

Trade name: Sulfasalazin medac

Status: 03.06.2008

Version: 2.0.0 / GB

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1.) Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name

Sulfasalazin medac

Use of the substance/preparation

pharmaceutical products

Company/undertaking identification

Address

medac Gesellschaft für klinische Spezialpräparate mbH

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Advice on Safety Data Sheet

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2.) Hazards identification

Classification

Repr.Cat.3; R63

Possible risk of harm to the unborn child.

Repr.Cat.2; R60

May impair fertility.

R42/43

May cause sensitisation by inhalation and skin contact.

Hazard symbols

T

Toxic

R phrases

60

May impair fertility.

42/43

May cause sensitisation by inhalation and skin contact.

63

Possible risk of harm to the unborn child.

3.) Composition / information on ingredients

Hazardous ingredients

propan-2-ol

EC no.	200-661-7	Index no.	603-117-00-0	CAS no.	67-63-0
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Concentration	> 1	< 5	%-b.w.		
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Classification	F; R11-Xi; R36-R67				
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Hazard symbols	F, Xi	R phrases	11-36-67		
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salazosulfapyridine

EC no.	209-974-3	Index no.	-	CAS no.	599-79-1
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Concentration	> 70	< 90	%-b.w.		
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Classification	Repr.Cat.3; R63	Repr.Cat.2; R60	R42/43		
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Hazard symbols	T	R phrases	60-42/43-63		
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4.) First aid measures

After inhalation

Ensure supply of fresh air. In case of respiratory arrest induce breathing with a respiratory device. Seek medical advice.

After skin contact

Remove contaminated clothing immediately, even underwear and shoes. In case of contact with skin wash off immediately with copious amounts of water. Seek medical attention.

After eye contact

In case of contact with eyes rinse thoroughly with copious amounts of water and seek medical advice.

After ingestion

Rinse mouth thoroughly with water. Seek medical attention.

Advice to doctor

Symptoms

Nausea; Headache; Vomiting; CNS disorders; Anorexia; Fever; Hyperglycaemia

Hazards

Risk of pancreas inflammation. Risk of medulla atrophy.

5.) Fire-fighting measures

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

Fire gas of organic material has to be classed invariably as respiratory poison.

Special protective equipment for fire-fighters

Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus.

Other information

Collect contaminated firefighting water separately, must not be discharged into the drains.

6.) Accidental release measures

Personal precautions

Cordon and mark contaminated area. Personal protection equipment for removal of unintentional contamination or in the event of rupture :

- Overshoes
- liquid-proof protective long-sleeved coat with close-fitting sleeve-band
- protective goggles
- protective gloves
- Protective face mask min. P2 according to the provisions of the professional organisation "Rules for use of breathing apparatuses"
- cut cellulose in sufficient quantity
- receptacle and waste container, shovel

Environmental precautions

Do not allow to enter drains or waterways.

Methods for cleaning up/taking up

Remove immediately and appropriately soiling. Keep ready a decontamination kit. Take-up of liquid drugs spill.

Cover contaminated area carefully using disposable cloth or cellulose, so that the liquid is completely absorbed.

Take-up of dry solid matters.

Cover with several layers of cellulose contaminated area carefully over its whole surface, so that the cellulose can be wetted cautiously from above.

Take-up of glass breakage.

Use of suitable means and use of an additional pair of protective gloves.

Clean thoroughly contaminated areas.

7.) Handling and storage

Handling

Advice on safe handling

Work only in fume cupboards. Production of the drug prepared for application using the Laminar Air Flow (safety bench category 2). Open and handle container with care. Only qualified and trained persons are authorised to handle

Storage

Advice on storage assembly

Adhere to the drug storage ruling provisions.

Further information on storage conditions

Keep container tightly closed in a well-ventilated place. Protect from heat and direct sunlight.

8.) Exposure controls / personal protection

Exposure limit values

propan-2-ol

CAS no.	67-63-0
EC no.	200-661-7

Occupational Exposure Standards (OESs) / EH40

Propan-2-ol				
TWA	999	mg/m ³	400	ml/m ³
STEL	1250	mg/m ³	500	ml/m ³

Personal protective equipment

Respiratory protection

If ventilation insufficient, use a respiratory protection apparatus.

