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

1.1 Product identifier

Product name: Barium sulfate

Barii sulfas
Bariumsulfaat
Baryum (sulfate de)

Bariumsulfat

N° CAS: 7727-43-7 N° EC: 231-784-4

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

Hazard statements:

Not applicable.

Precautionary statements:

Not applicable.

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Additional applicable label Not applicable.

elements:

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Barium sulfate

IUPAC name: Barium(2+);sulfate

Synonyms: Barite

Baritop

100%

 N° CAS:
 7727-43-7

 N° EC:
 231-784-4

 Molecular Formula:
 BaSO₄

3.2 Mixtures

Content:

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Fresh air.

After skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

After eye contact: Rinse out with plenty of water. Remove contact lenses.

After ingestion: Make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

We have no description of any symptoms of toxicity.

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: Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing media: For this substance/mixture no limitations of extinguishing agents are

given.

5.2 Special hazards arising from the substance/mixture

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Not combustible.

Ambient fire may liberate hazardous vapours. Fire may cause evolution of: Sulphur oxides

5.3 Advice for firefighters

Surrounding fires: Suppress (knock down) gases/vapours/mists with a water spray jet.

Protection against fire: In the event of fire, wear self-contained breathing apparatus.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

For emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

No special precautionary measures necessary.

6.3 Methods and material for containment and cleaning up

Observe possible material restrictions (see sections 7 and 10).

Take up dry.

Dispose of properly.

Clean up affected area.

Avoid generation of dusts.

6.4 Reference to other sections

Indications for waste treatment see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Observe label precautions. Change contaminated clothing. Wash

hands after working with substance.

Personal protection:

Technical protective measures:

Handling:

Not available.

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Tightly closed. Dry.

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Storage – away from: Not available.

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

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See section 7.1.

Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Protective clothing needs to be selected specifically for the workplace, depending

on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the

respective supplier.

Hand protection: Not required.

Respiratory protection: Required when dusts are generated. Recommended Filter type: Filter P 1 (acc. to

DIN 3181) for solid particles of inert substances.

The entrepreneur has to ensure that maintenance, cleaning and testing of

respiratory protective devices are carried out according to the instructions of the

producer. These measures have to be properly documented.

Thermal hazards: Not determined.

Environmental exposure control

No special precautionary measures necessary.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Fine, white or almost white powder, free from gritty particles.

Odour: Odourless.
Odour threshold: Not applicable.

pH: 3,5 - 10,0 at 100 g/l (20 °C) (suspension)

Melting/freezing point: 1 380 °C

Initial boiling point: Not applicable. (decomposition)

Boiling range: Not applicable. (decomposition)

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Flash point: Does not flash.

Evaporation rate: Not available.

Flammability (solid/gas): The product is not flammable.

Upper/lower flammability or

explosive limits:

Not applicable.

Vapour pressure: Low.

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

Solubility: Practically insoluble in organic solvents. It it very slightly soluble in acids and in

solutions of alkali hydroxides.

Solubility in water: Practically insoluble in water (3.1 mg/l at 20°C)

Partition coefficient (n-octanol/water):

Not applicable for inorganic substances.

Auto-ignition temperature: Not available.

Decomposition temperature: 1 580 °C

Viscosity: Not available.

Explosive properties: Not classified as explosive.

Oxidising properties: None.

9.2 Other information

Density: 3,08 - 3,97 g/cm³ (19,3 °C) Ignition temperature: not combustible.

Bulk density: ca. 500 kg/m³

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Risk of explosion with: Powdered aluminium, heat.

Risk of ignition or formation of inflammable gases or vapours with: Phosphorus.

Exothermic reaction with: Potassium.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

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10.6 Hazardous decomposition products

In the event of fire: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD50 (rat): 307 000 mg/kg (OECD Test Guideline 401) Skin corrosion/irritation: In vitro study, Result: negative (OECD Test Guideline 439)

The value is given in analogy to the following substances: barium chloride dihydrate.

Rabbit, Result: No eye irritation (OECD Test Guideline 405) Serious eye damage/irritation:

Respiratory/skin sensitisation: Local lymph node assay (LLNA) Mouse, Result: negative (OECD Test Guideline 429)

The value is given in analogy to the following substances: barium chloride dihydrate.

Germ cell mutagenicity: Genotoxicity in vitro:

Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

The value is given in analogy to the following substances: barium chloride dihydrate.

Mutagenicity (mammal cell test): chromosome aberration.

Chinese hamster ovary cells

Result: negative

Method: OECD Test Guideline 473

The value is given in analogy to the following substances: barium chloride dihydrate.

In vitro mammalian cell gene mutation test

Mouse lymphoma test Result: negative

Method: OECD Test Guideline 476

The value is given in analogy to the following substances: barium chloride dihydrate.

Carcinogenicity: Not available. Not available. Reproductive toxicity: Summary of evaluation of the

CMR properties:

Not available.

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

Other: Since the substance is poorly absorbed, no hazardous properties are to be

anticipated.

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Inhalation of the dusts should be avoided as even inert dusts may impair respiratory

organ functions.

Handle in accordance with good industrial hygiene and safety practice.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Not available.

Skin contact:

Not available.

Inhalation:

Not available.

Not available.

Aspiration:

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish:

static test LC50 Danio rerio (zebra fish): > 174 mg/l; 96 h

Analytical monitoring: yes OECD Test Guideline 203

The value is given in analogy to the following substances: barium chloride dihydrate.

Toxicity to algae:

Static test ErC50 Pseudokirchneriella subcapitata (green algae): > 100 mg/l; 72 h

Analytical monitoring: yes OECD Test Guideline 201

The value is given in analogy to the following substances: barium chloride dihydrate.

Static test NOEC Pseudokirchneriella subcapitata (green algae): >= 100 mg/l; 72 h

Analytical monitoring: yes OECD Test Guideline 201

The value is given in analogy to the following substances: barium chloride dihydrate.

Toxicity to bacteria:

Static test EC50 activated sludge: > 1 000 mg/l; 3 h

Analytical monitoring: yes OECD Test Guideline 209

The value is given in analogy to the following substances: barium chloride dihydrate

Toxicity to fish (Chronic toxicity):

Semi-static test NOEC Danio rerio (zebra fish): ≥ 100 mg/l; 33 d

Analytical monitoring: yes OECD Test Guideline 210

The value is given in analogy to the following substances: barium chloride dihydrate.

12.2 Persistence and degradability

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The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: Not applicable for inorganic substances.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information:

No ecological problems are to be expected when the product is handled and used with due care and attention.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must be specially treated adhering to official 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),

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

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

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

Not classified.

IATA/ICAO (Air):

14.4 Packing group

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

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

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

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

Not available.

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

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Not relevant.

14.8 Additional transport information

Not classified as dangerous in the meaning of transport regulations.

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

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 GoodsIUPAC: International Union of Pure and Applied ChemistryPBT: 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 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.

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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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