

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

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

1.1 Product identifier

N° CAS:

N° EC:

Product name: Dapsone

> Dapsonum Dapsone Dapsone Dapson 80-08-0 201-248-4

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

Identified uses: Active Pharmaceutical Ingredient.

1.3 Details of the supplier of the safety data sheet

Magis-Pharma NV Company:

> 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

Centre Antipoisons Belge Public utility foundation: Belgisch Antigifcentrum

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

Acute Tox. 4 H302 STOT SE 2 H371 STOT RE 2 H373 Aquatic Chronic 2 H411

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





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Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

H371 May cause damage to organs.

H373 May causes damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P264 Wash hands [and ...] thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.
P301+P317 IF SWALLOWED: Get medical help.

P308+P316 IF exposed or concerned: Get emergency medical help immediately.

P319 Get medical help if you feel unwell.

P330 Rinse mouth.
P391 Collect spillage.
P405 Store locked up.

P501 Dispose of contents/container to a waste disposal plant in accordance with local,

regional, national and/or 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: Dapsone

IUPAC name: 4-(4-aminophenyl)sulfonylaniline

Synonyms: Diaphenylsulfone

4,4'-Sulfonyldianiline4-Aminophenyl sulfone

Aczone

N° CAS: 80-08-0
N° EC: 201-248-4
Molecular Formula: $C_{12}H_{12}N_2O_2S$

Content: 99.0 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.



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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor. Show the safety data sheet to the doctor on duty.

After inhalation: Remove to fresh air. If breathing is irregular, call a doctor immediately. Only give

artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Remove all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

After eye contact: Remove contact lenses and rinse immediately with plenty of water, including under

the eyelids, for at least 15 minutes. Get medical attention.

After ingestion: If conscious, give the victim water (maximum 2 glasses) to drink. Never give anything

by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described on the label (see section 2.2) and/or under heading 11.

4.3 Indication of any immediate medical attention and special treatment needed

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

Neighbouring fires (fire-exposed containers): Water spray or water

fog.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Carbon oxides.

Nitrogen oxides (NO_x). Sulphur oxides (SOx).

5.3 Advice for firefighters

Cool containers with water to prevent decomposition of product and Surrounding fires:

> development of health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in

accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

> straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of



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the operator or the car (self protective) in case of large amounts of

smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8.

Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

For emergency responders

For exposure control and personal protective measures, see section 8.

Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2 Environmental precautions

Prevent release to the environment. Prevent entry into sewers and watercourses. If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Wash thoroughly after handling. Do not eat, drink or smoke while

handling this product. Ask for special instructions before use.

Personal protection: Not available.

Technical protective measures: Work with good ventilation of the processing area to avoid vapour

formation.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep container tightly closed in a cool, well-ventilated place.

Storage – away from: Keep away from direct sunlight, heat and sources of ignition.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN 165, EN 166, EN 167, EN

168.

Skin protection: Choose body protection according to the quantity and concentration of the

hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of EU Directive 89/686/EEC and the derived standards EN 374-1, EN

374-2, EN 374-3, EN 420.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust

mask type N95 (USA) or type P1 (EN 149). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

Evaporation rate:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or slightly yellowish-white, crystalline powder.

Not available.

Odour:
Odourless.
Odour threshold:
Not available.

PH:
Not available.

Melting/freezing point:
175 - 181 °C
Initial boiling point:
Not available.

Boiling range:
Not available.

Flash point:
Not available.



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Flammability (solid/gas): Not available.

Upper/lower flammability or

explosive limits:

Not available.

Vapour pressure: Not available. Not available. Vapour density: Relative density: Not available.

Solubility: Freely soluble in acetone, sparingly soluble in ethanol (96 per cent). It dissolves in

dilute mineral acids.

Solubility in water: Practically insoluble in water.

Partition coefficient

(n-octanol/water):

Not available.

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Not available. Viscosity: Not available. Explosive properties: Oxidising properties: Not available.

9.2 Other information

Density (25 °C): 1,374 g/cm³ Molecular Weight: 248,30 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Any source of ignition.

10.5 Incompatible materials

Strong oxidising agents and oxidising materials.

10.6 Hazardous decomposition products

Carbon oxides, nitrogen oxides (NO_x) and sulphur oxides (SO_x).



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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD50, rat): 1000 mg/kg

Skin corrosion/irritation: Not available. Not available. Serious eye damage/irritation: Respiratory/skin sensitisation: Not available. Germ cell mutagenicity: Not available. Not available. Carcinogenicity: Reproductive toxicity: Not available. Not available. Summary of evaluation of the

CMR properties:

STOT-single exposure: Not available. STOT-repeated exposure: Not available. Aspiration Hazard: Not available.

RTECS: BY8925000 Other:

11.2 Additional information on potential adverse human health effects and symptoms

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

Harmful if swallowed. Ingestion:

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

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12.6 Other adverse effects

This substance/mixture does not contain components that are considered to be persistent bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative and very persistent (vPvB) at levels of 0.1% or higher.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

14	.1	П	N	N	ıım	her

ADR/RID(Land),IMDG(Sea), IATA/ICAO (Air):

It is not dangerous in transport.

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

It is not dangerous in transport.

IATA/ICAO (Air):

14.6 Special precautions for user

It is not dangerous in transport.

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

Not applicable.

14.8 Additional transport information

Not available.

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SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Risk phrases: R22 Harmful if swallowed.

Safety phrases: S20/21 When using do not eat, drink or smoke.

S46 If swallowed, seek medical advice immediately and show this container or label.

R64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

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

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 United Nations (number)

vPvB: very Persistent and very Bioaccumalative

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.

UN (number):

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

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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

Magis-Pharma NV info@magis-pharma.be