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

Product Identifier

Material Name: Sulfasalazine Tablets

Trade Name: AZULFIDINE; SALAZOPYRIN; SALAZOPYRINE

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

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
Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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>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>Sulfasalazine</td>
<td>599-79-1</td>
<td>209-974-3</td>
<td>Repr. Cat.3; R62</td>
<td>Repr. 2 (H361f) Lact. (H362)</td>
<td>70-80</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>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</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.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16
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:  Water, carbon dioxide, dry chemical or foam

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion:  Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards:  Not applicable

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.  Use caution in approaching fire.

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.

Additional Consideration for Large Spills:  Non-essential personnel should be evacuated from affected area.  Report emergency situations immediately.  Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
7. HANDLING AND STORAGE
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
Refer to available public information for specific member state Occupational Exposure Limits.

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

Silica colloidal, Ph. Eur.
Austria OEL - MAKs 4 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³

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

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Tablets</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Sulfasalazine
No data available

Starch, pregelatinized
No data available

Silica colloidal, Ph. Eur.
No data available

Magnesium stearate
No data available

Povidone
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:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

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 remaining information 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)

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

**Magnesium stearate**
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m^3

**Povidone**
- Rat Oral LD50 100 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.

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**
11. TOXICOLOGICAL INFORMATION

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)

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

SULFASALAZINE TABLETS
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Magnesium stearate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Povidone
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List Not Listed

Silica colloidal, Ph. Eur.
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List Not Listed

Starch, pregelatinized
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 232-679-6

Sulfasalazine
CERCLA/SARA 313 Emission reporting Not Listed
carcinogen initial date 5/15/98
California Proposition 65 Not Listed
male reproductive toxicity initial date 1/29/99
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List 209-974-3

16. OTHER INFORMATION

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

SULFASALAZINE TABLETS
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: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 19-Nov-2014
Prepared by: Product Stewardship Hazard Communication

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