SAFETY DATA SHEETS

This SDS packet was issued with item:

078056429

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078921838

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078056437

SAFETY DATA SHEETS

This SDS packet was issued with item:

078056437

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078056429

MATERIAL SAFETY DATA SHEET

---------- 1. CHEMICAL PRODUCT and COMPANY IDENTIFICATION ----------

Product Name: ***SALIX™***
Product Family: ***PHARMACEUTICALS***

PRODUCT:	***PRODUCT CODE:***
SALIX™ TABLETS	*066999 - 12.5 mg*

SYNONYMS:

FUROSEMIDE

PRODUCT USE: Refer to product insert for proper usage.

COMPANY ADDRESS - Intervet Inc - 29160 Intervet Lane - Millsboro, DE 19966

---------- 2. COMPOSITION / INFORMATION on INGREDIENTS ----------

HAZARDOUS COMPONENT:	***CONCENTRATION:***	***CAS NUMBER:***
FUROSEMIDE LIQUID	*1.0%-5.0%*	*54-31-9*
FUROSEMIDE TABLETS	*12.5MG-50MG*	*54-31-9*

---------- 3. HAZARDS IDENTIFICATION----------

EMERGENCY OVERVIEW: *Warning: Milk taken from animals during treatment and for forty-eight hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within forty-eight hours following the last treatment.*

SIGNS AND SYMPTOMS OF EXPOSURE: *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.*

ROUTES OF ENTRY: *Dermal, Injection, Inhalation, Ingestion*

ACUTE EFFECTS OF EXPOSURE: *May cause irritation at site of contact.*

CHRONIC EFFECTS OF EXPOSURE: *None known*

TARGET ORGAN EFFECTS: *Kidney. Furosemide inhibits the absorption of sodium and chlorine in the proximal and distal tubules, and in the loop of Henley.*

CARCINOGENIC EFFECTS**:** *This product is not considered a carcinogen and is not listed by OSHA, IRA or NTT.*

---------- 4. FIRST AID MEASURES ----------

Treatment is symptomatic and includes replacement of fluid and electrolytes.

SKIN: *Wash immediately affected area with soap and water. Contact a physician.*

EYES: *Immediately flush with plenty of water for fifteen minutes Contact a physician.*

INHALATION: *Remove to fresh air. If not breathing, give artificial respiration and call for medical help immediately.*

INGESTION: *Seek medical attention immediately.*

---------- 5. FIRE FIGHTING MEASURES ----------

FLAMMABILITY: *Not Available*

EXTINGUISHING METHODS: *Use Water, Water Mist, Foam or Dry Chemical to extinguish fire.*

FIRE FIGHTING INSTRUCTIONS: W*ear full bunker gear, including SCBA. Keep upwind.*

---------- 6. ACCIDENTAL RELEASE MEASURES----------

PROCEDURES IN CASE OF SPILL OR LEAK**:** *Minor spillage may be flushed away with water. Large volume spills should be collected in salvage containers and should be incinerated in accordance with local, state and federal regulations.*

---------- 7. HANDLING and STORAGE ----------

STORAGE: *Store at room temperature (below 25C) in well-closed containers with safety closures. The product should be colorless to slightly brown. Do not use if solution is discolored. Product is light sensitive.*

SHELF LIFE: *See expiration date on product label.*

HANDLING PRECAUTIONS: *See product label.*

---------- 8. EXPOSURE CONTROL / PERSONAL PROTECTION ----------

Furosemide Workplace Exposure Limit: (interim) 0.5mg/m3

EYES*: Prevent eye contact by wearing appropriate eye protection for handling tasks.*

SKIN: *Avoid skin contact. Wear chemical resistant gloves, long-sleeves and trousers to prevent dermal contact.*

RESPIRATOR PROTECTION: *Under normal conditions of use, as stated in the product insert, no respiratory protection is necessary. However, if ventilation is inadequate wear a NIOSH approved respirator.*

---------- 9. PHYSICAL and CHEMICAL PROPERTIES ----------

APPEARANCE: *50mL vials, 12.5mg yellow tablet, or 50mg yellow tablet*

PH: *7.0-7.8*

---------- 10. STABILITY and REACTIVITY ----------

CHEMICAL STABILITY: *Stable*

CONDITIONS TO AVOID: *None known*

INCOMPATIBILITY*: None Known*

HAZARDOUS POLYMERIZATION: *Will not occur*

---------- 11. TOXICOLOGICAL INFORMATION ----------

Oral LD 50 Rat: *4600 mg/kg*
Intraperitoneal LD50 (rat): *Not available*
Intraperitoneal LD50 (mouse): *Not available*

---------- 12. ECOLOGICAL INFORMATION----------

ECOTOXITY*: Salix (Furosemide) administered to animals presents negligible impact on the environment.*

---------- 13. DISPOSAL CONSIDERATIONS----------

Minor spillage may be flushed away with water. Large volume spills should be collected in salvage containers and should be incinerated in accordance with local, state and federal regulations.

---------- 14. TRANSPORTATION ----------

DOT SHIPPING INFORMATION: Not regulated by the DOT

---------- 15. REGULATORY INFORMATION----------

US FEDERAL REGULATIONS: Salix (Furosemide) is regulated under the US FDA.

----------16. OTHER INFORMATION ----------

DISCLAIMER:

The information contained herein is true and accurate to the best of the knowledge of Intervet Inc. However, all data, instructions and/or recommendations are made without guarantee. The buyer and handler assume all risk and liability of use, storage and/or handling of this product not in accordance with the terms of the product label.

