

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

Sandwich, Kent CT13 9NJ United Kingdom

Ramsgate Road

Pfizer Ltd

+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

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022 Page 2/11 Version 2.21

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



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	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
				[CLP]			
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

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

Revision date 17-Apr-2022 Version 2.21

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	
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.

Page 3/11

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.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Water, carbon dioxide, dry chemical or foam.

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.

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

evision date 17-Apr-2022 Version 2.21

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn

Page 4/11

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.

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.

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

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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
 MAC: 10 mg

 Spain
 10 mg/m³

 Switzerland
 3 mg/m³

 OSHA PEL
 15 mg/m³

 5 mg/m³
 5 mg/m³

(vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction

Page 5/11

Version 2.21

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

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022 Page 6 / 11 Version 2.21

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 formulaMixtureMolecular weightMixture

<u>Property</u> <u>Values</u>

pHMelting point / freezing pointNo data availableNo data available

Boiling point / boiling range

Flash point No information available Evaporation rate No data available

Flammability (solid, gas)

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 No data available **Autoignition temperature Decomposition temperature** No data available Kinematic viscosity No data available **Dvnamic viscosity** No data available

Particle characteristics
Particle Size
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

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

10.1. Reactivity

No data available. Reactivity

10.2. Chemical stability

Stable under normal conditions. Stability

Explosion data

Sensitivity to Mechanical Impact No data available. Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

No information available. Possibility of hazardous reactions

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,

Page 7/11

Version 2.21

skin rash, changes in blood cell levels.

Based on available data, the classification criteria are not met. 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 STOT - single exposure Based on available data, the classification criteria are not met. 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 **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)	-	-	

Page 8 / 11

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

Revision date 17-Apr-2022 Version 2.21

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)

<u>Povidone</u>

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.

<u>12.1. Toxicity</u>

12.2. Persistence and degradability

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

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

SULFASALAZINE TABLETS

Page 9 / 11 Version 2.21

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

Revision date 17-Apr-2022 Version 2.21

Sulfasalazine

CERCLA/SARA Section 313 de minimus % Not Listed

California Proposition 65 carcinogen 5/15/1998

male reproductive toxicity 1/29/99

Page 10 / 11

EINECS 209-974-3 Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

Starch

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS 232-679-6 AICS

Povidone

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS Not Listed AICS

Magnesium Stearate

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS 209-150-3 AICS

Silica colloidal, Ph. Eur.

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed EINECS Not Listed AICS 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

<u>Legend:</u>

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

Product Name Sulfasalazine Tablets Revision date 17-Apr-2022

Revision date 17-Apr-2022 Version 2.21

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

Page 11 / 11

Information.

Revision date 17-Apr-2022

Prepared By Pfizer Global Environment, Health, and Safety

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