------------------|-------|-------|-------|-------|
| Starch | | | | | X |
| Microcrystalline cellulose | | | 3227 | | X |

| INGREDIENT | PARTK | MNRTK | MIRTK | RIRTK |
|----------------------------|-------|-------|-------|-------|
| Starch | X | X | | X |
| Microcrystalline cellulose | X | X | | X |

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

X: Listed on applicable state hazardous substance or right-to-know lists.

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| SECTION 16. OTHER INFORMATION |
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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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DEPARTMENT ISSUING MSDS:

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Merck & Co., Inc.
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Whitehouse Station, NJ 08889

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SIGNIFICANT CHANGES (US SUBFORMAT):

New regional format