

Magnesium Sulfate Heptahydrate 50% Concentrated Injection

Phebra Pty Ltd

Chemwatch: **25-4595** Version No: **2.1.1.1**

Safety Data Sheet according to WHS and ADG requirements

Chemwatch Hazard Alert Cod

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	Magnesium Sulfate Heptahydrate 50% Concentrated Injection		
Synonyms	Not Available		
Other means of identification	Not Available		

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Parenteral administration of MAGNESIUM SULFATE HEPTAHYDRATE 50% CONCENTRATED INJECTION is indicated for: The treatment of acute hypomagnesaemia. To prevent hypomagnesaemia in patients receiving total parenteral nutrition. The prevention and treatment of life-threatening seizures in the treatment of toxemias of pregnancy (pre-eclampsia and eclampsia). For emergency treatment of some arrhythmias such as Torsade de Pointes and those associated with hypokalemia.

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

Poisons Schedule	Not Applicable
Classification	Not Applicable

Label elements

Hazard pictogram(s)	Not Applicable
SIGNAL WORD	NOT APPLICABLE

Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

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See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
10034-99-8	50	Magnesium Sulphate heptahydrate
7732-18-5	50	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.
If skin or hair contact occurs: ► 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.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Magnesium is present in the blood, as a normal constituent, at concentrations between 1.6 to 2.2 meg/L. Some 30% is plasma bound. At serum magnesium levels of 3-4 meg/L, signs of CNS depression, loss of reflexes, muscular tone and power, and bradycardia occur. Cardiac arrest (sometimes fatal) and/or respiratory paralysis can occur at plasma levels of 10-15 meg/L. For acute or short term repeated exposures to magnesium:

- ▶ Symptomatic hypermagnesaemia appears rarely in the absence of intestinal or renal disease.
- Felevated magnesium levels may cause hypocalcaemia because of decreased parathyroid hormone activity and decreased end-organ responsiveness.
- ▶ Patients with severe hypermagnesemia may develop sudden respiratory arrest and must be watched closely for apnoea.
- Use fluids, then vasopressors for hypotension. Frequently hypotension responds to calcium administration.
- Induce emesis or administer lavage if patient presents within 4 hours of ingestion. Use sodium cathartics, with caution, in presence of cardiac or renal failure.
- Activated charcoal is not useful.
- Calcium is an antagonist of magnesium action and is an effective antidote when serum levels exceed 5 meq/L and the patient exhibits symptoms. The adult dose of calcium gluconate is 10 ml of a 10% solution over several minutes. [Ellenhorn and Barceloux: Medical Toxicology]

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

Special nazards arising from the substrate or mixture				
Fire Incompatibility	None known.			
Advice for firefighters				
 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 from path of fire. Equipment should be thoroughly decontaminated after use. 				
Fire/Explosion Hazard	 ► The material is not readily combustible under normal conditions. ► However, it will break down under fire conditions and the organic component may burn. ► Not considered to be a significant fire risk. ► Heat may cause expansion or decomposition with violent rupture of containers. ► Decomposes on heating and may produce toxic furnes of carbon monoxide (CO). ► May emit acrid smoke. Decomposition may produce toxic furnes of: , sulfur oxides (SOx) May emit poisonous furnes. May emit corrosive furnes. 			
HAZCHEM	Not Applicable			

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

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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

Frecautions for safe nationing				
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. No smoking, naked lights or ignition sources. 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. 			

Conditions for safe storage, including any incompatibilities

Suitable container	 Glass container is suitable for laboratory quantities Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks. 			
Storage incompatibility	None known			

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
Magnesium Sulphate heptahydrate	Magnesium sulfate heptahydrate	10 mg/m3	110 mg/m3	660 mg/m3
Magnesium Sulphate heptahydrate	Magnesium sulfate (1:1)	20 mg/m3	220 mg/m3	1,300 mg/m3

Ingredient	Original IDLH	Revised IDLH
Magnesium Sulphate heptahydrate	Not Available	Not Available
water	Not Available	Not Available

Exposure 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.

Appropriate engineering controls

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.

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Personal 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 Eye and face protection 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 The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Hands/feet protection Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended. Suitability and durability of glove type is dependent on usage. ▶ Wear chemical protective gloves, e.g. PVC. Wear safety footwear or safety gumboots, e.g. Rubber See Other protection below **Body protection** Overalls. ▶ P.V.C. apron. Other protection 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:

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Material	СРІ
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 "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.

