

# Material Safety Data Sheet

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

## CHLORPHENAMINI MALEAS

EN

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

#### 1.1 Product identifier

Product name: Chlorphenamine maleate  
Chlorphenamini maleas  
Chloorfenaminemaleaat  
Chlorphénamine (maléate de)  
Chlorphenaminmaleat

N° CAS: 113-92-8

N° EC: 204-037-5

#### 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. 3 H301

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H301 Toxic if swallowed.

Precautionary statements:

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

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:	Chlorphenamine maleate
IUPAC name:	(3RS)-3-(4-Chlorophenyl)-N,N-dimethyl-3-(pyridin-2-yl)propan-1-amine hydrogen (Z)-butenedioate
Synonyms:	Chlorpheniramine maleate Piriton
N° CAS:	113-92-8
N° EC:	204-037-5
Molecular Formula:	C <sub>20</sub> H <sub>23</sub> ClN <sub>2</sub> O <sub>4</sub>
Content:	98.0 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

General notes:	Consult a physician. Show this safety data sheet to the doctor in attendance.
After inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
After skin contact:	Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.
After eye contact:	Flush eyes with water as a precaution.
After ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

Drowsiness, headache, nausea.

### 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 water spray, alcohol resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media:	Not available.

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

Carbon oxides, nitrogen oxides (NO<sub>x</sub>), hydrogen chloride gas.

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### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus for fire fighting if necessary.
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

#### For emergency responders

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

### 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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

Pick up and arrange disposal without creating dust.  
Sweep up and shovel.  
Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For disposal, see section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Normal measures for preventive fire protection.
Personal protection:	Not available.
Technical protective measures:	Provide appropriate exhaust ventilation at places where dust is formed.
Handling:	Not available.

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

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store at a temperature below 25 °C. However, the product is stable at an ambient temperature and relative humidity.
Storage – away from:	Store protected from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Not available.

#### 8.2 Exposure controls

##### Appropriate engineering control

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

##### Individual protection measures

Eye/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection: Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate, use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 130 °C to 135 °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.

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Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in ethanol (96%).
Solubility in water:	Freely soluble 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

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Product is stable at an ambient temperature and relative humidity.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Not available.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 188 mg/kg
Skin corrosion/irritation:	Slightly irritant.
Serious eye damage/irritation:	Slightly irritant.
Respiratory/skin sensitisation:	Slightly irritant.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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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:	RTECS: US6504000

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	May be harmful if absorbed through skin. May cause skin irritation.
Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Toxic if swallowed. Effects and symptoms: Drowsiness, headache, nausea.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Possibly hazardous short term degradation products are not likely.  
However, long term degradation products may arise. The products of degradation are more toxic.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not applicable.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.  
Contaminated packaging: Dispose of as unused product.

## SECTION 14: TRANSPORT INFORMATION

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

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<b>14.1 UN Number</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	2811
<b>14.2 UN proper shipping name</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (Chlorpheniramine Maleate) IMDG: TOXIC SOLID, ORGANIC, N.O.S. (Chlorpheniramine Maleate) IATA: TOXIC SOLID, ORGANIC, N.O.S. (Chlorpheniramine Maleate)
<b>14.3 Transport hazard class(es)</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	6.1
<b>14.4 Packing group</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	III III
<b>14.5 Environmental hazards</b>	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR/RID: no. IMDG Marine pollutant: no. IATA: no.
<b>14.6 Special precautions for user</b>	
No exposure to environment, protect from light, heat, moisture etc.	
<b>14.7 Transport in bulk according to annex II of Marpol and the IBC Code</b>	
Not available.	
<b>14.8 Additional transport information</b>	
Not available.	
<b>SECTION 15: REGULATORY INFORMATION</b>	
<b>15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture</b>	
Not applicable.	
<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

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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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