

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



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

1.1 Product identifier

Product name: Sulpiride
Sulpiridum
Sulpiride
Sulpiride
Sulpirid

N° CAS: 15676-16-1

N° EC: 239-753-7

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

Repr. 2 H361

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H361 Suspected of damaging fertility or the unborn child.

Precautionary statements:

P281 Use personal protective equipment as required.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



SULPIRIDUM

P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P405	Store locked up.
P501	Dispose of contents/container according to official regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

As many organic powders, can form explosive mixture with air.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Sulpiride
IUPAC name:	<i>N</i> -[(1-ethylpyrrolidin-2-yl)methyl]-2-methoxy-5-sulfamoylbenzamide
Synonyms:	Sulpyrid Aiglonyl Dolmatil Dogmatil
N° CAS:	15676-16-1
N° EC:	239-753-7
Molecular Formula:	C ₁₅ H ₂₃ N ₃ O ₄ S
Content:	98.5 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Move the victim into fresh air. Apply artificial respiration if victim is not breathing. If breathing is difficult, give oxygen. Get medical attention.
After skin contact:	Take off contaminated clothing. Wash the exposed parts of body with plenty of soap and water. Get medical attention, if irritation persists.
After eye contact:	Rinse immediately with plenty of water for at least 15 minutes keeping eyelids open. Get medical attention, if irritation persists.
After ingestion:	Never give fluids if patient is unconscious. If the person is conscious, rinse mouth with water. In case of spontaneous vomiting be sure that vomitus can freely drain due to danger of suffocation. Do not induce vomiting. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

This product may cause irritation to eyes, skin and respiratory system. May cause drowsiness and tremors. In case of intake may causes gastrointestinal disturbances (intestinal hypermotility, diarrhoea).

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media:	Do not use water jet.

5.2 Special hazards arising from the substance/mixture

The substance is combustible and in case of fire can release CO_x, NO_x, SO_x.

5.3 Advice for firefighters

Surrounding fires:	In case of nearby fire, keep containers cool with water spray. Do not release chemically contaminated water into drains, soil or surface water. Sufficient measures must be taken to retain the water used for extinguishing. Dispose of contaminated water and soil according to local regulations.
Protection against fire:	Self-contained breathing apparatus and chemical-protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation. Ventilate confined areas. Sources of ignition should be kept well clear. Avoid contact with skin and eyes. Avoid dust inhalation. Wear mask with filter for organic dust, rubber gloves and protective clothing.

For emergency responders

Avoid dust formation. Avoid contact with skin and eyes. Avoid dust inhalation. Wear mask with filter for organic dust, rubber gloves and protective clothing.

6.2 Environmental precautions

Prevent entry into sewage systems, ground and surface waters.
Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and material for containment and cleaning up

Moisten with water the product spilled and take up with absorbent non combustible material.
After material pickup is complete, wash spill site and ventilate area.

6.4 Reference to other sections

For more information on protective equipment, see section 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. Protect from light.
Personal protection:	Not available.

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



Technical protective measures:

Take precautionary measures against static electricity.
Containers should be electrically grounded/bonded during transfer of material to prevent static spark/electrostatic discharge.
Explosion-proof electrical fixture should be present in areas of use.

Handling:

Advice on general occupational hygiene: Observe the usual precautionary measures for handling chemicals. Avoid eye, skin, and clothing contact. Do not inhale. Do not reuse contaminated clothing. Wash hands thoroughly after handling. Do not eat, drink or smoke with dirty hands. Close containers immediately after

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Store in tightly closed and properly labelled containers.
Store in a dry, well-ventilated and cool place.
Avoid incompatible materials.
Keep at temperature not exceeding 30 °C.

Storage – away from:

Keep away from ignition sources and direct sunlight.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limit value: Not available.

DNEL: For this substance, the Chemical safety assessment is not required.

PNEC: For this substance, the Chemical safety assessment is not required.

8.2 Exposure controls

Appropriate engineering control

Ensure adequate ventilation, especially in enclosed spaces.

Individual protection measures

Eye/face protection: Safety glasses /face shield.

Skin protection: Protective clothing.

Hand protection: Rubber gloves (i.e. nitrile). When prolonged or frequently contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.

Respiratory protection: Mask with filter for organic dust (UNI EN 143).

Thermal hazards: N.A.

Environmental exposure control

Provide all technical precautions to avoid the dispersion of material in the surrounding environment.