Respiratory filter (part): min. P2

Hand protection

Disposable gloves with long gauntlet and, if possible, revolving sleeve made of natural Latex, PVC or synthetics with tight closing band around the gauntlet (i.e. Biogel®Standard; Biogel®Skinsense™ or Biogel®Indicator)

- unpowdered, poor protein content, close-fitting, firm surface
- quality requirements according to DIN EN 374
- finger area designed with double wall thickness

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- advantageous: dyed gloves recommendation
 - Wearing of two pairs of gloves (i.e. Biogel®Indicator™)
- Material thickness > 0,2 mm

Eye protection

Safety glasses with side protection shield (EN 166)

Skin protection

Liquid-proof protective long-sleeved coat with close-fitting sleeve-band obligatory.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Remove soiled or soaked clothing immediately. An antechamber equipped with separated storage facilities must exist for changing (protective clothes and normal clothes) before the working space (lock). At work do not eat, drink, smoke or take drugs. Keep separated from food-stuffs and feed-stocks.

9.) Physical and chemical properties

General information

Form crystalline
Colour yellow-brown

Important health, safety and environmental information

Changes in physical state

Type Melting point (decomposition)
Value 240 - 245 °C

Solubility in water

Remarks insoluble

10.) Stability and reactivity

Hazardous decomposition products

Carbon monoxide and carbon dioxide; Nitrous oxides (NO_x)

Thermal decomposition

Remarks No decomposition if used as prescribed.

11.) Toxicological information

Acute toxicity

Acute oral toxicity

LD50 15600 mg/kg
Species rat

Acute dermal toxicity

Remarks No data available.

Acute inhalational toxicity

Remarks No data available.

Sensitisation

Evaluation sensitizing

Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Mutagenicity

Value Information on genotoxicity in vitro available.

Reproduction toxicity

Remarks Indications of toxic effects are available from reproduction studies in animals.

Other information (chapter 11.)

Our data are not sufficient for a complete toxicological judgement. Follow the usual hygienic directives for handling with chemicals.

12.) Ecological information

Other adverse effects

Do not discharge product unmonitored into the environment.
Ecological data are not available.

13.) Disposal considerations

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Uncontaminated packaging may be taken for recycling.
Packaging that cannot be cleaned should be disposed off as product waste.

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14.) Transport information

Other information (chapter 14.)

No hazardous material as defined by the transport regulations.
 Containerise toxic drugs in unbreakable, liquid-proof and tight closing containers
 Marking of transport containers:
 Name and address of patient or surgery or hospital ward
 if necessary label: „Caution CMR-substance“
 if necessary label:„refrigerated ware“
 if necessary label:„Caution breakable glass“,and instructions for the event of breakage
 Heat-sealing of primary containers recommended.

15.) Regulatory information

Labelling in accordance with EC directives

The product is classified and labelled in accordance with EC Directive 1999/45/EC.

Hazard symbols

T Toxic

Hazardous component(s) to be indicated on label, contains:

salazosulfapyridine

R phrases

60 May impair fertility.
 42/43 May cause sensitisation by inhalation and skin contact.
 63 Possible risk of harm to the unborn child.

S phrases

53 Avoid exposure --- obtain special instructions before use.
 37 Wear suitable gloves.
 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Special labelling for certain preparations

"Restricted to professional users"

Restriction of occupation

Observe employment restrictions for young people.
 Observe employment restrictions for child bearing mothers and nursing mothers.

Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Remarks Annex I: not listed.

16.) Other information

Further information

The information is based on our current knowledge however it does not represent a guarantee of product properties nor does it create any legal obligation.

Processing notes Please read packing specification of the drug for additional drug related information.
 Data in the safety data sheet refer to the substance in the tube.

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.
 Regulation (EC) No 1907/2006 (REACH) as amended in each case.
 EC Directives 2000/39/EC, 2006/15/EC as amended in each case.
 National Threshold Limit Values of the corresponding countries as amended in each case.
 Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.
 The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Relevant R-phrases (chapter 3):

11 Highly flammable.
 36 Irritating to eyes.
 42/43 May cause sensitisation by inhalation and skin contact.
 60 May impair fertility.
 63 Possible risk of harm to the unborn child.
 67 Vapours may cause drowsiness and dizziness.

Department issuing safety data sheet

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Ready-made medical preparations are not ruled by the chemical's act, so that the submission of a safety data sheet is not obligatory. Medac, however, opts for this form because the safety data sheet constitutes a reliable source of information regarding the handling of hazardous substances and preparations, and because many occupational safety measures are basing on the safety data sheet structure.

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