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SAFETY DATA SHEET

According to Regulation (EC). No.1272/2008[CLP]

Document No.: SDS/FM/0107 Version No.: 1.0 Effective Date: 22 Jun 2022

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

1.1 PRODUCT IDENTIFIERS

Product Name : Hydroxychloroquine Sulfate Tablets USP 200 mg

Synonyms : 2-[[4-[(7-Chloroquinolin-4-yl) amino] pentyl] amino] ethanol;
2-[[4-[(7-Chloro-4-quinolyl) amino] pentyl] ethylamino] ethanol sulfate;

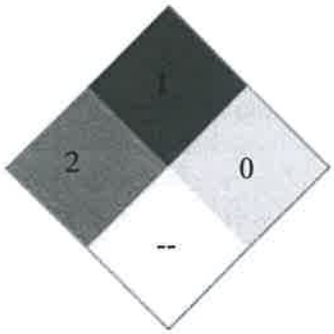
CAS No. : 747-36-4

Molecular Weight : 434.00 g/ mol

Molecular Formula : $C_{18}H_{26}ClN_3O.\ H_2SO_4$

NFPA Rating

Health (Blue);
Flammability (Red);
Reactivity (Yellow);
Specific (White);



NFPA RATING			
Rating	NFPA-Blue	NFPA-Red	NFPA-Yellow
0	None	None	None
1	Very Low	Very Low	Very Low
2	Low	Low	Low
3	High	High	High
4	Very High	Very High	Very High
White (symbol & Nature)			
OXY - Oxidizer		W - Use No Water	
ACID - Acid		☢ - Radiation Hazard	
ALK - Alkali		SA - Simple Asphyxiant	
COR - Corrosive		-- - Not Applicable	

1.2 CONTACT INFORMATION

Corporate Office : Laurus Labs Limited, 2nd Floor, Serene Chambers, Road No # 7, Banjara hills, Hyderabad-500034. Telangana, India. Tel: 040-39804333

Registered Office : Laurus Labs Limited, Plot No. 21, JN Pharma City, Parawada, Visakhapatnam – 531021.Andhra Pradesh, India. Tel: 0891 3061222

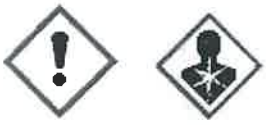
SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Hazard Code	Hazard Category	Hazard Description
H302	Category 4	Acute Toxicity- Oral
H315	Category-2	Skin irritation
H319	Category-2A	Eye irritation

2.2 LABEL ELEMENTS

Pictogram



Signal word **Warning**

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statement(s)

P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

CAS #	Chemical name	Percent
747-36-4	Hydroxychloroquine sulfate	93.0 – 107.0
9005-25-8	Maize starch	q.s.
64044-51-5	Lactose monohydrate (Granulac 200)	q.s.
9003-39-8	Povidone K-30	q.s.
557-04-0	Magnesium Stearate (Ligamed M-F-2-V)	q.s.
None Assigned	Opadry II Complete film coating system 85F580019 White	q.s.
None Assigned	Opadry II Complete film coating system 85F580019-CN White	q.s.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES:

Eye contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

Skin contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient / Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician

immediately / Loosen tight clothing such as a collar, tie, belt or waistband.

4.2 MOST IMPORTANT SYMPTOMS/ EFFECTS - ACUTE AND DELAYED:

The most important known symptoms and effects are described in the labelling (see section 2)

4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:

Treat Symptomatically.

SECTION 5: FIRE AND EXPLOSION DATA

5.1 EXTINGUISHING MEDIA:

Suitable extinguishing media: Water, Foam (Alcohol resistant AFFF),ABC Powder, Carbon Dioxide, Dry Sand, DCP (Dry Chemical Powder)

Unsuitable extinguishing media: For this substance/ mixture no limitations of extinguishing agents are given.

5.2 SPECIFIC HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

Carbon oxides, Nitrogen oxides (NOx).

5.3 ADVICE FOR FIRE FIGHTERS:

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

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

6.2 ENVIRONMENTAL PRECAUTIONS:

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

6.3 Methods and materials for containment and cleaning up:

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

During handling wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

Store at temperatures not exceeding 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 CONTROL PARAMETERS:

Type	Sub Type	Comment (Body Parts)	Value
-	-	-	Remarks: This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

8.2 EXPOSURE CONTROLS:

Appropriate Engineering Controls:

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 PERSONAL PROTECTIVE EQUIPMENT:

Eye/Face Protection:

Not required under normal conditions of therapeutic administration and use..

Skin & body protection:

Not required under normal conditions of therapeutic administration and use.

Respiratory protection:

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard: EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Physical state & Appearance	:	White to off white, capsule shaped, biconvex, film coated tablets debossed with 'L7' on one side and plain on the other side.
Colour	:	White to off white
Odor	:	Odourless
Odour threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Boiling point / range	:	No data available
Flash point	:	No data available
Flammability (solid, gas)	:	No data available
Flammability or explosive limits - Upper	:	No data available
Flammability or explosive limits - Lower	:	No data available
Evaporation rate	:	No data available
Vapour pressure	:	No data available
Vapour density	:	No data available
Relative density	:	No data available
Water solubility	:	Soluble in water
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Special gravity	:	No data available
Oxidizing properties	:	No data available
Viscosity	:	Not applicable - Solid

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY:

No data available.

10.2 CHEMICAL STABILITY:

Stable under normal ambient and anticipated storage and handling conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

No hazardous reactivity has been reported.

