

# Material Safety Data Sheet

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

## CHININI SULFAS

EN

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

#### 1.1 Product identifier

Product name: Quinine sulfate  
Chinini sulfas  
Kininesulfaat  
Quinine (sulfate de)  
Chininisulfat

N° CAS: 6119-70-6

N° EC: 212-359-2

#### 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

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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### Precautionary statements:

P270	Do not eat, drink or smoke when using this product.
P285	In case of inadequate ventilation wear respiratory protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Quinine sulfate
IUPAC name:	[(R)-[(2S,4S,5R)-5-ethenyl-1-azabicyclo[2.2.2]oct-2-yl](6-methoxyquinolin-4-yl)methanol] sulfate dihydrate.
Synonyms:	Quinine sulfate hydrate
N° CAS:	6119-70-6
N° EC:	212-359-2
Molecular Formula:	C <sub>40</sub> H <sub>50</sub> N <sub>4</sub> O <sub>8</sub> S <sub>2</sub> H <sub>2</sub> O
Content:	99.0 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:	Never give anything by mouth to an unconscious person or a person with cramps. Show this safety data sheet to the doctor in attendance. Treat symptomatically.
After inhalation:	Keep at rest. Provide fresh air. In case of shortness of breath, give oxygen. Get medical advice/attention.
After skin contact:	Wash off immediately with plenty of water. When in doubt or if symptoms are observed, get medical advice. Take off immediately all contaminated clothing. Wash contaminated clothing before reuse.
After eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists: Get medical advice/attention.
After ingestion:	Rinse mouth. Rinse mouth immediately and drink plenty of water. Call a physician immediately.

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

Inhalation: May cause sensitization by inhalation.

Skin contact: May cause sensitisation by skin contact. The following symptoms may occur: erythema (redness), rash, itching.

Eye contact: Pain, erythema (redness), blurred vision.

Ingestion: Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

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### 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 spray, alcohol resistant foam, carbon dioxide, dry extinguishing powder.

Unsuitable extinguishing media: None.

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

Fire hazard: Combustible.

Specific hazards: Burning produces noxious and toxic fumes. Hazardous decomposition products  $\text{NO}_x$ ,  $\text{CO}_x$ ,  $\text{SO}_x$ . Do not allow run-off from fire-fighting to enter drains or water courses. Dispose according to legislation.

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Use personal protective equipment as required. In case 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 contact with skin, eyes and clothes. Do not breathe dust. Use personal protective equipment as required. Provide adequate ventilation.

#### For emergency responders

Ensure procedures and training for emergency decontamination and disposal are in place.

### 6.2 Environmental precautions

Do not allow to enter into surface water or drains.

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

Avoid generation of dust. Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose according to legislation.

### 6.4 Reference to other sections

Personal protection equipment: see section 8.

Disposal: see section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling: Keep good industrial hygiene. Avoid contact with skin, eyes and clothes. Avoid generation of dust. Use only in well-ventilated areas. Do not breathe dust. Take off contaminated clothing.

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Personal protection:	Use personal protective equipment as required. Personal protection equipment: see section 8.
Technical protective measures:	Not available.
Handling:	Wash hands and face before breaks and immediately after handling of the product. Take off any contaminated clothing.

### 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, well-ventilated place. Protected from light.
Storage – away from:	Protected from light. Do not store near or with any of the incompatible materials listed in section 10.

### 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

Provide adequate ventilation.

#### Individual protection measures

Eye/face protection:	Goggles (EN 166).
Skin protection:	Wear suitable protective clothing.
Hand protection:	Rubber gloves. (EN 374). The selection of specific gloves for a specific application and time of use in a working area, should also take into account other factors on the working space, such as (but not limited to): other chemicals that are possibly used, physical requirements (protection against cutting/drilling, skill, thermal protection), and the instructions/specification of the supplier of gloves.
Respiratory protection:	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards:	Not determined.

#### Environmental exposure control

Do not allow to enter into surface water or drains. Comply with applicable Community environmental protection legislation.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline power or fine, colourless needles.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	5.7 to 6.6 (1% solution)

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Melting/freezing point:	± 225°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.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in boiling water and in ethanol (96%).
Solubility in water:	Slightly soluble in water (1.24 g/l, 20 °C)
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not applicable. The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.
Oxidising properties:	Not applicable. The classification procedure does not need to be applied because there are no chemical groups present in the molecule which are associated with oxidising properties.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

The product is stable under storage at normal ambient temperatures (5years).

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Exposure to sunlight.

### 10.5 Incompatible materials

Strong oxidising agents, bases.

### 10.6 Hazardous decomposition products

Decomposes on heating. Burning produces noxious and toxic fumes. Hazardous decomposition products: NO<sub>x</sub>, CO<sub>x</sub>, SO<sub>x</sub>.

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### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Harmful if swallowed. ATE CLP (oral): 500 mg/kg bodyweight Oral LD50 (mouse): 1160 mg/kg Oral (rat) : 456 mg/kg
Skin corrosion/irritation:	Not irritating. May cause an allergic skin reaction.
Serious eye damage/irritation:	No irritant effect.
Respiratory/skin sensitisation:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity:	Ames test: negative.
Carcinogenicity:	Experimental references show that there are no carcinogenic effects on laboratory animals.
Reproductive toxicity:	Experimental references show that there are no reproductive toxicity effects on laboratory animals.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Symptoms related to the physical, chemical and toxicological characteristics. Reference to other sections: 4.2

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

Eye contact:	Pain, erythema (redness), blurred vision.
Skin contact:	May cause sensitisation by skin contact. The following symptoms may occur: erythema (redness), rash, itching.
Inhalation:	May cause sensitization by inhalation.
Ingestion:	Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
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.

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### 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

Product waste: Can be incinerated, when in compliance with local regulations.

Contaminated packaging: In accordance with local and national regulations.

List of proposed waste codes/waste designations in accordance with EWC: Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. The following Waste Codes are only suggestions:

07 01 99 - Wastes not otherwise specified.

070513 - Solid wastes containing dangerous substances.

150110 - Packaging containing residues of or contaminated by dangerous substances.

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : IATA: Quinine Sulphate

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 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

Not Classified as dangerous in the meaning of transport regulation.

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### SECTION 15: REGULATORY INFORMATION

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

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 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

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