1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Trimethoprim/Sulfametopyrazine Syrup

Trade Name: KELFIPRIM*
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>212-006-2</td>
<td>1</td>
</tr>
<tr>
<td>Monoammonium glycyrrhizinate</td>
<td>53956-04-0</td>
<td>258-887-7</td>
<td>*</td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>68-35-9</td>
<td>200-685-8</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agar</td>
<td>9002-18-0</td>
<td>232-658-1</td>
<td>*</td>
</tr>
<tr>
<td>Licorice Essence</td>
<td>Not Assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Ethylparaben</td>
<td>120-47-8</td>
<td>204-399-4</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 20</td>
<td>9005-64-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium saccharin USP</td>
<td>128-44-9</td>
<td>204-886-1</td>
<td>*</td>
</tr>
<tr>
<td>Cocoa Extract</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Brown liquid
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed. Possible risk of harm to the unborn child
**4. FIRST AID MEASURES**

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

---

**5. FIRE FIGHTING MEASURES**

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Emits fumes of carbon dioxide  sulfur oxides  nitrogen oxides

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

---

**6. ACCIDENTAL RELEASE MEASURES**

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

<table>
<thead>
<tr>
<th>OSHA - Final PELS - TWAs:</th>
<th>= 15 mg/m³ TWA total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>= 10 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>= 10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Sucrose

<table>
<thead>
<tr>
<th>OSHA - Final PELS - TWAs:</th>
<th>= 15 mg/m³ TWA total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>= 5 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>= 10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Trimethoprim

Pfizer OEL TWA-8 Hr: 0.1 mg/m³

Sulfadiazine

Pfizer OEL TWA-8 Hr: 2 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Analytical Method: Analytical method available for trimethoprim; sulfadiazine. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

<table>
<thead>
<tr>
<th>Hands:</th>
<th>Not required for the normal use of this product. Wear protective gloves when working with large quantities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes:</td>
<td>Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.</td>
</tr>
<tr>
<td>Skin:</td>
<td>Not required for the normal use of this product. Wear protective clothing when working with large quantities.</td>
</tr>
<tr>
<td>Respiratory protection:</td>
<td>Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Brown</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Trimethoprim
- Rat Oral LD50 200 mg/kg
- Rat Intraperitoneal LD50 500 mg/kg
- Mouse Oral LD50 2764 mg/kg
- Mouse Intravenous LD50 200 mg/kg
- Mouse Intraperitoneal LD50 1870 mg/kg

Sulfadiazine
- Mouse Oral LD50 1500 mg/kg

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD 50 50 mg/kg

Citric acid
- Rat Oral LD50 3000 mg/kg

Sodium saccharin USP
- Mouse Oral LD50 17.5 g/kg
- Rat Oral LD50 14.2 - 17 g/kg

Methylparaben
- Mouse Oral LD50 > 8000 mg/kg
- Rat Oral LD50 2280 mg/kg

Propylparaben
- Mouse Oral LD 50 6332 mg/kg
- Mouse Intraperitoneal LD 50 200 mg/kg

Sucrose
- Rat Oral LD50 29.7 g/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Propylparaben
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s)  Rat  Oral  347.2 mg/kg  LOAEL  Male reproductive system

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Trimethoprim**
- Reproductive & Fertility-Males  Rat  Oral  70 mg/kg/day  NOAEL  Fertility
- Reproductive & Fertility - Females  Rat  Oral  14 mg/kg/day  NOAEL  Fertility
- Embryo / Fetal Development  Rabbit  Oral  30 mg/kg  LOAEL  Embryotoxicity
- Embryo / Fetal Development  Rat  Oral  200 mg/kg  LOAEL  Maternal Toxicity, Teratogenic
- Embryo / Fetal Development  Mouse  Oral  70 mg/kg  NOAEL  Not Teratogenic

**Sulfadiazine**
- Embryo / Fetal Development  Rat  Oral  500 mg/kg/day  NOEL  Not teratogenic
- Embryo / Fetal Development  Mouse  Oral  500 mg/kg/day  NOEL  Not Teratogenic
- Reproductive & Fertility  Rabbit  Oral  250 mg/kg/day  NOEL  Not Teratogenic

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Trimethoprim**
- Bacterial Mutagenicity (Ames)  *Salmonella*, *E. coli*  Negative
- *In Vitro* Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative
- *In Vitro* Chromosome Aberration  Human Lymphocytes  Negative

**Carcinogen Status:**  See below

**Titanium dioxide**
- IARC:  Group 2B
- OSHA:  Present

**Sodium saccharin USP**
- IARC:  Group 3

12. **ECOLOGICAL INFORMATION**

**Environmental Overview:**  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. **DISPOSAL CONSIDERATIONS**

**Disposal Procedures:**  Dispose of waste in accordance with all applicable laws and regulations.

14. **TRANSPORT INFORMATION**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
### 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**OSHA Label:**
WARNING
May be harmful if swallowed.
Possible risk of harm to the unborn child

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 2, Subdivision A

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS List</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agar</strong></td>
<td>XU</td>
<td>Present</td>
<td>232-658-1</td>
</tr>
<tr>
<td><strong>Methylparaben</strong></td>
<td>Inventory</td>
<td>Present</td>
<td>202-785-7</td>
</tr>
<tr>
<td><strong>Propylparaben</strong></td>
<td>Inventory</td>
<td>Present</td>
<td>202-307-7</td>
</tr>
<tr>
<td><strong>Water, purified</strong></td>
<td>Inventory</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
<tr>
<td><strong>Ethylparaben</strong></td>
<td>Inventory</td>
<td>Present</td>
<td>204-399-4</td>
</tr>
<tr>
<td><strong>Polysorbate 20</strong></td>
<td>Inventory</td>
<td>XU</td>
<td></td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong></td>
<td>Inventory</td>
<td>Present</td>
<td></td>
</tr>
</tbody>
</table>
### 16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>Present</td>
<td>236-675-5</td>
</tr>
<tr>
<td>Citric acid</td>
<td>Present</td>
<td>201-069-1</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Present</td>
<td>212-006-2</td>
</tr>
<tr>
<td>Sodium saccharin USP</td>
<td>Present</td>
<td>204-886-1</td>
</tr>
<tr>
<td>Monoammonium glycyrrhizinate</td>
<td>Present</td>
<td>258-887-7</td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>Present</td>
<td>200-685-8</td>
</tr>
</tbody>
</table>

**Reasons for Revision:**
Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

**Prepared by:**
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

**End of Safety Data Sheet**