

## Safety Data Sheet



### Section 1: Identification

#### Product identifier

#### Product Name

- Erythromycin Ethylsuccinate for Oral Suspension, USP 200 mg / 5mL (10 Day In-Use), 200 mg / 5mL (35 Day In-Use) and 400 mg / 5mL (35 Day In-Use)

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

#### Recommended use

- An antibiotic used to treat certain infections caused by bacteria, such as bronchitis; diphtheria; Legionnaires' disease; pertussis (whooping cough); pneumonia; rheumatic fever; venereal disease (VD); and ear, intestine, lung, urinary tract, and skin infections.

#### 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

- Not classified

#### Label elements

#### OSHA HCS 2012

Hazard statements • No label element(s) required

#### Other hazards

#### OSHA HCS 2012

- This product is not considered hazardous under the U.S. OSHA 29 CFR 1910.1200 Hazard Communication Standard.

### 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 |
| Succinic acid, monoethyl ester, monoester with erythromycin | CAS:1264-62-6 | 5.25% TO 10.5% | NDA                                                                                                              | OSHA HCS 2012: Not Classified                     | NDA      |
| Sucrose                                                     | CAS:57-50-1   | N/A            | Ingestion/Oral-Rat LD50 • 29700 mg/kg                                                                            | OSHA HCS 2012: Comb. Dust                         | 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      |
| Sodium citrate                                              | CAS:68-04-2   | N/A            | NDA                                                                                                              | OSHA HCS 2012: Eye Irrit. 2                       | NDA      |
| Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | CAS:9003-39-8 | N/A            | Ingestion/Oral-Rat LD50 • 100 g/kg                                                                               | OSHA HCS 2012: Not Classified                     | NDA      |
| Maltodextrin                                                | CAS:9050-36-6 | N/A            | NDA                                                                                                              | OSHA HCS 2012: Comb. Dust                         | NDA      |
| Ethyl acetate                                               | CAS:141-78-6  | N/A            | Ingestion/Oral-Rat LD50 • 5620 mg/kg<br>Skin-Rabbit LD50 • >20 mL/kg<br>Inhalation-Rat LC50 • 1600 ppm 8 Hour(s) | OSHA HCS 2012: Exposure limit                     | NDA      |
| beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | CAS:5965-66-2 | N/A            | NDA                                                                                                              | OSHA HCS 2012: Not Classified                     | NDA      |
| Benzoic acid, p-hydroxy-, methyl ester                      | CAS:99-76-3   | N/A            | NDA                                                                                                              | OSHA HCS 2012: Eye Irrit. 2                       | NDA      |

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- Move victim to fresh air. Give artificial respiration if victim is not breathing. Administer oxygen if breathing is difficult.

#### 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

- Rinse mouth. Do not give anything by mouth to an unconscious person.

### 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, CO<sub>2</sub>, water spray or regular foam.

**Unsuitable Extinguishing Media** • No data available

### Special hazards arising from the substance or mixture

**Unusual Fire and Explosion Hazards** • No data available

**Hazardous Combustion Products** • No data available

### Advice for firefighters

- Wear positive pressure self-contained breathing apparatus (SCBA). Structural firefighters' protective clothing will only provide limited protection.

## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions** • Ventilate enclosed areas. Do not walk through spilled material.

**Emergency Procedures** • As an immediate precautionary measure, isolate spill or leak area for at least 25 meters (75 feet) in all directions. If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions. Keep unauthorized personnel away.

### Environmental precautions

- Avoid run off to waterways and sewers.

### Methods and material for containment and cleaning up

**Containment/Clean-up Measures** • Avoid generating dust.  
SMALL DRY SPILLS: With clean shovel place material into clean, dry container and cover loosely; move containers from spill area.  
LARGE SPILLS: Cover powder spill with plastic sheet or tarp to minimize spreading.

## Section 7 - Handling and Storage

### Precautions for safe handling

**Handling** • Use only with adequate ventilation. Wear appropriate personal protective equipment, avoid direct contact. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

### Conditions for safe storage, including any incompatibilities

**Storage** • Store granules, prior to mixing, below 86°F (30°C). After mixing the 200 mg/ 5mL (10 Day In-Use), refrigerate and use within ten days. After mixing the 200 mg/ 5mL (35 Day In- Use) and the 400 mg/ 5mL (35 Day In-Use) products must be stored at or below 77°F (25°C) and used within 35 days; refrigeration is not required.

