

# Material Safety Data Sheet

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

## METHYLIS PARAHYDROXYBENZOAS

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



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

#### 1.1 Product identifier

Product name:	Methyl parahydroxybenzoate Methylis parahydroxybenzoas Methylparahydroxybenzoaat Méthyle (parahydroxybenzoate de) Methylparahydroxybenzoat
N° CAS:	99-76-3
N° EC:	202-785-7

#### 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

Aquatic Chronic 3	H412
-------------------	------

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements:	
P273	Avoid release to the environment.
Additional applicable label elements:	Not applicable.

# Material Safety Data Sheet

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

## METHYLIS PARAHYDROXYBENZOAS

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



### 2.3 Other hazards

None known.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Methyl parahydroxybenzoate
IUPAC name:	Methyl 4-hydroxybenzoate
Synonyms:	Methylparaben Nipagin
N° CAS:	99-76-3
N° EC:	202-785-7
Molecular Formula:	C <sub>8</sub> H <sub>8</sub> O <sub>3</sub>
Content:	98.0 per cent to 102.0 per cent

### 3.2 Mixtures

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 a doctor if feeling unwell.

### 4.2 Most important symptoms and effects, both acute and delayed

Irritant effects.

### 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, foam, carbon dioxide (CO <sub>2</sub> ), dry powder.
Unsuitable extinguishing media:	For this substance, no limitations of extinguishing agents are given.

### 5.2 Special hazards arising from the substance/mixture

Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.

### 5.3 Advice for firefighters

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/9

## METHYLIS PARAHYDROXYBENZOAS

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



Surrounding fires:

Prevent fire extinguishing water from contaminating surface water or the ground water system. 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

Do not let product enter drains.

#### 6.3 Methods and material for containment and cleaning up

Cover drains. Collect, bind and pump off spills. 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 about waste treatment, see section 13.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:

Observe label precautions.

Personal protection:

Change contaminated clothing. Wash hands after working with substance.

Technical protective measures:

Not available.

Handling:

Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Tightly closed. Dry.

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

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/9

## METHYLIS PARAHYDROXYBENZOAS

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



### Appropriate engineering control

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

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.

### Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Not determined.

Hand protection: Full contact/splash contact:

Glove material: Nitrile rubber

Glove thickness: 0.11 mm

Breakthrough time: > 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/696/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374, please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

Respiratory protection: Required when dusts are generated.

Recommender filter type: Filter P2 (acc. to DIN 3181) for solid and liquid particles or harmful 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

Do not let product enter drains.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder or colourless crystals.

Odour: Odourless.

Odour threshold: Not applicable.

pH: Ca. 5.8 at 20 °C (saturated solution)

Melting/freezing point: 125 °C to 128 °C

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9

## METHYLIS PARAHYDROXYBENZOAS

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



Initial boiling point:	Not applicable (decomposition).
Boiling range:	Not applicable (decomposition).
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	0.000005 hPa (20 °C)
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96 per cent) and in methanol.
Solubility in water:	Very slightly soluble in water. 1.88 g/l (20 °C) (Method: OECD Test Guideline 105)
Partition coefficient (n-octanol/water):	Log Pow: 1.98 (22 °C) (OECD Test Guideline 107) Bioaccumulation is not expected.
Auto-ignition temperature:	> 403 °C (Method: Relative self-ignition temperature for solids)
Decomposition temperature:	270 – 280 °C
Viscosity:	Not available.
Explosive properties:	Not classified as explosive.
Oxidising properties:	None.

### 9.2 Other information

Density: 1.38 g/cm<sup>3</sup> (20 °C) (Method: OECD Test Guideline 109)

Ignition temperature: > 600 °C

Bulk density: ca. 300 – 400 kg/m<sup>3</sup>

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: In correspondingly fine distribution, when whirled up, a dust explosion potential may generally be assumed.

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Violent reactions possible with: bases, strong oxidising agents.

### 10.4 Conditions to avoid

Strong heating (decomposition).

### 10.5 Incompatible materials

Not available.

# Material Safety Data Sheet

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

## METHYLIS PARAHYDROXYBENZOAS

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



### 10.6 Hazardous decomposition products

Not available.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): > 5 000 mg/kg (OECD Test Guideline 401)
Skin corrosion/irritation:	Rabbit, result: no irritation.
Serious eye damage/irritation:	Rabbit, result: slight irritation. Possible damages: slight irritation.
Respiratory/skin sensitisation:	Maurer optimization test Guinea pig, result: negative (OECD Test Guideline 406)
Germ cell mutagenicity:	Genotoxicity in vivo: Dominant lethal test, rat (male), oral, result: negative (OECD Test Guideline 478) Genotoxicity in vitro: Ames test, result: negative
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:	Other dangerous properties can not be excluded. 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.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

#### Toxicity to fish

Semi-static test LD50 *Oryzias latipes* (Orange-red killifish): 59.5 mg/l; 96h

Analytical monitoring: yes

OECD Test Guideline 203

#### Toxicity to daphnia and other aquatic invertebrates

Static test EC50 *Daphnia magna* (Water flea): 11.2 mg/l; 48 h

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



## METHYLIS PARAHYDROXYBENZOAS

### Toxicity to algae

Static test EC50 *Pseudokirchneriella subcapitata* (algae): 91 mg/l; 72 h

ISO 8692

### Toxicity to bacteria

EC0 *Pseudomonas fluorescens*: 500 mg/l

### Toxicity to daphnia and other aquatic invertebrates (chronic toxicity)

Semi-static test NOEC Daphnia magna (Water flea): 0.2 mg/l; 21 d

Analytical monitoring: yes

OECD Test Guideline 211

### 12.2 Persistence and degradability

Biodegradability:

89 %; 28 d; aerobic

OECD Test Guideline 301B

Readily biodegradable

### 12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: log Pow: 1.98 (22 °C) (OECD Test Guideline 107)

Bioaccumulation is not expected.

### 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

Discharge into the environment must be avoided.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Recommendation: Must be specially treated adhering to official regulations.

Contaminated 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)

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



## METHYLIS PARAHYDROXYBENZOAS

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
<b>14.4 Packing group</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
<b>14.5 Environmental hazards</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
<b>14.6 Special precautions for user</b>	
Not available.	
<b>14.7 Transport in bulk according to annex II of Marpol and the IBC Code</b>	
Not relevant.	
<b>14.8 Additional transport information</b>	
Not classified as dangerous in the meaning of transport regulations.	
<b>SECTION 15: REGULATORY INFORMATION</b>	
<b>15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture</b>	
Hazard symbol:	Not applicable.
Risk phrases:	R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases:	S61 Avoid release to the environment. Refer to special instructions/safety data sheet.
<b>15.2 Chemical safety assessment</b>	
A chemical safety assessment has not been carried out.	
<b>SECTION 16: OTHER INFORMATION</b>	
<b>16.1 Changes since the previous version</b>	
Not applicable.	
<b>16.2 Abbreviations and acronyms used</b>	
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



# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 07/04/2022

Revision: 07/04/2022

Version: 00



## METHYLIS PARAHYDROXYBENZOAS

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 knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

[info@magis-pharma.be](mailto:info@magis-pharma.be)