



SAFETY DATA SHEET

Revision date 17-Apr-2022

Version 2.21

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Sulfasalazine Tablets

Product Code(s) SULFASALAZINE TABLETS

Trade Name: AZULFIDINE; SALAZOPYRIN; SALAZOPYRINE

Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as anti-inflammatory

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Reproductive toxicity Category 2
Effects on or via lactation

2.2. 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
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up

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P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sulfasalazine (CAS #: 599-79-1)	70-80		209-974-3	Repr.2 (H361f) Lact. (H362)	Not Listed	No data available	No data available
Starch (CAS #: 9005-25-8)	*	-	232-679-6	Not classified as hazardous	Not Listed	No data available	No data available
Magnesium Stearate (CAS #: 557-04-0)	*	-	209-150-3	Not classified as hazardous	Not Listed	No data available	No data available
Silica colloidal, Ph. Eur. (CAS #: 112945-52-5)	*	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Povidone (CAS #: 9003-39-8)	*	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sulfasalazine 599-79-1	15600	No data available	No data available	No data available	No data available
Povidone 9003-39-8	100000	No data available	No data available	No data available	No data available
Magnesium Stearate 557-04-0	> 2000	No data available	>2	No data available	No data available
Silica colloidal, Ph. Eur. 112945-52-5	3160	No data available	No data available	No data available	No data available

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Water, carbon dioxide, dry chemical or foam.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Not applicable.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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5.3. Advice for firefighters

Special protective equipment for fire-fighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

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

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections

See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on 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 thoroughly after handling. 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.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s)

Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

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Sulfasalazine

Pfizer OEL TWA-8 Hr: 600 µg/m³

Starch

ACGIH TLV

10 mg/m³

Bulgaria

10.0 mg/m³

Czech Republic

4.0 mg/m³

Ireland

10 mg/m³

4 mg/m³

STEL: 30 mg/m³

STEL: 12 mg/m³

MAC: 10 mg/m³

Russia

10 mg/m³

Spain

3 mg/m³

Switzerland

15 mg/m³

OSHA PEL

5 mg/m³

(vacated) TWA: 15 mg/m³ total dust

(vacated) TWA: 5 mg/m³ respirable fraction

United Kingdom

TWA: 10 mg/m³

TWA: 4 mg/m³

STEL: 30 mg/m³

STEL: 12 mg/m³

Povidone

Russia

MAC: 10 mg/m³

Magnesium Stearate

ACGIH TLV

10 mg/m³

3 mg/m³

Ireland

10 mg/m³

STEL: 30 mg/m³

Spain

10 mg/m³

Silica colloidal, Ph. Eur.

Austria

4 mg/m³

Germany

0.02 mg/m³

Ceiling / Peak: 0.16 mg/m³

8.2. 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.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is

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exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Tablets
Color	Yellow-orange
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

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10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

Hazardous polymerization Will not occur.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

STOT - single exposure

Based on available data, the classification criteria are not met.

STOT - repeated exposure

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

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

Povidone

Rat Oral LD50 100 g/kg

Magnesium Stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sulfasalazine	= 15600 mg/kg (Rat)	-	-
Povidone	= 100 g/kg (Rat)	-	-
Silica colloidal, Ph. Eur.	= 3160 mg/kg (Rat)	-	-

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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

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Development Toxicity: (Duration, 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

Carcinogenicity

See below

Sulfasalazine

IARC

Group 2B (Possibly Carcinogenic to Humans)

Povidone

IARC

Group 3 (Not Classifiable)

Silica colloidal, Ph. Eur.

IARC

Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

12.2. Persistence and degradability

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Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 wastewater 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.

Section 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.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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Sulfasalazine

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
carcinogen 5/15/1998
male reproductive toxicity 1/29/99

EINECS
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

209-974-3
Schedule 4

Starch

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
Not Listed

TSCA
EINECS
AICS

Present
232-679-6
Present

Povidone

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
Not Listed

TSCA
EINECS
AICS

Present
Not Listed
Present

Magnesium Stearate

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
Not Listed

TSCA
EINECS
AICS

Present
209-150-3
Present

Silica colloidal, Ph. Eur.

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
Not Listed

EINECS
AICS

Not Listed
Present

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

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Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under 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

Data Sources:	Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reason for revision	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
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Prepared By	Pfizer Global Environment, Health, and Safety

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