MATERIAL SAFETY DATA SHEET

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

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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Sulfasalazine Delayed Release Tablets

Trade Name: AZULFIDINE EN-TABS(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anti-inflammatory

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Magnesium stearate	557-04-0	209-150-3	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Silicon dioxide, NF	7631-86-9	231-545-4	*
Corn Starch	9005-25-8	232-679-6	*
Glyceryl monostearate	31566-31-1	250-705-4	*
Propylene glycol	57-55-6	200-338-0	*
Sulfasalazine	599-79-1	209-974-3	70-80

Ingredient	CAS Number	EU EINECS List	%
Povidone	9003-39-8	Not listed	*
Polyethylene glycol	25322-68-3	Not listed	*
White wax	8006-40-4	Not listed	*
Carnauba wax	8015-86-9	232-399-4	*
Cellulose acetate phthalate	9004-38-0	Not listed	*

Additional Information: * Proprietary

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

3. 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:

EU Risk Phrases:

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

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

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: Wash skin with soap and water. If irritation occurs or persists, get 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.

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

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
ACGIH Threshold Limit Value (TWA)	= 2 mg/m^3 TWA
Australia TWA	= 2.5 mg/m^3 TWA containing no asbestos fibers

Silicon dioxide, NF

OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO2) mg/m^3 TWA = 20 mppcf TWA
Australia TWA	= 2 mg/m^3 TWA

Corn Starch

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

Glyceryl monostearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA

Propylene glycol

Australia TWA	= 10 mg/m^3 TWA = 150 ppm TWA = 474 mg/m^3 TWA

Sulfasalazine

Pfizer OEL TWA-8 Hr: 0.6 mg/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.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	**Color:**	Gold
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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.
Polymerization: Will not occur

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)

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

Povidone
Rat Oral LD50 100 g/kg

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

Silicon dioxide, NF
Rat Oral LD50 10 g/kg

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

Propylene glycol
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Glyceryl monostearate
Mouse IP LD50 200 mg/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)

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Propylene glycol
Skin Irritation Rabbit Mild
Eye 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

Povidone
IARC: Group 3

Silicon dioxide, NF
IARC: Group 3

Talc (non-asbestiform)
IARC: Group 3

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.

14. TRANSPORT INFORMATION

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

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 List	209-150-3

Povidone

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

Polyethylene glycol

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

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Glyceryl monostearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	250-705-4

Carnauba wax

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-399-4

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

Cellulose acetate phthalate

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

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 List	209-974-3

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet