

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • Sulfamethoxazole Trimethoprim Oral Suspension USP

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Pharmaceutical product used as antibiotic agent; Pharmaceutical product used as antibiotic agent

Details of the supplier of the safety data sheet

Manufacturer • ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, MN 56623
United States
www.anipharmaeaceuticals.com
customerservice@anipharmaeaceuticals.com

Telephone (General) • 800.434.1121 ext. 3607

Emergency telephone number

Manufacturer • 800-308-6755

Section 2: Hazard Identification

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012 • Skin Sensitization 1
Eye Irritation 2
Respiratory Sensitization 1
Reproductive Toxicity 2

Label elements

OSHA HCS 2012

DANGER



Hazard statements • May cause an allergic skin reaction
Causes serious eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention • Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.

Avoid breathing mist, vapors, and/or spray.
 Wash thoroughly after handling.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 In case of inadequate ventilation wear respiratory protection.

- Response •** IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 Call a POISON CENTER/doctor.
 If on skin: Wash with plenty of water.
 Wash contaminated clothing before reuse.
 Specific treatment, see supplemental first aid information.
 If skin irritation or rash occurs: Get medical advice/attention.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 If eye irritation persists: Get medical advice/attention.
 IF exposed or concerned: Get medical advice/attention.

- Storage/Disposal •** Store locked up.
 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

OSHA HCS 2012

- Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance.

Mixtures

Composition					
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	CAS:723-46-6	N/A	NDA	OSHA HCS 2012: Not Classified	NDA
Sorbitan, monooleate polyoxyethylene deriv.	CAS:9005-65-6	N/A	Ingestion/Oral-Rat LD50 • 34500 µL/kg	OSHA HCS 2012: Eye Irrit. 2	NDA
Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	CAS:738-70-5	N/A	NDA	OSHA HCS 2012: Skin Sens. 1; Resp. Sens. 1; Repr. 2	NDA
Glycerine	CAS:56-81-5	N/A	Ingestion/Oral-Rat LD50 • 12600 mg/kg	OSHA HCS 2012: Eye Irrit. 2	NDA
Glucitol	CAS:50-70-4	N/A	NDA	OSHA HCS 2012: Comb. Dust	NDA
Ethanol	CAS:64-17-5	N/A	Ingestion/Oral-Rat LD50 • 7 g/kg Inhalation-Rat LC50 • 5900 mg/m ³ 6 Hour(s)	OSHA HCS 2012: Exposure limit	NDA
Cellulose, carboxymethyl ether, sodium salt	CAS:9004-32-4	N/A	Ingestion/Oral-Rat LD50 • 27000 mg/kg Inhalation-Rat LC50 • >5800 mg/m ³ 4 Hour(s) Skin-Rabbit LD50 • >2 g/kg	OSHA HCS 2012: Not Classified	NDA
			Ingestion/Oral-Rat LD50 •		

Cellulose	CAS:9004-34-6	N/A	>5 g/kg Inhalation-Rat LC50 • >5800 mg/m ³ 4 Hour(s) Skin-Rabbit LD50 • >2 g/kg	OSHA HCS 2012: Comb. Dust	NDA
Benzoic acid, sodium salt	CAS:532-32-1	N/A	Ingestion/Oral-Rat LD50 • 4070 mg/kg	OSHA HCS 2012: Comb. Dust; Eye Irrit. 2	NDA
Benzoic acid, p-hydroxy-, methyl ester	CAS:99-76-3	N/A	NDA	OSHA HCS 2012: Eye Irrit. 2	NDA
1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	CAS:128-44-9	N/A	NDA	OSHA HCS 2012: Not Classified	NDA

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- Move victim to fresh air. Administer oxygen if breathing is difficult. Give artificial respiration if victim is not breathing. If signs/symptoms continue, get medical attention.
- Skin**
- In case of contact with substance, immediately flush skin with running water for at least 20 minutes.
- Eye**
- In case of contact with substance, immediately flush eyes with running water for at least 20 minutes.
- Ingestion**
- If large quantities are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

- Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed

- Notes to Physician**
- All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- LARGE FIRE: Water spray, fog or regular foam.
SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.