10.4 CONDITIONS TO AVOID:

Avoid exposure to extreme heat, light and moisture.

10.5 INCOMPATIBLE MATERIALS:

Strong oxidizing agents

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

Acute Toxicity:

Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Type	Species	Value	Unit	Any other
LD50 Oral	Mouse	mg/kg	1240	--

Skin corrosion/irritation:

No data available.

Serious eye damage/eye irritation:

No data available.

Respiratory or skin sensitization:

No data available.

Germ cell Mutagenicity

No data available.

Carcinogenicity

IARC: No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Reproductive toxicity:

No data available.

Specific target organ toxicity - single exposure:

Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Specific target organ toxicity - repeated exposure:

Overexposure may result in serious illness or death. Eye contact may result in redness or pain.

Aspiration hazard

No data available.

11.2 ADDITIONAL INFORMATION :

Malaria: Suppression

In adults, 400 mg (=310 mg base) on exactly the same day of each week. In infants and children, the weekly suppressive dosage is 5 mg, calculated as base, per kg of body weight, but should not exceed the adult dose regardless of weight.

Treatment of the acute attack

In adults, an initial dose of 800 mg (=620 mg base) followed by 400 mg (=310 mg base) in six to eight hours and 400 mg (=310 mg base) on each of two consecutive days (total 2 g hydroxychloroquine sulfate or 1.55 g base).

Adverse Effects

CNS Reactions: Irritability, nervousness, emotional changes, nightmares, psychosis, headache, dizziness, vertigo, tinnitus, nystagmus, nerve deafness, convulsions, and ataxia.

Neuromuscular Reactions: Skeletal muscle palsies or skeletal muscle myopathy or neuromyopathy and atrophy of proximal muscle.

Ocular Reactions:

- Ciliary body: Blurred vision.
- Cornea: Transient edema, punctate to lineal opacities, decreased corneal sensitivity.
- Retina: Macula: Edema, atrophy, abnormal pigmentation, loss of foveal reflex.
- Visual field defects: Pericentral or paracentral scotoma, central scotoma with decreased visual acuity, rarely field constriction, abnormal color vision.

Dermatologic Reactions: Bleaching of hair, alopecia, pruritus, skin and mucosal pigmentation.

Hematologic Reactions: Various blood dyscrasias such as aplastic anemia, agranulocytosis, leukopenia, anemia, thrombocytopenia (hemolysis in individuals with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency).

Gastrointestinal Reactions: Anorexia, nausea, vomiting, diarrhea, and abdominal cramps. Isolated cases of abnormal liver function and fulminant hepatic failure.

Allergic Reactions: Urticaria, angioedema and bronchospasm have been reported.

Over Dose Effect : The 4-aminoquinoline compounds are very rapidly and completely absorbed after ingestion, and in accidental overdosage, or rarely with lower doses in hypersensitive patients, toxic symptoms may occur within 30 minutes.

Medical Conditions: These consist of headache, drowsiness, visual disturbances, cardiovascular collapse, and convulsions, followed by sudden and early respiratory and cardiac arrest. The electrocardiogram may reveal atrial standstill, nodal rhythm, prolonged intraventricular conduction time, and progressive bradycardia leading to ventricular fibrillation and/or arrest

Contraindications:

Use of this drug is contraindicated (1) in the presence of retinal or visual field changes attributable to any 4-aminoquinoline compound, (2) in patients with known hypersensitivity to 4-aminoquinoline compounds, and (3) for long-term therapy in children. Pregnancy Comments

Usage of this drug during pregnancy should be avoided except in the suppression or treatment of malaria when in the judgment of the physician the benefit outweighs the possible hazard. It should be noted that radioactively-tagged chloroquine administered intravenously to pregnant, pigmented CBA mice passed rapidly across the placenta. It accumulated selectively in the melanin structures of the fetal eyes and was retained in the ocular tissues for five months after the drug had been eliminated from the rest of the body.

Pregnancy Category: --

SECTION 12: ECOLOGICAL INFORMATION

12.1 ECO-TOXICITY

Do not empty into drains.

12.2 PERSISTENCE AND DEGRADABILITY:

Biodegradability: Soluble in water Persistence is unlikely based on information available.

12.3 BIOACCUMULATIVE POTENTIAL:

No data available.

12.4 MOBILITY IN SOIL: Will likely be mobile in the environment due to its water solubility

12.5 OTHER ADVERSE EFFECTS :

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal methods -Waste must be segregated, stored and disposed of in accordance with central, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

	TRANSPORT	ADR/RID	IMDG	IATA
14.1	UN NUMBER	--	--	--
14.2	UN PROPER SHIPPING NAME	Not a dangerous goods	Not a dangerous goods	Not a dangerous goods
14.3	TRANSPORT HAZARD CLASS(ES)	--	--	--
14.4	PACKAGING GROUP	--	--	--
14.5	ENVIRONMENTAL HAZARD	No	No	No
14.6	SPECIAL PRECAUTIONS FOR USER	No data available		
14.7	SYMBOL	--		

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations specific for the substance or mixture

This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.

SECTION 16: OTHER INFORMATION

Disclaimer:

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

Revision Log:

Revision No.	Reason for revision	Effective Date
0.0	First Issue	09 Jun 2021
1.0	Templated is changed and Section -1 Product Name, Section -3 Product percentage, Section -7 Storage Condition and Section -9 Physical State & Appearance updated as spec.. and Sections – 2 and Section -11 are modified.	22 Jun 2022

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END OF SAFETY DATA SHEET

----- This is an electronically generated SDS, and hence need not be signed ------