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)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Magnesium Sulfate Heptahydrate 50% Concentrated Injection is a clear, colourless solution; mixes with water. Magnesium Sulfate Heptahydrate 50% Concentrated Injection is an aqueous solution.		
Physical state	Liquid	Relative density (Water = 1)	1.22 approx.
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	5.5-7	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 Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available

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Flammability	Not Available	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)	Not Available	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

ormation on toxicological	effects			
Inhaled	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.			
Ingestion	Accidental ingestion of the material may be damaging to the h	nealth of the individual.		
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 Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.			
Eye	There is some evidence to suggest that this material can cause	se eye irritation and damage in som	e persons.	
Chronic	Long-term exposure to the product is not thought to produce onevertheless exposure by all routes should be minimised as a ln a case of chronic abuse of magnesium citrate, symptoms of Blood tests revealed extremely high levels of magnesium, and followed. A patient with normal kidney function developed stoppage of be Animal testing suggests that magnesium sulfate may reduce	matter of course. een included tiredness and severe to the patient was found to have a perforeathing and slow heart rate after re	ow blood pressure which did not respond to treatment. orated ulcer of the duodenum. Kidney failure and death eceiving 90 grams of magnesium sulfate over 18 hours.	
Magnesium Sulfate	TOXICITY	IRRITATION		
Heptahydrate 50% Concentrated Injection	Not Available	Not Available		
	TOXICITY IRRITATION			
Magnesium Sulphate heptahydrate	dermal (rat) LD50: >2000 mg/kg ^[1]	Not Available	Not Available	
першиушае	Oral (rat) LD50: >2000 mg/kg ^[1]			
	TOXICITY	IRRITATION		
water	Not Available	Not Available		
Legend:	Value obtained from Europe ECHA Registered Substances data extracted from RTECS - Register of Toxic Effect of chen		from manufacturer's SDS. Unless otherwise specified	
MAGNESIUM SULPHATE HEPTAHYDRATE	Oral (man) TDLo: 183 mg/kg/4h-l Nil reported			
Magnesium Sulfate Heptahydrate 50% Concentrated Injection & WATER	No significant acute toxicological data identified in literature search.			
Acute Toxicity	0	Carcinogenicity	0	
Skin Irritation/Corrosion	0	Reproductivity	0	
Serious Eye Damage/Irritation	0	STOT - Single Exposure	0	
Respiratory or Skin sensitisation	0	STOT - Repeated Exposure	0	
Mutagenicity	0	Aspiration Hazard	0	

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ьедена:

Data available but does not till the criteria for classification — Data available to make classification

N - Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Magnesium Sulfate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURC
Heptahydrate 50% Concentrated Injection	Not Available	Not Available	Not Available	Not Available	Not Available
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURC
	LC50	96	Fish	2820mg/L	4
Magnesium Sulphate heptahydrate	EC50	48	Crustacea	343.56mg/L	4
	EC50	72	Algae or other aquatic plants	=2700mg/L	1
	EC0	72	Algae or other aquatic plants	=220mg/L	1
	NOEC	504	Crustacea	360mg/L	4
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURC
water	Not Available	Not Available	Not Available	Not Available	Not Available

Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (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
Magnesium Sulphate heptahydrate	HIGH	HIGH
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
Magnesium Sulphate heptahydrate	LOW (LogKOW = -2.2002)
water	LOW (LogKOW = -1.38)

Mobility in soil

Ingredient	Mobility
Magnesium Sulphate heptahydrate	LOW (KOC = 6.124)
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 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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Labels Required

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

MAGNESIUM SULPHATE HEPTAHYDRATE(10034-99-8) 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	Y
Canada - DSL	Y
Canada - NDSL	N (water; Magnesium Sulphate heptahydrate)
China - IECSC	Υ
Europe - EINEC / ELINCS / NLP	Υ
Japan - ENCS	Υ
Korea - KECI	Υ
New Zealand - NZIoC	Υ
Philippines - PICCS	Υ
USA - TSCA	Υ
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

 ${\sf PC-TWA: Permissible \ Concentration-Time \ Weighted \ Average}$

 ${\sf PC-STEL} : {\sf Permissible \ Concentration-Short \ Term \ Exposure \ Limit}$

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit $_{\circ}$

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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