- Unsuitable Extinguishing Media**
- No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- Some may burn but none ignite readily.

- Hazardous Combustion Products**
- No data available

Advice for firefighters

- Move containers from fire area if you can do it without risk.
Wear positive pressure self-contained breathing apparatus (SCBA).
Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.
Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- Do not walk through spilled material. Use appropriate Personal Protective Equipment (PPE)
- Emergency Procedures**
- Keep unauthorized personnel away. Stay upwind.

Environmental precautions

- Avoid run off to waterways and sewers.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- Stop leak if you can do it without risk.
SMALL SPILLS: Take up with sand or other non-combustible absorbent material and place into containers for later disposal.
LARGE SPILLS: Dike far ahead of liquid spill for later disposal.

Section 7 - Handling and Storage

Precautions for safe handling

- Handling**
- Use good safety and industrial hygiene practices. Wear appropriate personal protective equipment, avoid direct contact. Avoid breathing mist, vapours and/or spray. Avoid contact with skin, eyes, and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Conditions for safe storage, including any incompatibilities

- Storage**
- Store in a cool, dry place.

Specific end use(s)

- Refer to Section 1.2 - Relevant identified uses.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines					
	Result	ACGIH	Manufacturer	NIOSH	OSHA
Cellulose (9004-34-6)	TWAs	10 mg/m ³ TWA	Not established	10 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable dust)	15 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable fraction)
Ethanol (64-17-5)	TWAs	Not established	Not established	1000 ppm TWA; 1900 mg/m ³ TWA	1000 ppm TWA; 1900 mg/m ³ TWA
	STELs	1000 ppm STEL	Not established	Not established	Not established
Glycerine (56-81-5)	TWAs	Not established	Not established	Not established	15 mg/m ³ TWA (mist, total particulate); 5 mg/m ³ TWA (mist, respirable fraction)
	TWAs	Not established	1 mg/m ³ TWA , Sulfamethoxazole (CAS 723-46-6) 700 µg/m ³ TWA , Teva OEL (8hr-TWA) CAS 738-70-5	Not established	Not established

Exposure controls

- Engineering Measures/Controls**
- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- In case of insufficient ventilation, wear suitable respiratory equipment.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses).

Skin/Body

- Wear appropriate gloves.

Environmental Exposure Controls

- Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways. Follow best practice for site management and disposal of waste.

Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygiene

NIOSH = National Institute of Occupational Safety and Health

OSHA = Occupational Safety and Health Administration

STEL = Short Term Exposure Limits are based on 15-minute exposures

TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Semi-solid	Appearance/Description	Pink, syrupy suspension.
Color	Pink	Odor	No data available
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	5 to 6.5
Specific Gravity/Relative Density	1.17 to 1.23 Water=1	Water Solubility	Negligible < 0.1 %
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- Hazardous polymerization will not occur.

Conditions to avoid

- No data available

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)- (N/A)	738-70-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >5300 mg/kg; Reproductive: Ingestion/Oral-Rat TDLo • 2250 mg/kg (11-13D preg); <i>Reproductive Effects:Effects on Fertility:Post-implantation mortality; Reproductive Effects:Effects on Embryo or Fetus:Fetotoxicity (except death, e.g., stunted fetus)</i>
Benzoic acid, p-hydroxy-, methyl ester (N/A)	99-76-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2100 mg/kg; Irritation: Skin-Rabbit • 0.1 mL 24 Hour(s) • Mild irritation; Mutagen: Cytogenetic analysis • Ingestion/Oral-Mouse • 25 g/kg 5 Day(s)-Intermittent
Benzoic acid, sodium salt (N/A)	532-32-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 4070 mg/kg; Irritation: Skin-Human • 10 % 1 Hour(s)-Open; Reproductive: Ingestion/Oral-Rat TDLo • 44 g/kg (1-22D preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Homeostasis; Reproductive Effects:Specific Developmental Abnormalities:Eye, ear; Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system</i> ; Ingestion/Oral-Rat TDLo • 44 g/kg (1-22D preg); <i>Reproductive Effects:Effects on Newborn:Viability index (e.g., # alive at day 4 per # born alive)</i>