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 inhclude 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).

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.

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

SECTION 7. HANDLING AND STORAGE

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.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

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:	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.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

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

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.

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

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.

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:	Global Safety & the Environment Merck & Co., Inc. 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

SAFETY DATA SHEET

Furosemide Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/24/2019
5.2	09/13/2019	645633-00008	Date of first issue: 05/03/2016

SECTION 1. IDENTIFICATION

Product name : Furosemide Solid Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Specific target organ toxicity - repeated exposure : Category 1 (Kidney, Liver)

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H372 Causes damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

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

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 50 - < 70
Furosemide	54-31-9	>= 10 - < 20
Cellulose	9004-34-6	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products	:	Nitrogen oxides (NOx) Carbon oxides Sulfur oxides Chlorine compounds
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m³	ACGIH
		TWA (Respirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1
Furosemide	54-31-9	TWA	200 µg/m³	Internal
		TWA	OEB 2 (>=100 - 1000 ug/m3)	Internal
Cellulose	9004-34-6	TWA	10 mg/m³	ACGIH
		TWA (Respirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1

Engineering measures : Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

		Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
Hand protection Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact

Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Starch:

Acute oral toxicity	:	LD50 (Mouse): > 5,000 mg/kg

Furosemide:

Acute oral toxicity	:	LD50 (Rat): 2,600 mg/kg LD50 (Dog): 2,000 mg/kg LD50 (Rabbit): 800 mg/kg
Acute toxicity (other routes of administration)	:	LD0 (Humans): 6 - 29 mg/kg Application Route: Intravenous LD50 (Rat): 800 mg/kg Application Route: Intravenous

Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Furosemide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: mammalian liver cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Test system: Chinese hamster cells
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Chinese hamster
Application Route: Ingestion
Result: negative

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Furosemide:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	104 weeks
LOAEL	:	16 mg/kg body weight
Result	:	equivocal

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	2 Years
LOAEL	:	91 mg/kg body weight
Result	:	positive

Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Furosemide:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
General Toxicity Parent: NOAEL: 90 mg/kg body weight
Result: No effects on reproduction parameters.

Test Type: One-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
General Toxicity Parent: NOAEL: 200 mg/kg body weight
Result: No effects on reproduction parameters.

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
General Toxicity Maternal: LOAEL: 50 mg/kg body weight
Developmental Toxicity: NOAEL: 300 mg/kg body weight
Result: No embryotoxic effects., No teratogenic effects.

Test Type: Fertility/early embryonic development
Species: Mouse
Application Route: Ingestion
General Toxicity Maternal: LOAEL: 25 mg/kg body weight
Result: Maternal toxicity observed., Fetal effects.

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Ingestion
General Toxicity Maternal: LOAEL: <= 12 mg/kg body weight
Developmental Toxicity: LOAEL: 12.5 mg/kg body weight
Result: Maternal toxicity observed., Reduced number of viable fetuses.

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Ingestion
General Toxicity Maternal: LOAEL: 15 mg/kg body weight
Result: Maternal toxicity observed., No effects on fetal development.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Components:

Furosemide:

Routes of exposure : Ingestion
Target Organs : Kidney
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Furosemide:

Species : Dog
NOAEL : 4 mg/kg

LOAEL	:	8 mg/kg
Application Route	:	Ingestion
Exposure time	:	12 Months
Target Organs	:	Kidney
Symptoms	:	Blood disorders
Remarks	:	Significant toxicity observed in testing

Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Furosemide:

Inhalation	:	Remarks: May be harmful if inhaled.
Skin contact	:	Remarks: May irritate skin.
Eye contact	:	Remarks: May cause eye irritation.
Ingestion	:	Symptoms: Kidney disorders, Headache, electrolyte imbalance, dry mouth, hearing loss, Irregular cardiac activity, Gastrointestinal disturbance, hypotension

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Furosemide:

Toxicity to fish	:	LC50: 500 mg/l Exposure time: 96 h

Cellulose:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

Persistence and degradability

Components:

Cellulose:

Biodegradability	:	Result: Readily biodegradable.

Bioaccumulative potential

Components:

Furosemide:

Partition coefficient: n-octanol/water : log Pow: 2.03

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Starch	9005-25-8
D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate	64044-51-5
Furosemide	54-31-9
Cellulose	9004-34-6

California Permissible Exposure Limits for Chemical Contaminants

Starch	9005-25-8
Cellulose	9004-34-6

The ingredients of this product are reported in the following inventories:

AICS : not determined

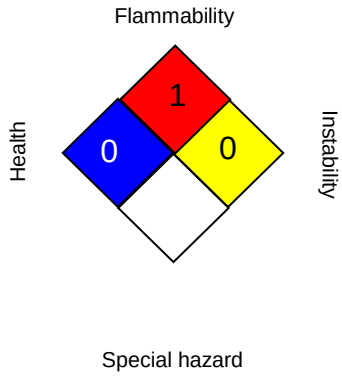
DSL : not determined

IECSC : not determined

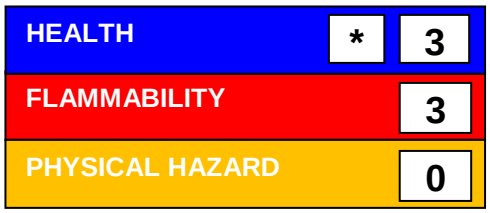
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average

NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	09/13/2019

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8