

Material Safety Data Sheet

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

BISMUTHI SUBGALLAS

EN

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Version: 00



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

1.1 Product identifier

Product name:	Bismuth subgallate Bismuthi subgallas Bismutsubgallaat Bismuth (sous-gallate de) Bismutgallat, Basisches
N° CAS:	99-26-3
N° EC:	202-742-2

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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

The substance is not classified according to regulation (EC) 1272/2008 (CLP).

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

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2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Bismuth subgallate
IUPAC name:	2,7-dihydroxy-1,3,2-benzodioxabismole-5-carboxylic acid
Synonyms:	Wismutgallathydroxid Gallic acid bismuth basic salt
N° CAS:	99-26-3
N° EC:	202-742-2
Molecular Formula:	C ₇ H ₆ BiO ₆
Content:	48.0 per cent to 51.0 per cent of Bi (A _r 209.0) (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	It is not specifically necessary. In any case, compliance with the rules of good industrial hygiene is recommended.
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4.2 Most important symptoms and effects, both acute and delayed

There are no known relevant acute or delayed effects derived from exposure to the product.

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:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

Avoid breathing products derived from combustion.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to avoid decomposition of the product and the development of potential health hazards. Always wear full fire protection. Collect the water that should not enter the sewer.
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Protection against fire:

Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Helmet with a visor, fire-retardant clothing (jacket and trousers with suspenders around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with a full face mask that covers the entire face of the operator or the car (self-protective) in the 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

In case of vapours or dust dispersed in the air, use respiratory protection.

For emergency responders

In case of vapours or dust dispersed in the air, use respiratory protection.

6.2 Environmental precautions

Prevent further leakage or spillage if it can be done safely. Do not allow product to enter sewage system. Discharge into the environment should be avoided.

6.3 Methods and material for containment and cleaning up

Collect and prepare disposal without creating dust.

Clean and shovel.

Store in appropriate closed containers for disposal.

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:

Avoid contact with eyes and skin. Avoid formation of dust and aerosols.

Personal protection:

Not available.

Technical protective measures:

Adequate extraction should be provided where dust is formed.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Keep container tightly closed.

Conditions for safe storage, including any incompatibilities:

Store in a cool place. Keep container tightly closed in a dry and well-ventilated place.

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Storage – away from:

Protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

It contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures must 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.

Individual protection measures

Eye/face protection: No protection is required for this product.

Skin protection: No protection is required for this product.

Hand protection: No protection is required for this product.

Respiratory protection: No protection is required for this product.

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: Yellow powder.

Odour: Odourless.

Odour threshold: Not available.

pH: 7

Melting/freezing point: Not available.

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.

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Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	0.5 g/ml
Solubility:	Practically insoluble in ethanol (96%). It dissolves in mineral acids with decomposition and in solutions of alkali hydroxides, producing a reddish-brown liquid.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Dry residue: 100.00%
VOC (Directive 2010/754 / EC): 0.0%
VOC (volatile carbon): 0.0%

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly. No special conditions.

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

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Not available.

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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:	Not 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

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

PBT/vPvB assessment is not available as chemical safety assessment is not required/has not been performed.

12.6 Other adverse effects

Use in accordance with good industrial practices, avoiding dispersal of the product into the environment.
Notify the competent authorities if the product reaches watercourses, sewers, soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

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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 container: Dispose of as unused product.

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

Not available.

14.8 Additional transport information

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).

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

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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
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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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