

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

SULFASALAZINUM

EN

FORM-06-14-01 (V00)

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

1.1 Product identifier

Product name: Sulfasalazine
Sulfasalazinum
Sulfasalazine
Sulfasalazine
Sulfasalazin

N° CAS: 599-79-1

N° EC: 209-974-3

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Skin Sens. 1 H317

Resp. Sens. 1 H334

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements:

P261 Avoid breathing dust.

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P280	Wear protective gloves.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Sulfasalazine
IUPAC name:	2-hydroxy-5-[[4-(pyridin-2-ylsulfamoyl)phenyl]diazenyl]benzoic acid
Synonyms:	Salazosulfapyridine Azulfidine Salicylazosulfapyridine
N° CAS:	599-79-1
N° EC:	209-974-3
Molecular Formula:	C ₁₈ H ₁₄ N ₄ O ₅ S
Content:	97.0 per cent to 101.5 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.
After skin contact:	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing. Serious skin contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.
After eye contact:	Check and remove any contact lenses. Do not use an eye ointment. Seek medical attention.
After ingestion:	Do not induce vomiting. Loosen tight clothing such as collar, tie, belt or waistband. If victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use waters spray, fog or foam. Do not use water jet.
Unsuitable extinguishing media:	Do not use water jet.

5.2 Special hazards arising from the substance/mixture

Flammability of the product: May be combustible at high temperature.
Products of combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂).

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Not available.
Hazardous combustion products:	Carbon oxides (CO, CO ₂), nitrogen oxides (NO, NO ₂).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

Not available.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
Large spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing if ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

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7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Preserve in tight, light resistant containers.
Storage – away from:	Store protected from light. Combustible material should be stored away from extreme heat and away from strong oxidising agents.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures

Eye/face protection:	Splash goggles. In case of large spill: Splash goggles.
Skin protection:	Lab coat. In case of large spill: Full suit. Boots. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Hand protection:	Gloves. In case of large spill: Gloves.
Respiratory protection:	Dust respirator. Be sure to use an approved/certified respirator or equivalent. In case of large spill: Dust respirator. A self-contained breathing apparatus should be used to avoid inhalation of the product.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Bright yellow or brownish-yellow, fine powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.

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Melting/freezing point:	Decomposes. 242.5 °C or 468.5 °F
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Very slightly soluble in ethanol (96 per cent). Practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides.
Solubility in water:	Practically insoluble in water. Insoluble in cold water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 398.4 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

Corrosivity: Non-corrosive in presence of glass.

Polymerisation: No.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

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10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (mouse): 12 500 mg/kg
Skin corrosion/irritation:	Hazardous in case of skin contact (irritant).
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	May cause an allergic skin reaction.
Inhalation:	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Slightly hazardous in case of inhalation (lung irritant).
Ingestion:	Slightly hazardous in case of ingestion.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

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12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal: Waste must be disposed of in accordance with local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

DOT classification: Not a DOT controlled material.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful

Risk phrases:

R42/43 May cause sensitization by inhalation and skin contact.

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Safety phrases: S22 Do not breathe dust.
S29/56 Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS: Chemical Abstracts Service (division of the American Chemical Society)
EC (number): European Community (number)
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
IMDG: International Maritime Code for Dangerous Goods
IUPAC: International Union of Pure and Applied Chemistry
PBT: Persistent, Bioaccumulative and Toxic substance
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)
vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation

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(EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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