## Section 8 - Exposure Controls/Personal Protection

### Control parameters

| Exposure Limits/Guidelines |        |                          |                                                                                  |                                                                                      |
|----------------------------|--------|--------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
|                            | Result | ACGIH                    | NIOSH                                                                            | OSHA                                                                                 |
| Ethyl acetate (141-78-6)   | TWAs   | 400 ppm TWA              | 400 ppm TWA; 1400 mg/m <sup>3</sup> TWA                                          | 400 ppm TWA; 1400 mg/m <sup>3</sup> TWA                                              |
| Sucrose (57-50-1)          | TWAs   | 10 mg/m <sup>3</sup> TWA | 10 mg/m <sup>3</sup> TWA (total dust); 5 mg/m <sup>3</sup> TWA (respirable dust) | 15 mg/m <sup>3</sup> TWA (total dust); 5 mg/m <sup>3</sup> TWA (respirable fraction) |

## Exposure controls

### Engineering Measures/Controls

- Adequate ventilation systems as needed to control concentrations of airborne contaminants below applicable threshold limit values. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is not leakage from the equipment).

### Personal Protective Equipment

#### Respiratory

- For limited exposure use an N95 dust mask. For prolonged exposure use an air-purifying respirator with high efficiency particulate air (HEPA) filters. Follow the OSHA respirator regulations found in 29 CFR 1910.134. Use a NIOSH/MSHA approved respirator if exposure limits are exceeded or symptoms are experienced.

#### Eye/Face

- Wear safety goggles.

#### Skin/Body

- Wear appropriate gloves. Wear long sleeves and/or protective coveralls.

### 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

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                       | Solid             | Appearance/Description       | White granulated powder. |
| Color                               | White             | 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                           | 7 to 9                   |
| Specific Gravity/Relative Density   | No data available | Water Solubility             | 10 to 99 %               |
| 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

- Avoid generating dust.

## Incompatible materials

- No data available

## Hazardous decomposition products

- No data available

## Section 11 - Toxicological Information

### Information on toxicological effects

| Components                                                                   |           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Succinic acid, monoethyl ester, monoester with erythromycin (5.25% TO 10.5%) | 1264-62-6 | <b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • >10 g/kg                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Benzoic acid, p-hydroxy-, methyl ester (N/A)                                 | 99-76-3   | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2100 mg/kg; Intravenous-Mouse TDLo • 100 mg/kg; <b>Vascular:Shock; Lungs, Thorax, or Respiration:Respiratory depression;</b><br><b>Irritation:</b> Skin-Rabbit • 0.1 mL 24 Hour(s) • Mild irritation;<br><b>Mutagen:</b> Cytogenetic analysis • Ingestion/Oral-Mouse • 25 g/kg 5 Day(s)-Intermittent                                                                                                                                                                    |
| Poly(1-vinyl-2-pyrrolidinone) homopolymer (N/A)                              | 9003-39-8 | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 100 g/kg; <b>Gastrointestinal:Hypermotility, diarrhea</b>                                                                                                                                                                                                                                                                                                                                                                                                               |
| Sorbitan, monooleate polyoxyethylene deriv. (N/A)                            | 9005-65-6 | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 34500 µL/kg;<br><b>Reproductive:</b> Ingestion/Oral-Rat TDLo • 635 g/kg (multigenerations); <b>Reproductive Effects:Effects on Newborn:Viability index (e.g., # alive at day 4 per # born alive); Reproductive Effects:Effects on Newborn:Weaning or lactation index;</b><br><b>Tumorigen / Carcinogen:</b> Ingestion/Oral-Rat TDLo • 2163 g/kg 2 Year(s)-Continuous; <b>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Endocrine:Adrenal cortex tumors</b> |
| Sucrose (N/A)                                                                | 57-50-1   | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 29700 mg/kg; <b>Behavioral:Somnolence (general depressed activity); Lungs, Thorax, or Respiration:Cyanosis; Gastrointestinal:Hypermotility, diarrhea;</b><br><b>Reproductive:</b> Ingestion/Oral-Rat TDLo • 1548 g/kg (21D pre/1-22D preg); <b>Reproductive Effects:Specific Developmental Abnormalities:Central nervous system</b>                                                                                                                                     |

