

Material Safety Data Sheet

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

EN

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Version: 00



DEXAMFETAMINI SULFAS

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

1.1 Product identifier

Product name: Dexamfetamine sulfate
Dexamfetamini sulfas
Dexamfetaminesulfaat
Dexamfétamine (sulfate de)
Dexamfetaminsulfat

N° CAS: 51-63-8

N° EC: 200-111-6

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

Acute Tox. 2	H300
Acute Tox. 3	H311
Acute Tox. 3	H331

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

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H300	Fatal if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
Precautionary statements:	
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P304+P340	IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P311	Call a POISON CENTER/doctor.
Additional applicable label elements:	

2.3 Other hazards

Produces effects on the nervous system.
Possible addiction.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dexamfetamine sulfate
IUPAC name:	(2S)-1-phenylpropan-2-amine;sulfuric acid
Synonyms:	D-Amphetamine sulfate Dexedrine
N° CAS:	51-63-8
N° EC:	200-111-6
Molecular Formula:	C ₁₈ H ₂₈ N ₂ O ₄ S
Content:	99.0 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:	Remove the victim into fresh air and keep at rest in a position comfortable for breathing. Immediately consult a doctor/medical service.
After skin contact:	Wash immediately with plenty of soap and water. Consult a doctor/medical service.
After eye contact:	Rinse immediately with plenty of water. Take victim to an ophthalmologist
After ingestion:	

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Rinse mouth with water. Give nothing or little to drink. Victim is fully conscious: immediately induce vomiting. Induce vomiting by giving a 0.9 % saline solution. Immediately consult a doctor/medical service.

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.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, polyvalent foam, ABC powder, carbon dioxide.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

On burning: release of toxic and corrosive gases/vapours (nitrous vapours, sulphur oxides, carbon monoxide - carbon dioxide).

5.3 Advice for firefighters

Surrounding fires: Dilute toxic gases with water spray. Take account of toxic fire-fighting water. Use water moderately and, if possible, collect or contain it.

Protection against fire: Gloves, face-shield, protective clothing. Dust cloud production: compressed air/oxygen apparatus, dust-tight suit. Heat/fire exposure: compressed air/oxygen apparatus.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Take away any source of inflammation, have a good ventilation, evacuate the high-risk area. Personal protection: see section 8.

For emergency responders

Take away any source of inflammation, have a good ventilation, evacuate the high-risk area. Personal protection: see section 8.

6.2 Environmental precautions

Contain released substance, pump into suitable containers. Plug the leak, cut off the supply. Dam up the solid spill. Knock down/dilute dust cloud with water spray. Take account of toxic/corrosive precipitation water. Prevent soil and water pollution. Prevent spreading in sewers. See section 13.

6.3 Methods and material for containment and cleaning up

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Prevent dust cloud formation. Scoop solid spill into closing containers. Carefully collect the spill/leftovers. Clean contaminated surfaces with an excess of water. Take collected spill to manufacturer/competent authority. Wash clothing and equipment after handling.

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 naked flames/heat. Observe strict hygiene. Do not discharge the waste into the drain. Do not eat, drink, or smoke in working area. Wash hands after handling the material. Remove contaminated clothing and protective equipment before entering the canteen.

Personal protection:

Not available.

Technical protective measures:

Avoid raising dust.

Handling:

Observe strict hygiene.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Keep locked up. Meet the legal requirements.

Conditions for safe storage, including any incompatibilities:

Store in a cool area.

Storage – away from:

Store protected from light. Keep away from oxidising agents and (strong) bases.

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

Carry out work in the open air/under local exhaust/ventilation or with respiratory protection.

Do not eat, drink, or smoke in working area.

Wash hands after handling the material.

Remove contaminated clothing and protective equipment before entering the canteen.

Individual protection measures

Eye/face protection:

Face shield. In case of dust production: protective goggles.

Skin protection:

Protective clothing. In case of dust production: head/neck protection, dustproof clothing.

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Hand protection: Gloves.
Respiratory protection: Dust production: dust mask with filter type P3.
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: White or almost white powder.
Odour: Odourless.
Odour threshold: Not available.
pH: 5 – 6 (solution concentration 5%)
Melting/freezing point: > 300 °C
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.
Solubility in water: Freely soluble in water (10g/100ml).
Partition coefficient (n-octanol/water): 6.81 (estimated)
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Explosive properties: Not available.
Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

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10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Possible fire hazard with heat sources.

10.5 Incompatible materials

Oxidising agents and (strong) bases.

10.6 Hazardous decomposition products

On burning: release of toxic and corrosive gases/vapours (nitrous vapours, sulphur oxides, carbon monoxide - carbon dioxide).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Ingestion LD50 (mouse): 10 mg/kg Ingestion LD50 (rat): 32 mg/kg Dermal LD50 (rat): 200 mg/kg bw
Skin corrosion/irritation:	Not available.
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:	Chronic toxicity: Produces effects on the nervous system. Possible addiction. Acute effects: Central nervous system stimulation, sleeplessness, accelerated heart action, high arterial pressure, dilated pupils.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritation of the eye tissue.
Skin contact:	Toxic in contact with skin. Tingling/irritation of the skin.
Inhalation:	Toxic if inhaled. AFTER INHALATION OF DUST: Irritation of the respiratory tract.

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Ingestion: Fatal if swallowed.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Log Pow: 6.81 (estimated).

Bioaccumulative.

12.4 Mobility in soil

Volatile organic compounds (VOC): 0 %.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not dangerous for the ozone layer (Council Regulation (EC) no 1005/2009).

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Send to an authorized treatment centre.

Apply all the relevant local community regulation concerning the waste.

Provisions relating to waste: Waste material code (Directive 2008/98/EC, decision 2001/118/EC) 16 05 06: laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals. Depending on branch of industry and production process, also other EURAL codes may be applicable. Hazardous waste according to Directive 2008/98/EC.

Disposal methods: Remove to an authorized incinerator equipped with an afterburner and a flue gas scrubber with energy recovery. Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed with other waste. Different types of hazardous waste may not be mixed with each other if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities storing, transporting or handling hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals.

Packaging/Container: Waste material code packaging (Directive 2008/98/EC) 15 01 10: packaging containing residues of or contaminated by dangerous substances.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Toxic solid, organic, n.o.s. (dexamphetamine sulphate)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Marine pollutant: No.
IATA/ICAO (Air) :

14.6 Special precautions for user

Hazard number: 60.

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

Not available.

14.8 Additional transport information

ADR/RID Classification code: T2

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R23 Toxic by inhalation.
R24 Toxic in contact with skin.
R28 Very toxic if swallowed.

Safety phrases:

S23 Avoid breathing dust/fumes/gas/mist/vapours/spray.
S28 After contact with skin, wash immediately with plenty of soap and water.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S46 If swallowed, seek medical advice immediately and show this container or label.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

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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 (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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