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

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ChemSafe (24 hours): +44 (0)208 762 8322

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

Material Name: Sulfasalazine Tablets

- Trade Name: AZULFIDINE®
- Chemical Family: Mixture
- Intended Use: Pharmaceutical product used as anti-inflammatory

2. HAZARDS IDENTIFICATION

- Appearance: Gold tablets
- Signal Word: WARNING

Statement of Hazard:
- May cause allergic reaction in individuals sensitive to sulfonamides
- Suspected of damaging fertility.
- May cause harm to breastfed babies.

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.

EU Indication of danger:
- Toxic to Reproduction; Category 3

EU Hazard Symbols: Xn

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

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.
2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>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>*</td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</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 R64</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>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>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the _R_ phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Water, carbon dioxide, dry chemical or foam

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

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

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES
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 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.

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

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

General 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.

Storage Conditions: Store as directed by product packaging.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs = 5 mg/m³ LLV

Silicon dioxide, NF

Australia TWA = 2 mg/m³ TWA
Austria OEL - MAKs Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
Germany (DFG) - MAK = 4 mg/m³ MAK
Ireland OEL - TWAs = 2.4 mg/m³ TWA
= 6 mg/m³ TWA
Latvia OEL - TWA Listed
OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO2) mg/m³ TWA
= 20 mppcf TWA
Slovenia OEL - TWA Listed

Corn Starch

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Czech Republic OEL - TWA Listed
Greece OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA
= 4 mg/m³ TWA
OSHA - Final PELS - TWAs:
= 15 mg/m³ TWA total
= 5 mg/m³ TWA
Portugal OEL - TWA Listed
Spain OEL - TWA Listed

Sulfasalazine

Pfizer OEL TWA-8 Hr: 600µg/m³

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

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Protection Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hands</td>
<td>Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Wear safety glasses or goggles if eye contact is possible.</td>
</tr>
<tr>
<td>Skin</td>
<td>Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.</td>
</tr>
<tr>
<td>Respiratory</td>
<td>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:

- Physical State: Tablets
- Color: Gold
- Molecular Formula: Mixture
- Molecular Weight: Mixture
- Polymerization: Will not occur

10. STABILITY AND REACTIVITY

- Stability: Stable under normal conditions of use.
- Conditions to Avoid: None known
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: Thermal decomposition products include oxides of carbon, nitrogen, and sulfur.
11. TOXICOLOGICAL INFORMATION

General Information: The remaining information describes the potential hazards of the individual ingredients.

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

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

Povidone
- Rat Oral LD50 100 g/kg

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

Silicon dioxide, NF
- Rat Oral LD50 10 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
- 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
11. TOXICOLOGICAL INFORMATION

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

Povidone
  IARC: Group 3 (Not Classifiable)

Silicon dioxide, NF
  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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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

EU Symbol: Xn
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.

EU Safety Phrases:
- S22 - Do not breathe dust.
- S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic reaction in individuals sensitive to sulfonamides
Suspected of damaging fertility.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications

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

Magnesium stearate
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-150-3

Povidone
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present

Silicon dioxide, NF
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-545-4
- EEC No. 418-260-2

Corn Starch
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 232-679-6
15. REGULATORY INFORMATION

Sulfasalazine

- California Proposition 65: carcinogen, initial date 5/15/98
- male reproductive toxicity, initial date 1/29/99
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 209-974-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 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 13 - Disposal Considerations.

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