| GHS Properties                       | Classification                    |
|--------------------------------------|-----------------------------------|
| <b>Acute toxicity</b>                | OSHA HCS 2012 • No data available |
| <b>Skin corrosion/Irritation</b>     | OSHA HCS 2012 • No data available |
| <b>Serious eye damage/Irritation</b> | OSHA HCS 2012 • No data available |
| <b>Skin sensitization</b>            | OSHA HCS 2012 • No data available |
| <b>Respiratory sensitization</b>     | OSHA HCS 2012 • No data available |
| <b>Aspiration Hazard</b>             | OSHA HCS 2012 • No data available |
| <b>Carcinogenicity</b>               | OSHA HCS 2012 • No data available |
| <b>Germ Cell Mutagenicity</b>        | OSHA HCS 2012 • No data available |
| <b>Toxicity for Reproduction</b>     | OSHA HCS 2012 • No data available |

|         |                                   |
|---------|-----------------------------------|
| STOT-SE | OSHA HCS 2012 • No data available |
| STOT-RE | OSHA HCS 2012 • No data available |

## Potential Health Effects

### Inhalation

- Acute (Immediate)**
  - Exposure to dust may cause irritation. Processes such as cutting, grinding, crushing, or impact may result in generation of excessive amounts of airborne dusts in the workplace. Nuisance dust may affect the lungs but reactions are typically reversible.
- Chronic (Delayed)**
  - No data available

### Skin

- Acute (Immediate)**
  - Exposure to dust may cause mechanical irritation.
- Chronic (Delayed)**
  - No data available

### Eye

- Acute (Immediate)**
  - Exposure to dust may cause mechanical irritation. Excessive concentrations of nuisance dust in the workplace may reduce visibility and may cause unpleasant deposits in eyes.
- Chronic (Delayed)**
  - No data available

### Ingestion

- Acute (Immediate)**
  - Excessive concentrations of nuisance dust in the workplace may cause mechanical irritation to mucous membranes.
- Chronic (Delayed)**
  - No data available

#### 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 |
| Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Yes  |
| beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Yes  |
| Ethyl acetate                                               | 141-78-6  | Yes  |
| Maltodextrin                                                | 9050-36-6 | Yes  |
| Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Yes  |
| Sodium citrate                                              | 68-04-2   | Yes  |
| Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Yes  |
| Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | No   |
| Sucrose                                                     | 57-50-1   | Yes  |

**United States****Labor****U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals**

|                                               |           |            |
|-----------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester      | 99-76-3   | Not Listed |
| • Maltodextrin                                | 9050-36-6 | Not Listed |
| • Sodium citrate                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv. | 9005-65-6 | Not Listed |
| • Sucrose                                     | 57-50-1   | Not Listed |

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

**U.S. - OSHA - Specifically Regulated Chemicals**

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |                                    |
|---------------------------------------------------------------|-----------|------------------------------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed                         |
| • Maltodextrin                                                | 9050-36-6 | Not Listed                         |
| • Sodium citrate                                              | 68-04-2   | Not Listed                         |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed                         |
| • Sucrose                                                     | 57-50-1   | Not Listed                         |
| • Ethyl acetate                                               | 141-78-6  | 5000 lb final RQ; 2270 kg final RQ |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed                         |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed                         |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed                         |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                          |           |            |
|------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester | 99-76-3   | Not Listed |
| • Maltodextrin                           | 9050-36-6 | Not Listed |
| • Sodium citrate                         | 68-04-2   | Not Listed |

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

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

|                                                               |           |            |
|---------------------------------------------------------------|-----------|------------|
| • Benzoic acid, p-hydroxy-, methyl ester                      | 99-76-3   | Not Listed |
| • Maltodextrin                                                | 9050-36-6 | Not Listed |
| • Sodium citrate                                              | 68-04-2   | Not Listed |
| • Sorbitan, monooleate polyoxyethylene deriv.                 | 9005-65-6 | Not Listed |
| • Sucrose                                                     | 57-50-1   | Not Listed |
| • Ethyl acetate                                               | 141-78-6  | Not Listed |
| • beta-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-          | 5965-66-2 | Not Listed |
| • Poly(1-vinyl-2-pyrrolidinone) homopolymer                   | 9003-39-8 | Not Listed |
| • Succinic acid, monoethyl ester, monoester with erythromycin | 1264-62-6 | Not Listed |

## Section 16 - Other Information

**Revision Date**

- 13/November/2018

**Preparation Date**

- 13/November/2018

**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