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

Product Identifier

Material Name: Sulfasalazine Delayed Release Tablets
Trade Name: AZULFIDINE EN; SALAZOPYRIN; SALAZOPYRINE; PYRALIN
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anti-inflammatory

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2
Effects on or via lactation

EU Classification:
EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:
R62 - Possible risk of impaired fertility.
R64 - May cause harm to breastfed babies.

Label Elements

Signal Word: Warning
Hazard Statements:
H361f - Suspected of damaging fertility
H362 - May cause harm to breast-fed children
Precautionary Statements:

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glycerol monostearate</td>
<td>31566-31-1</td>
<td>250-705-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>599-79-1</td>
<td>209-974-3</td>
<td>R62</td>
<td>Lact. (H362)</td>
<td>70-80</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beeswax</td>
<td>8012-89-3</td>
<td>232-383-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carnauba wax</td>
<td>8015-86-9</td>
<td>232-399-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Cellulose acetate phthalate</td>
<td>9004-38-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
SAFETY DATA SHEET

Material Name: Sulfasalazine Delayed Release Tablets
Revision date: 19-Nov-2014

7. HANDLING AND STORAGE

Precautions for Safe Handling
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Glyceryl monostearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Sulfasalazine
Pfizer OEL TWA-8 Hr: 600 ug/m³

Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL -TWAs 1000 ppm

Propylene glycol
Australia TWA 150 ppm
474 mg/m³
10 mg/m³
Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³
Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

Silica colloidal, Ph. Eur.
Austria OEL - MAKs 4 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Starch, pregelatinized

<table>
<thead>
<tr>
<th>Material</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

Talc (non-asbestiform)

<table>
<thead>
<tr>
<th>Material</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 fiber/cm³</td>
</tr>
<tr>
<td></td>
<td>6.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.3 fiber/cm³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.5 fiber/cm³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20mppcf</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

Exposure Controls

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

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>Gold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility: | No data available |
| Water Solubility: | No data available |
| pH: | No data available |
| Melting/Freezing Point (°C): | No data available |
| Boiling Point (°C): | No data available |
| Partition Coefficient: (Method, pH, Endpoint, Value) | No data available |

- Cellulose acetate phthalate
  - No data available
- Carnauba wax
  - No data available
- Silica colloidal, Ph. Eur.
  - No data available
- Glyceril monostearate
  - No data available
- Magnesium stearate
  - No data available
- Povidone
  - No data available
- Talc (non-asbestiform)
  - No data available
- Propylene glycol
  - No data available
- Beeswax
  - No data available
- Polyethylene glycol
  - No data available
- Sulfasalazine
  - No data available

| Decomposition Temperature (°C): | No data available |
| Evaporation Rate (Gram/s): | No data available |
| Vapor Pressure (kPa): | No data available |
| Vapor Density (g/ml): | No data available |
| Relative Density: | No data available |
| Viscosity: | No data available |

| Flammability: | No data available |
| Autoignition Temperature (Solid) (°C): | No data available |
| Flammability (Solids): | No data available |
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Known Clinical Effects: The most common adverse effects seen with the therapeutic use of sulfasalazine are anorexia, headache, nausea, vomiting, gastric distress, and apparently reversible decreased sperm count. Clinical use of this drug has caused abnormal liver function tests, skin rash, changes in blood cell levels.

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

- **Glyceryl monostearate**
  - Mouse IP LD50 200 mg/kg

- **Magnesium stearate**
  - Rat Oral LD50 > 2000 mg/kg
  - Rat Inhalation LC50 > 2000 mg/m³

- **Povidone**
  - Rat Oral LD50 100 g/kg

- **Talc (non-asbestiform)**
  - Rat Oral LD50 > 1600 mg/kg

- **Propylene glycol**
  - Rat Oral LD50 22,000 mg/kg
  - Mouse Oral LD 50 24,900mg/kg
  - Rabbit Dermal LD 50 20,800mg/kg

- **Sulfasalazine**
  - Rat Oral LD50 15,600 mg/kg
  - Rat Para-periosteal LD50 1520mg/kg
  - Mouse Oral LD 50 12,500mg/kg
  - Rabbit Oral LD 50 > 7,500mg/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.
11. TOXICOLOGICAL INFORMATION

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

**Propylene glycol**
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

**Polyethylene glycol**
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

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

**Sulfasalazine**
16 Week(s)  Rat  Oral  675 mg/kg/day  NOAEL  Gastrointestinal System, Thymus, Thyroid, Pituitary
13 Week(s)  Mouse  Oral  675 mg/kg/day  LOAEL  Liver
6 Month(s)  Rat  Oral  200 mg/kg/day  NOAEL  Thyroid, Pituitary
6 Month(s)  Dog  Oral  250 mg/kg/day  NOAEL  Thyroid, Male reproductive system

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

**Sulfasalazine**
Reproductive & Fertility  Rat  Oral  200 mg/kg/day  NOAEL  Maternal toxicity, Fertility
Embryo / Fetal Development  Rat  Oral  200 mg/kg/day  NOAEL  Fetotoxicity, Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  800 mg/kg/day  NOAEL  Not Teratogenic

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

**Sulfasalazine**
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Negative
In Vivo Cytogenetics  Mouse Bone Marrow  Negative
In Vivo Micronucleus  Mouse Lymphocytes  Positive
Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Sulfasalazine**
104 Week(s)  Mouse  Oral  675 mg/kg/day  NOAEL  Malignant tumors, Liver, Benign tumors, Spleen
104 Week(s)  Rat  No route specified  84 mg/kg/day  LOAEL  Tumors, Kidneys

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Silica colloidal, Ph. Eur.
IARC:  Group 3 (Not Classifiable)

Povidone
IARC:  Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)
12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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

Magnesium stearate
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beeswax</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Povidone</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-383-7</td>
</tr>
<tr>
<td>Carnauba wax</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-399-4</td>
</tr>
<tr>
<td>Cellulose acetate phthalate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>250-705-4</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Carcinogen initial date 5/15/98</td>
<td>Present</td>
<td>209-974-3</td>
</tr>
<tr>
<td>Sulfasalazine Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td></td>
<td></td>
<td></td>
<td>Schedule 4</td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, pregelatinized</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>200-338-0</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>238-877-9</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

- Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility
- Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

**Toxic to Reproduction: Category 3**

- R62 - Possible risk of impaired fertility.
- R64 - May cause harm to breastfed babies.

**Data Sources:** Safety data sheets for individual ingredients. Pfizer proprietary drug development information.
SAFETY DATA SHEET

Material Name: Sulfasalazine Delayed Release Tablets
Revision date: 19-Nov-2014

Reasons for Revision:
Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 19-Nov-2014
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet