

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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Revision: XX/XX/XXXX

Version: 00



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HYDROXYCHLOROQUINI SULFAS

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

1.1 Product identifier

Product name:	Hydroxychloroquine sulfate Hydroxychloroquini sulfas Hydroxychloroquinesulfaat Hydroxychloroquine (sulfate d') Hydroxychloroquinsulfat
N° CAS:	747-36-4
N° EC:	212-019-3

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

Acute Tox. 4	H302
Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

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Hazard statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statements:

P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hydroxychloroquine sulfate
IUPAC name:	2-[4-[(7-chloroquinolin-4-yl)amino]pentyl-ethylamino]ethanol;sulfuric acid
Synonyms:	Ercoquin Oxichlorochine sulfate
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N° EC:	212-019-3
Molecular Formula:	C ₁₈ H ₂₈ ClN ₃ O ₅ S
Content:	98.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing immediately and dispose off safely. Never give anything by mouth to an unconscious person or a person with cramps. In case of accident or if you feel unwell, seek medical advice immediately (show this label if possible).
After inhalation:	Move to fresh air. Artificial respiration and/or oxygen may be necessary. Consult a physician after significant exposure.
After skin contact:	Wash off with soap and plenty of water. Take off contaminated clothing and shoes immediately. If skin irritation persists, call a physician.
After eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists, consult a specialist.
After ingestion:	Rinse mouth immediately and drink large quantities of water. Immediately call a POISON CENTER or doctor/physician.
Self-protection of the first aider:	First aid assistant: Pay attention to self-protection!

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:	Water, foam.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear a self-contained breathing apparatus and chemical resistant suit.
Hazardous combustion products:	Not available.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unprotected people away and stay on the upwind side.

Avoid breathing dust/fumes/gas/mist/vapours/spray.

Provide adequate ventilation.

For emergency responders

Use appropriate personal protective equipment.

Remove all sources of ignition.

Avoid contact with eyes.

Notification procedures: In the event of a spill or accidental release, notify relevant authorities in accordance with applicable regulations.

6.2 Environmental precautions

Do not allow product to enter into surface water or drains.

Inform the relevant authorities if the product has caused environmental pollution.

6.3 Methods and material for containment and cleaning up

For containment: Stop leak if safe to do so.

For cleaning up: Avoid generation of dust. Wet clean or vacuum up solids. Collect in closed containers for disposal. Pick up and transfer to properly labelled containers.

Other information: Dangerous areas must be delimited and marked with appropriate warning and safety signs.

6.4 Reference to other sections

See detailed information in section 8/section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Dust explosion category: St 1.

Avoid exposure – obtain special instructions before use. Supervision of automation process by workers.

Measures to prevent fire:

Take precautionary measures against static discharges. Ensure the grounding of containers, apparatus, pumps and suction equipment. Keep away from heat sources (e.g. hot surfaces), sparks and open flames.

Measures required to protect the environment:

Use isolated drainage to prevent discharge to soil. Wet scrubber for elimination of volatile components from waste gases. Use the following chemical treatment methods for waste water: incineration. Use the following recovery and/or abatement technique for cleaning waste gases: exhaust air scrubber.

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Personal protection:	<u>Advice on general occupational hygiene:</u> Preventive industrial medical examinations are to be carried out. Wash thoroughly after handling. Regular changing of working clothes.
Technical protective measures:	Not available.
Handling:	<u>Measures to prevent aerosol and dust generation:</u> Provide adequate ventilation as well as local exhaustion at critical locations. Transfer and handle product only in closed systems.
7.2 Conditions for safe storage, including any incompatibilities	
Storage:	Storage class (TRGS510): 11, combustible solids. Packaging materials: Keep/store only in original container.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a cool, dry, well-ventilated place. Store locked up. Access is only to be granted to authorized persons. Ensure containers are properly labelled. Remove all sources of ignition. Controlled room temperature: 15 – 25 °C.
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	
TWA (EC): 0.4 mg/m ³ , basis on J%J OEL/PBOEL	
8.2 Exposure controls	
Appropriate engineering control Provide adequate ventilation. Provide eye wash in the immediate working surroundings and label its location conspicuously. Emergency shower installed. Protective equipment should be selected specifically for the working place.	
Individual protection measures	
Eye/face protection:	Suitable eye protection: Eye glasses with side protection. Face protection shield. (DIN EN 166)
Skin protection:	Wear suitable protective clothing depending on activity and possible exposure: apron, protecting boots, chemical protection suit or air fed suit with exhaust valve. Wash contaminated clothing before reuse.
Hand protection:	Use protective gloves complying with EC directive 89/686/EEC and the resultant standard EN374/EN388. The glove material has to be impermeable and resistant to the substance. Suitable gloves type: PVC (Polyvinyl chloride). Butyl rubber. NBR (Nitrile rubber).
Respiratory protection:	In case of inadequate ventilation, wear respiratory protection.

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Thermal hazards: A NIOSH/MSHA-approved or CE-marked respiratory protection equipment with assigned protection factor above 20 should be used.
Respirator with combination filter for vapour/particulate (EN141).
Not determined.

Environmental exposure control

See section 7.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or slightly yellowish, crystalline powder.
Odour:	Very faint.
Odour threshold:	Not available.
pH:	3.5 – 5.5
Melting/freezing point:	Ca. 245 °C
Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Not applicable.
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 applicable.
Solubility:	Practically insoluble in ethanol (96 per cent) and in methylene chloride.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Log Pow: -4.3
Auto-ignition temperature:	450 °C (Method: M.I.T. Dust Cloud BAM)
Decomposition temperature:	260 °C
	140 kJ/kg
	Minimum T
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

Stable under ambient temperatures and pressures.

10.3 Possibility of hazardous reactions

Strong bases.
Strong oxidising agents.

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:	Oral LD50 (mouse): 1 240 mg/kg
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:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Causes skin irritation.
Inhalation:	May cause respiratory irritation.

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Ingestion: Harmful if swallowed.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish:

LC50 (*Danio rerio* (zebra fish)): > 100 mg/l (96h) (method: OECD Test Guideline 203)

NOEC (*Danio rerio* (zebra fish)): 100 mg/l (method: OECD Test Guideline 203)

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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/packaging disposal: Send to a hazardous waste incinerator facility under observation of official regulations.

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) : Not classified.

14.3 Transport hazard class(es)

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

14.4 Packing group

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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

For personal protection, see section 8.

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

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Risk phrases:

R22 Harmful if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

S1 Keep locked up.

S7/9 Keep container tightly closed and in a well-ventilated place.

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

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

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S27 Take off immediately all contaminated clothing.

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

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

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S51 Use only in well-ventilated areas.

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

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

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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

FAC SECUNDUM ARTEM NV

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