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012 • No data available
Skin corrosion/Irritation	OSHA HCS 2012 • No data available
Serious eye damage/Irritation	OSHA HCS 2012 • Eye Irritation 2
Skin sensitization	OSHA HCS 2012 • Skin Sensitizer 1
Respiratory sensitization	OSHA HCS 2012 • Respiratory Sensitizer 1
Aspiration Hazard	OSHA HCS 2012 • No data available
Carcinogenicity	OSHA HCS 2012 • No data available
Germ Cell Mutagenicity	OSHA HCS 2012 • No data available
Toxicity for Reproduction	OSHA HCS 2012 • Toxic to Reproduction 2
STOT-SE	OSHA HCS 2012 • No data available
STOT-RE	OSHA HCS 2012 • No data available

Potential Health Effects

Inhalation

Acute (Immediate)

- Not expected to be hazardous in final pharmaceutical form.

Chronic (Delayed)

- Repeated and prolonged exposure may cause sensitization of the respiratory system.

Skin

Acute (Immediate)

- May cause skin sensitization. Symptoms include redness, and skin rash.

Chronic (Delayed)

- No data available

Eye

Acute (Immediate)

- Causes serious eye irritation.

Chronic (Delayed)

- No data available

Ingestion**Acute (Immediate)**

- No data available

Chronic (Delayed)

- No data available

Reproductive Effects

- Repeated and prolonged exposure may cause reproductive effects.

Key to abbreviations

LD = Lethal Dose

TD = Toxic Dose

Section 12 - Ecological Information**Toxicity**

- Non-mandatory section - information about this substance not compiled for this reason.

Persistence and degradability

- Non-mandatory section - information about this substance not compiled for this reason.

Bioaccumulative potential

- Non-mandatory section - information about this substance not compiled for this reason.

Mobility in Soil

- Non-mandatory section - information about this substance not compiled for this reason.

Other adverse effects

- Non-mandatory section - information about this substance not compiled for this reason.

Section 13 - Disposal Considerations**Waste treatment methods****Product waste**

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	NDA

Special precautions for user

- None specified.

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

- No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Inventory		
Component	CAS	TSCA
1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Yes
Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Yes
Benzoic acid, sodium salt	532-32-1	Yes
Cellulose	9004-34-6	Yes
Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Yes
Ethanol	64-17-5	Yes
Glucitol	50-70-4	Yes
Glycerine	56-81-5	Yes
Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	No
Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Yes
Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Yes

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed

• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

Environment**U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants**

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed

• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed

• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	carcinogen, 4/29/2011 (in alcoholic beverages)
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	developmental toxicity, 10/1/1987 (in alcoholic beverages)
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed

• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Glucitol	50-70-4	Not Listed
• Benzoic acid, p-hydroxy-, methyl ester	99-76-3	Not Listed
• Sorbitan, monooleate polyoxyethylene deriv.	9005-65-6	Not Listed
• 1,2-Benzisothiazolin-3-one, 1,1-dioxide, sodium salt	128-44-9	Not Listed
• Sulfanilamide, N'-(5-methyl-3-isoxazolyl)-	723-46-6	Not Listed
• Benzoic acid, sodium salt	532-32-1	Not Listed
• Cellulose	9004-34-6	Not Listed
• Cellulose, carboxymethyl ether, sodium salt	9004-32-4	Not Listed
• Ethanol	64-17-5	Not Listed
• Glycerine	56-81-5	Not Listed
• Pyrimidine, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)-	738-70-5	Not Listed

Other Information

- **WARNING:** This product contains a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

Section 16 - Other Information**Revision Date**

- 29/April/2019

Preparation Date

- 11/March/2019

Disclaimer/Statement of Liability

- The information herein is given in good faith but no warranty, expressed or implied, is made.

Key to abbreviations

NDA = No Data Available