



Phebra Pty Ltd

Chemwatch: 4745-10 Version No: 6.1.1.1 Safety Data Sheet according to WHS and ADG requirements Chemwatch Hazard Alert Code: 1

Issue Date: 27/06/2017 Print Date: 02/03/2018 S.GHS.AUS.EN

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

Product Identifier

Product name	Phebra Quinine Dihydrochloride Sterile Concentrate 6%
Synonyms	Phebra Quinine Dihydrochloride Sterile Concentrate 6% Injection.
Other means of identification	Not Available
Relevant identified uses of the substance or mixture and uses advised against	

	Medicine used for the treatment of severe malaria or when the patient is unable to take medication by mouth. It is also used in the treatment of Babesiosis, a
Relevant identified uses	rare disease caused by an infection carried by ticks. The solution should be diluted before administration. Administration is by intravenous injection or
	intramuscular injection.

Details of the supplier of the safety data sheet

Registered company name	Phebra
Address	19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199 1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	info@phebra.com

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	+61 401 264 004
Other emergency telephone numbers	N/A

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

P305+P351+P338

classification of the substan	
Poisons Schedule	S4
Classification ^[1]	Skin Corrosion/Irritation Category 1A, Serious Eye Damage Category 1
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI
Label elements	
Hazard pictogram(s)	
SIGNAL WORD	DANGER
Hazard statement(s)	
H314	Causes severe skin burns and eye damage.
Precautionary statement(s) P	revention
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary statement(s) R	esponse
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310	Immediately call a POISON CENTER or doctor/physician.
P363	Wash contaminated clothing before reuse.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Precautionary statement(s) St	orage
Precautionary statement(s) St P405	orage Store locked up.

P501 Dispose of contents/container in accordance with local regulations.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
60-93-5	1-10	Quinine Dihydrochloride
7732-18-5	>60	water

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	 If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Ingestion	 If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice. If poisoning occurs, contact a doctor or Poisons Information Centre.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

for quinine intoxication:

- · If large doses have been ingested, the stomach should be emptied by aspiration and lavage and a purgative such as sodium sulfate (30 g in 250 ml water) may be given.
- Elimination from the body may be assisted by acidification of the urine with ammonium chloride and ensuring an adequate fluid balance; this has limited application since quinine is extensively metabolised in the liver with only a small amount excreted unchanged.
- Blood pressure should be supported.
- · Signs of haemolytic anaemia may be indicative of the need to treat acute renal failure.
- Assisted respiration may be necessary to combat respiratory failure.
- Cardiac rhythm should be monitored.
- Vasodilators such as amyl nitrate and nicotinic acid may be given in an attempt to reverse visual impairment; beneficial effects have been achieved with stellate ganglion blocks.
 MARTINDALE; The Extra Pharmacopoeia, 29th Edition.

For quinine and its derivatives.

- Symptoms of mild cinchonism (which may occur from standard therapeutic doses of quinine) include flushed and sweaty skin, ringing of the ears (tinnitus), blurred vision, impaired hearing, confusion, reversible high-frequency hearing loss, headache, abdominal pain, rashes, drug-induced lichenoid reaction (lichenoid photosensitivity), vertigo, dizziness, dysphoria, nausea, vomiting and diarrhoea.
- Most symptoms of cinchonism (except in severe cases) are reversible and disappear once quinine is withdrawn.
- Mild symptoms normally resolve promptly; however, serious symptoms may persist for multiple months
- Quinine, like chloroquine, inactivates enzymes in the lysosomes of cells, and has an anti-inflammatory effect, hence its use in rheumatoid arthritis. However switching off these enzymes can also cause abnormal accumulation of glycogen and phospholipids in lysosomes, causing a toxic myopathy. It is possible this is the root cause of cinchonism.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

• There is no restriction on the type of extinguisher which may be used.

• Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

Fire Incompatibility None known.

Advice for firefighters

Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers fire. Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	 Non combustible. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
Major Spills	Moderate hazard. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	 Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke.
Other information	 Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS. Keep cool. Store below 25 deg.C Protect from light.

Conditions for safe storage, including any incompatibilities

Suitable container	 Glass container is suitable for laboratory quantities glass vial
Storage incompatibility	None known
Storage incompatibility	

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Phebra Quinine Dihydrochloride Sterile Concentrate 6%	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Quinine Dihydrochloride	Not Available	Not Available
water	Not Available	Not Available

Exposure controls

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure. General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	 Safety glasses with side shields. Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly.
Skin protection	See Hand protection below
Hands/feet protection	 Wear chemical protective gloves, e.g. PVC. Wear safety footwear or safety gumboots, e.g. Rubber
Body protection	See Other protection below
Other protection	 Overalls. P.V.C. apron. Barrier cream. Skin cleansing cream. Eye wash unit.
Thermal hazards	Not Available

