


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	SULFASALAZINE, USP
PRODUCT CODE	0176
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Sensitization - Skin (Category 1) Sensitization - Respiratory (Category 1) Carcinogenicity (Category 2) Toxic to Reproduction (Category 2) Chronic Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. Toxic to aquatic life with long lasting effects.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable

PRECAUTIONARY STATEMENT(S)	Prevention	Avoid breathing dust, fume, gas, mist, vapors, spray. In case of inadequate ventilation wear respiratory protection. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment.		
	Response	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, get medical help immediately call a poison center or medical professional. IF EXPOSED OR CONCERNED: Get medical advice. COLLECT SPILLAGE		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
HMS CLASSIFICATION	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	H

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Benzoic Acid, 2-hydroxy-5-[[4-[(2-pyridinylamino) sulfonyl]-phenyl]azo]
BOTANICAL NAME	Not applicable
SYNONYM	5-[[p-(2-Pyridylsulfamoyl)phenyl]azo]salicylic acid; Salicylazosulfapyridine
CHEMICAL FORMULA	C ₁₈ H ₁₄ N ₄ O ₅ S
CHEMICAL FAMILY	Aromatic sulfanilamide derivative (sulfonamide); salicylate
CAS NUMBER	599-79-1
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	398.3976

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
SULFASALAZINE	599-79-1	209-974-3	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: SULFASALAZINE CAS #: 599-79-1

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Bright yellow or brownish yellow, odorless, fine powder.

SOLUBILITY

Very slightly soluble in alcohol; practically insoluble in water, in ether, in chloroform, in benzene; soluble in aqueous solutions of alkali hydroxides.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	(240-255)°C, (464-491)°F
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	3.81 (20°C)	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(240-255)°C, (464-491)°F (decomposes)
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Light sensitive and may be sensitive to prolonged exposure to air. Dust can be explosive when suspended in air at specific concentrations.
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 15 600 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

SKIN SENSITIZATION

May cause an allergic skin reaction.
Suspected skin sensitizer: The Toolbox profiler 'Protein binding alerts for skin sensitization by OASIS v1.3' gives an alert for skin sensitisation

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.
Suspected mutagen: The Toolbox profiler 'DNA alerts for AMES, MN and CA by OASIS v.1.3' gives an alert for mutagenicity; The Toolbox profiler 'in vitro mutagenicity (Ames test) alerts by ISS' gives an alert for mutagenicity; The Toolbox profiler 'Protein binding alerts for Chromosomal aberration by OASIS v1.1' gives an alert for mutagenicity; In vivo micronucleus test outcome positive according to ISSMIC

CARCINOGENICITY

OSHA SULFASALAZINE is not listed.
NTP SULFASALAZINE is not listed.
IARC SULFASALAZINE is listed in group 2b (possibly carcinogenic to humans).
California Proposition This product contains the following chemical known to the State of California to cause cancer and birth defects or other reproductive harm (male): SULFASALAZINE.

**ADDITIONAL CARCINOGENICITY
INFORMATION**

Suspected of causing cancer. IARC: Group 2B; Possibly carcinogenic to humans. Studies in rats have shown that long-term administration of sulfonamides may cause thyroid malignancy. However, rats appear to be especially susceptible to the goitrogenic effects of sulfonamides.
675 - 2700 mg/kg/day Carcinogenicity study
Result: Increase in hepatocellular adenomas and carcinomas.
Species: Mouse
Test Duration: 2 years
84 - 337.5 mg/kg/day Carcinogenicity study
Result: Increase in bladder cell papillomas.
Species: Rat
Test Duration: 2 years

REPRODUCTIVE TOXICITY

May cause reproductive disorders. Treatment with sulfasalazine has been associated with male infertility, and with abnormalities in semen analyses, including oligospermia and reduced sperm motility. Possible risk of congenital malformation in the fetus.
Suspected of damaging fertility or the unborn child. Sulfasalazine impairs male fertility during therapeutic use, but the effect is reversible. Sulfonamides given to pregnant women prior to delivery may cause jaundice, brain damage, and hemolytic anemia in the offspring. Studies in rats and mice given high oral doses have shown that certain sulfonamides cause a significant increase in the incidence of cleft palate and other bony abnormalities in the fetus.
Rat: < 800 mg/kg/day Reproductivity; Result: Impaired fertility.

**SPECIFIC TARGET ORGAN
TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN
TOXICITY - REPEATED
EXPOSURE**

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

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

**SIGNS AND SYMPTOMS OF
EXPOSURE**
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Sulfonamides: Pseudomembranous colitis. Crystalluria. Stevens-Johnson syndrome

Symptoms related to the physical, chemical, and toxicological characteristics:

Sulfonamides: Nausea. Vomiting. Diarrhea. Loss of appetite. Dizziness. Headache. Skin rash. Fever. Itching. Increased sensitivity of skin to sunlight. Sore throat. Unusual bleeding or bruising. Difficulty swallowing. Vision problems. Yellow eyes or skin. Lower back pain. Difficult or painful urination. Blood in urine. Joint pain. Muscle pain. Redness, peeling or loosening of skin. Fatigue.

Cross sensitivity:

Persons sensitive to sulfonamides or to furosemide, thiazide diuretics, sulfonyleureas, salicylates, or carbonic anhydrase inhibitors may be sensitive to this material also.

Medical conditions aggravated by exposure:

Sulfonamides: Allergies. Asthma. HIV or AIDS. Lupus erythematosus. Blood disorders. Impaired kidney or liver function. Porphyria.

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled
Ingestion	May be harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction
Eyes	May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: Daphnia: (mg/L): 5.17*

LC50: 96 Hr: Fish: (mg/L): 7.7*

EC50: 72 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND
DEGRADABILITY**

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable

BIOACCUMULATIVE POTENTIAL

Log Pow: 3.81 (20°C)

MOBILITY IN SOIL

Practically insoluble in water

OTHER ADVERSE EFFECTS

Not available

NOTES

This product is not intended to be released into the environment

*Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME Not dangerous good
 UN NUMBER Not applicable
 CLASS Not applicable
 PACKING GROUP Not applicable

AUSTRALIA

HAZCHEM Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE Not listed

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A Appendix B		Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
SULFASALAZINE, 599-79-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
SULFASALAZINE, 599-79-1	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
SULFASALAZINE, 599-79-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.