

Material Safety Data Sheet

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

MESALAZINUM

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: Mesalazine
Mesalazinum
Mesalazine
Mésalazine
Mesalazin

N° CAS: 89-57-6

N° EC: 201-919-1

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: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
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 Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H315 Causes skin irritation.

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H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	IF ON SKIN: Wash with plenty of water.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P321	Specific treatment (see on this label).
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Mesalazine
IUPAC name:	5-amino-2-hydroxybenzoic acid
Synonyms:	5-Aminosalicylic acid 5-hydroxyanthranilic acid
N° CAS:	89-57-6
N° EC:	201-919-1
Molecular Formula:	C ₇ H ₇ NO ₃
Content:	98.5 % to 101.5 % (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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General notes:	Immediately remove any clothing soiled by the product.
After inhalation:	Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably inside position for transportation.
After skin contact:	Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
After ingestion:	Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.
Self-protection of the first aider:	Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge the toxicity of this substance has not been fully investigated, thus symptoms and effects are not fully known. Irritation effects such as skin and eye irritation and to upper respiratory tractate expected. Other adverse effects cannot be excluded.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	CO ₂ , extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

In case of fire, the following can be released:
Nitrogen oxides (NO_x)
Carbon monoxide (CO)
No explosivity or flammability data identified. High concentrations of finely divided air borne organic particles can potentially explode if ignited.

5.3 Advice for firefighters

Surrounding fires:	Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems.
Protection against fire:	Fire fighters should wear positive self-contained breathing apparatus. Wear suitable protective clothing to avoid contact with skin.
Hazardous combustion products:	Not available.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective equipment. Keep unprotected persons away. Avoid formation of dust.

For emergency responders

Wear protective equipment. Keep unprotected persons away. Avoid formation of dust.

6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

A small spill may be handled with water moistened disposable cloth and placed in container for chemical waste. A larger spill should be collected and placed in container for disposal. Use recommended personal protective equipment. Wash spill site with water after completed pickup.

6.4 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

7.1 Precautions for safe handling

Precautions for safe handling:

Ensure good ventilation/exhaustion at the workplace. Prevent formation of dust. Avoid contact with eyes and skin.

Personal protection:

Not available.

Technical protective measures:

The material may form flammable dust clouds in air. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel. Ensure good ventilation/exhaustion at the workplace.

Dust explosion class: St 2H

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by store rooms and receptacles: In an airtight container, protected from light.

Information about storage in one common storage facility: Avoid contact with acids, acid chlorides, acid anhydrides, strong oxidants.

Conditions for safe storage, including any incompatibilities:

Keep receptacle tightly sealed.

Storage – away from:

Not available.

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7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with limit values that require monitoring at the workplace: Not required.

Additional occupational exposure limit values for possible hazards during processing:

89-57-6

5-amino salicylic acid

Permitted daily exposure (PDE) value

10 mg/day or 1000 µg/day

Occupational exposure limit (OEL) value

0.2 mg/m³/day or 200 µg/m³/day

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

General protective and hygienic measures:

Keep away from food stuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

Eye/face protection:

Tightly sealed goggles.

Skin protection:

Impervious protective clothing.

Hand protection:

Protective gloves.

The glove material has to be impermeable and resistant to the product / the substance / the preparation. Due to missing test no recommendation to the glove material can be given for the product / the preparation / the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves: The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection:

Required when dusts are generated. Where risk assessment shows than an air-purifying respirators appropriate, use filter of type P3 (EN143) or N100 (NIOSH) or types recommended in applicable federal, state and national legislation.

Thermal hazards:

Not determined.

Environmental exposure control

Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Almost white or light grey or light pink powder or crystals.
Odour:	Not available.
Odour threshold:	Not available.
pH:	3.5 – 4.5
Melting/freezing point:	280 °C (536 °F)
Initial boiling point:	345 °C (653 °F) (estimated)
Boiling range:	345 °C (653 °F) (estimated)
Flash point:	280 °C (536 °F) (open cup)
Evaporation rate:	Not available.
Flammability (solid/gas):	Product is not flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	At 25 °C (77 °F): 0hPa (estimated)
Vapour density:	Not available.
Relative density:	At 25 °C (77 °F): >1g/cm ³ (>8.345 lbs/gal)
Solubility:	Very slightly soluble in water, practically insoluble in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides and in dilute hydrochloric acid.
Solubility in water:	At 25 °C (77 °F): 11g/l
Partition coefficient (n-octanol/water):	At 25 °C (77 °F): 0.98 logPOW
Auto-ignition temperature:	Product is not self igniting.
Decomposition temperature:	Not available.
Viscosity:	Dynamic: Not applicable.
Explosive properties:	Product does not present an explosion hazard. The material may form flammable dust clouds in air. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources.
Oxidising properties:	Not available.

9.2 Other information

Minimum Ignition Energy:	10 mJ < MIE < 30 mJ / Es = 17 mJ
Ignition temperature:	>280 °C (>536 °F)
Dissociation constant:	pKa = 1.9 at 20 °C

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reactivity stable at ambient temperature and under normal conditions of use.

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10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Avoid exposure to sunlight.

10.4 Conditions to avoid

Thermal decomposition/conditions to be avoided: The substance is chemically stable at standard room temperature conditions.

No further relevant information available.

10.5 Incompatible materials

Acids, acid chlorides, acid anhydrides, strong oxidants.

10.6 Hazardous decomposition products

Under fire conditions - Carbon oxides, nitrogen oxides (NO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

LD/LC ₅₀ values that are relevant for classification:		
Oral	LD ₅₀	2800 mg/kg (rat)
Dermal	LD ₅₀	>5000 mg/kg bw (rabbit)

Skin corrosion/irritation:

Irritant to skin and mucous membranes.

The substance is considered to be irritating to skin on the basis of QSAR prediction.

Serious eye damage/irritation:

Irritating effect.

The substance is considered to be irritating to eyes on the basis of QSAR prediction.

Respiratory/skin sensitisation:

Sensitization possible through skin contact.

The substance is considered to be sensitizing to skin on the basis of QSAR prediction.

Germ cell mutagenicity:

Not available.

Carcinogenicity:

ACGIH – Not listed.

Carcinogenic categories:

IARC (*International Agency for Research on Cancer*): Substance is not listed.

NTP (*National Toxicology Program*): Substance is not listed.

OSCHA-Ca (*Occupational Safety & Health Administration*): Substance is not listed.

Reproductive toxicity:

Not available.

Summary of evaluation of the CMR properties:

Not available.

STOT-single exposure:

Respiratory irritation possible on inhalation exposure.

STOT-repeated exposure:

Not available.

Aspiration Hazard:

Not available.

Other:

Not available.

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11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

EC ₅₀ (96hrs)	66 mg/L (Algae) (Estimated)
LC ₅₀ (48hrs)	12 mg/L (Daphnia Sp.) (Estimated)
LC ₅₀ (96hrs)	155 mg/L (Fish) (Estimated)

12.2 Persistence and degradability

The substance is estimated to be readily biodegradable but failing the 10-day window.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

General notes: Do not allow product to reach ground water, water course of sewage system. Danger to drinking water if even small quantities leak into the ground.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment methods - Recommendation: Dispose of waste material according to local, state and federal regulations.

Uncleaned packaging – Recommendation: Disposal must be made according to official 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

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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 applicable.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

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

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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 (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

Quality Department

FAC SECUNDUM ARTEM NV

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