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the *computer-*

generated selection: Phebra Quinine Dihydrochloride Sterile Concentrate 6%

Material	CPI
BUTYL	С
NATURAL RUBBER	С
NEOPRENE	С
PVA	С
VITON	С

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. - * Where the glove is to be used on a short term, casual or infrequent basis, factors such as

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	-AUS / Class1 P2	-
up to 50	1000	-	-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	-2 P2
up to 100	10000	-	-3 P2
100+			Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Appearance	Almost colourless to light yellow, particle-free liquid; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	1.0138-1.0159
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available

pH (as supplied)	1.5-3.0	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled H	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product			
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. Large doses of quinine and its derivatives may produce severe poisoning characterised by headache, fever, vomiting, muscle weakness, excitement, confusion, blindness (possibly permanent), deafness and loss of consciousness; blood pressure falls and a feeble pulse results. Occasionally, renal failure ensues; death may occur, usually in coma, from respiratory failure.			
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material			
F\/0	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).			
Chronic F	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Repeated exposure to quinines can result in symptoms such as nausea, vomiting, headache, ringing in the ear, deafness, visual disturbance and temporary blindness. Some people are hypersensitive to quinine, and small doses in these persons may cause swelling, asthma and other allergic phenomena.			
Phebra Quinine	TOXICITY			
Dihydrochloride Sterile Concentrate 6%	Not Available Not Available			
Quinine Dihydrochloride	TOXICITY	IRRITATION		
-	Oral (rat) LD50: 1392 mg/kg ^[2] Not Available			
TOXICITY		IRRITATION		
water	Not Available Not Available			
	1. Value obtained from Europe ECHA Registered Substan data extracted from RTECS - Register of Toxic Effect of ch	es - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified emical Substances		
	reactive airways dysfunction syndrome (RADS) which can RADS include the absence of previous airways disease in a nours of a documented exposure to the irritant. Other criter severe bronchial hyperreactivity on methacholine challenge asthma) following an irritating inhalation is an infrequent di substance. On the other hand, industrial bronchitis is a dis	ars after exposure to the material ends. This may be due to a non-allergic condition known as occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to ia for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to testing, and the lack of minimal lymphocytic inflammation, without eosinophila. RADS (or sorder with rates related to the concentration of and duration of exposure to the irritating yrder that occurs as a result of exposure due to high concentrations of irritating substance (ofte es. The disorder is characterized by difficulty breathing, cough and mucus production.		
	No significant acute toxicological data identified in literature search.			

Acute Toxicity	\otimes	Carcinogenicity	0
Skin Irritation/Corrosion	✓	Reproductivity	0
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	0
Respiratory or Skin sensitisation	0	STOT - Repeated Exposure	0
Mutagenicity	\otimes	Aspiration Hazard	0
		.	Data available but does not fill the criteria for classification Data available to make classification

🚫 – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Phebra Quinine	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOUR
	Not Available	Not Available	Not Available	Not Not Available Availab
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOUR
Quinine Dihydrochloride Not Ava	Not Available	Not Available	Not Available	Not Not Available Availab
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE SOUR
water	Not Available	Not Available	Not Available	Not Not Available Availab

(Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air	
water	LOW	LOW	
Bioaccumulative potential			

Ingredient	Bioaccumulation
water	LOW (LogKOW = -1.38)

Mobility in soil

Ingredient	Mobility
water	LOW (KOC = 14.3)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In
	some areas, certain wastes must be tracked.
	A Hierarchy of Controls seems to be common - the user should investigate:
	▶ Reduction
	▶ Reuse
	▶ Recycling
	 Disposal (if all else fails)
	This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may
	be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this
Des last (Des lasting lines at	type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
Product / Packaging disposal	DO NOT allow wash water from cleaning or process equipment to enter drains.
	It may be necessary to collect all wash water for treatment before disposal.
	In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
	Where in doubt contact the responsible authority.
	► Recycle wherever possible.
	Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal
	facility can be identified.
	 Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after
	admixture with suitable combustible material).
	Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

SECTION 14 TRANSPORT INFORMATION

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Phebra Quinine Dihydrochloride Sterile Concentrate 6%

 Marine Pollutant
 NO

 HAZCHEM
 Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

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

QUININE DIHYDROCHLORIDE(60-93-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

WATER(7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Υ
Canada - DSL	Υ
Canada - NDSL	N (water; Quinine Dihydrochloride)
China - IECSC	N (Quinine Dihydrochloride)
Europe - EINEC / ELINCS / NLP	Υ
Japan - ENCS	N (Quinine Dihydrochloride)
Korea - KECI	N (Quinine Dihydrochloride)
New Zealand - NZIoC	Υ
Philippines - PICCS	Υ
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

TEL (+61 3) 9572 4700.

PC — TWA: Permissible Concentration-Time Weighted Average PC — STEL: Permissible Concentration-Short Term Exposure Limit IARC: International Agency for Research on Cancer ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit, IDLH: Immediately Dangerous to Life or Health Concentrations OSF: Odour Safety Factor NOAEL: No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level TLV: Threshold Limit Value LOD: Limit of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index

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