

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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## HYDROCHLOROTHIAZIDUM

Publication:

3/10/2022

Revision:

XX/XX/XX

Version: 00

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

#### 1.1 Product identifier

Product name: Hydrochlorothiazide  
Hydrochlorothiazidum  
Hydrochloorthiazide  
Hydrochlorothiazide  
Hydrochlorothiazid

N° CAS: 58-93-5

N° EC: 200-403-3

#### 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. 4	H302
Skin Sens. 1	H317
Resp. Sens. 1	H334
STOT RE 1	H372

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302 Harmful if swallowed.

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H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H372	Causes damage to organs through prolonged or repeated exposure.
Precautionary statements:	
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P285	In case of inadequate ventilation wear respiratory protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water and non-abrasive soap.
P304+P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P314	Get medical advice/attention if you feel unwell.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P363	Wash contaminated clothing before reuse.
P501	Dispose of contents/container to ....
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Hydrochlorothiazide
IUPAC name:	6-Chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide
Synonyms:	HCTZ Hypothiazide
N° CAS:	58-93-5
N° EC:	200-403-3
Molecular Formula:	C <sub>7</sub> H <sub>8</sub> ClN <sub>3</sub> O <sub>4</sub> S <sub>2</sub>
Content:	97.5 per cent to 102.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

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### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

After inhalation:	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.
After skin contact:	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap.
After eye contact:	In case of eye contact, rinse with water for several minutes.
After ingestion:	Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as collar, tie, belt, or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

#### 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:	Small fire: use dry chemical powder. Large fire: use water spray, fog or foam.
Unsuitable extinguishing media:	Do not use water jet.

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

Flammability of the product: Combustible at very high temperature.

#### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Not available.
Hazardous combustion products:	Carbon oxides (CO, CO <sub>2</sub> ), nitrogen oxides (NO, NO <sub>2</sub> ), Sulfur oxides (SO <sub>2</sub> , SO <sub>3</sub> ), halogenated compounds.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Not available.

##### For emergency responders

Not available.

#### 6.2 Environmental precautions

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Not available.

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

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.

### 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 heat. Keep away from sources of ignition. Do not ingest. Do not breathe dust.
Personal protection:	Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.
Technical protective measures:	Ground all equipment containing material.
Handling:	Not available.

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

Storage:	Keep container tightly closed.
Conditions for safe storage, including any incompatibilities:	Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place.
Storage – away from:	Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

### 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

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### Individual protection measures

Eye/face protection:	Safety glasses. In case of large spill: Splash goggles.
Skin protection:	Lab coat.

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	In case of large spill: Full suit, boots. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.
Hand protection:	In case of large spill: Gloves.
Respiratory protection:	Not determined.
Thermal hazards:	Not determined.
<b>Environmental exposure control</b>	
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:	273°C – 275°C
Initial boiling point:	Decomposes.
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:	Soluble in acetone, sparingly soluble in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.
Solubility in water:	Very slightly 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.

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### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

Not available.

#### 10.2 Chemical stability

This product is stable under normal storage conditions.

#### 10.3 Possibility of hazardous reactions

Polymerization: No.

#### 10.4 Conditions to avoid

Not available.

#### 10.5 Incompatible materials

Non corrosive in presence of glass.

#### 10.6 Hazardous decomposition products

Not available.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD <sub>50</sub> ): 1175 mg/kg (rat)
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 effects on humans: The substance is toxic to lungs, mucous membranes.

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

Eye contact:	Not available.
Skin contact:	Avoid skin contact.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

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### 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

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Disposal recommendations

Contact a licensed professional waste disposal service to dispose of the material.

Regulatory requirements

Observe all federal, state and local environmental 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

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Not available.

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

Not available.

### 14.8 Additional transport information

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purpose.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

R43 May cause sensitisation by skin contact.

R48 Danger of serious damage to health by prolonged exposure.

Safety phrases:

S20/21 When using do not eat, drink or smoke.

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

S28 After contact with skin, wash immediately with plenty of water and non-abrasive soap.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S38 In case of insufficient ventilation wear suitable respiratory equipment

S46 If swallowed, seek medical advice immediately and show this container or label.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

S64 If swallowed, rinse mouth with water (only if the person is conscious).

### 15.2 Chemical safety assessment

Not available.

## 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



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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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