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not applicable.
pH:	9.5 (aqueous suspension)
Melting/freezing point:	177 – 181 °C
Initial boiling point:	Decomposes before boiling.
Boiling range:	Not available.
Flash point:	Not applicable (This property is only relevant for the liquid at room temperature ref. Regulation Reach).
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:	0.5 g/cm ³
Solubility:	Sparingly soluble in methanol, slightly soluble in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of mineral acids and alkali hydroxides. Practically insoluble in ether and chloroform.
Solubility in water:	Practically insoluble in water. 2280 mg (experimental value; 5.37e-01 mg/ml (estimated value by ALOGPS)
Partition coefficient (n-octanol/water):	Log Pow: 0.6 (experimental value); 1.20 (estimated value by ALOGPS)
Auto-ignition temperature:	Not available.
Decomposition temperature:	220 °C
Viscosity:	Not applicable (Relevant property only for liquids Regulation Reach)
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The substance does not present additional dangers of reactivity than those reported in the next subtitle.

10.2 Chemical stability

Stable under normal handling procedures.

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



10.3 Possibility of hazardous reactions

No hazardous polymerisation.

10.4 Conditions to avoid

Avoid exposure to high temperatures (decomposes at $T > 220^{\circ}\text{C}$). Avoid exposure to heat, direct sunlight and sources of ignition. Take precautionary measures against static electricity.

10.5 Incompatible materials

Strong oxidizing agents. Strong bases and acids.

10.6 Hazardous decomposition products

When heated to decomposition, may emit toxic fumes (CO_x , NO_x , SO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	LD ₅₀ oral rat: 9800 mg/kg LD ₅₀ oral mouse: 1700 mg/kg LD ₅₀ oral dog: 2000 mg/kg LD ₅₀ intraperitoneal rat: 210 mg/kg LD ₅₀ intravenous rat: 40 mg/kg LD ₅₀ intraperitoneal mouse: 170 mg/kg LD ₅₀ intravenous mouse: 48 mg/kg LD ₅₀ intravenous rabbit: 63 mg/kg LD ₅₀ intravenous dog: 137 mg/kg LD ₅₀ subcutaneous rat: 210 mg/kg LD ₅₀ subcutaneous rat: 360 mg/kg LD ₅₀ subcutaneous mouse: 290 mg/kg LD ₅₀ subcutaneous dog: 350 mg/kg
Skin corrosion/irritation:	No literature information concerning this product is available. According to the molecular structure can not be excluded by the substance is irritating.
Serious eye damage/irritation:	No literature information concerning this product is available. According to the molecular structure can not be excluded by the substance is irritating
Respiratory/skin sensitisation:	No literature information concerning this product is available.
Germ cell mutagenicity:	No literature information concerning this product is available
Carcinogenicity:	No literature information concerning this product is available
Reproductive toxicity:	TDLo (rat – subcutaneous) 1015 mg/kg - exposition time 29 days (before copulation) TDLo (rat – subcutaneous) 181 mg/kg - exposition time 1 day (before copulation) TDLo (dog- oral) 45500 mg/kg exposition time 95 days (before copulation)
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	No literature information concerning this product is available. According to the molecular structure can not be excluded by the substance may cause respiratory irritation.
STOT-repeated exposure:	No literature information concerning this product is available.

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



Aspiration Hazard: Not applicable.

Other: No literature information concerning this product is available.

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

No literature information concerning this product is available.

12.2 Persistence and degradability

No literature information concerning this product is available.

12.3 Bioaccumulative potential

No literature information concerning this product is available.

12.4 Mobility in soil

As insoluble in water, presumably assumes a low mobility in soil.

12.5 Results of PBT and vPvB assessment

No literature information concerning this product is available.

12.6 Other adverse effects

No literature information concerning this product is available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Do not dispose the product, either new or used, by discharging into sewers, tunnels, lakes or water courses. Dispose wastes and contaminated packaging 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 - non dangerous product

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.

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



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

N.A.

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

N.A.

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:



Harmful

Risk phrases:

R62 Possible risk of impaired fertility.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.
S53 Avoid exposure - obtain special instructions before us.

15.2 Chemical safety assessment

A chemical safety assessment 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 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

Material Safety Data Sheet

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

SULPIRIDUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 19/04/2022

Revision: XX/XX/XXXX

Version: 00



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

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