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Methylene Blue, 50mg in 5mL, Injection

Phebra Pty Ltd

Chemwatch: 25-4596

Version No: 2.1.1.1 Material Safety Data Sheet according to NOHSC and ADG requirements Chemwatch Hazard Alert Code: 0

Issue Date: 27/06/2017 Print Date: 07/03/2018 S.Local.AUS.EN

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

Product Identifier

Product name	Methylene Blue, 50mg in 5mL, Injection
Chemical Name	water
Synonyms	Not Available
Other means of identification	Not Available

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

Relevant identified uses Methylene Blue Injection is mainly used in the treatment of idiopathic and drug-induced methaemoglobinaemia. Methylene Blue Injection is also used as a bacteriological stain, as a dye in diagnostic procedures such as fistula detection and gastro-oesophageal reflux in infants and children and for the delineation of certain body tissues during surgery.

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

NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to NOHSC Criteria, and ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max	
Flammability	0		
Toxicity	0		0 = Minimum
Body Contact	0		1 = Low 2 = Moderate
Reactivity	0		3 = High
Chronic	0		4 = Extreme

Poisons Schedule	S4
Risk Phrases ^[1]	Not Applicable
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Not Applicable

Relevant risk statements are found in section 2

Indication(s) of danger Not Applicable

SAFETY ADVICE

Not Applicable

Other hazards

Limited evidence of a carcinogenic effect*.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
61-73-4	1.01	methylene blue
7732-18-5	98.99	water

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with eyes: Wash out immediately with water. If irritation continues, seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	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	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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 from path of fire. Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	 Non combustible. Not considered a significant fire risk, however containers may burn.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

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	 Minor hazard. Clear area of personnel. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment as required. Prevent spillage from entering drains or water ways. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

	1
Safe handling	 Limit all unnecessary personal contact. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling.
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
	Glass container is suitable for laboratory quantities

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	Avoid contamination of water, foodstuffs, feed or seed. 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	
Methylene Blue, 50mg in 5mL, Injection	Not Available	Not Available	Not Available	Not Available	
Ingredient	Original IDLH		Revised IDLH		
methylene blue	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 property. 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 equipmen 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. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]
Skin protection	See Hand protection below
Hands/feet protection	Wear general protective gloves, eg. light weight rubber gloves. 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. 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.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. OTHERWISE: • Overalls. • Barrier cream. • Eyewash 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:

Methylene Blue, 50mg in 5mL, Injection

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

"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

 $\begin{array}{l} \mbox{A(All classes)} = \mbox{Organic vapours, B AUS or B1} = \mbox{Acid gasses, B2} = \mbox{Acid gas or hydrogen cyanide(HCN), B3} = \mbox{Acid gas or hydrogen cyanide(HCN), E} = \mbox{Sulfur dioxide(SO2), G} = \mbox{Agricultural chemicals, K} = \mbox{Ammonia(NH3), Hg} = \mbox{Mercury, NO} = \mbox{Oxides of nitrogen, MB} = \mbox{Methyl bromide, AX} = \mbox{Low boiling point organic compounds(below 65 degC)} \end{array}$

Appearance	Methylene Blue Injection is a clear, blue solution; mixes with water. Methylene Blue Injection is an aqueous solution.		
Physical state	Liquid	Relative density (Water = 1)	1.002 approx.
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	3-4.5	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
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)	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	Product is considered stable and 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

Continued...

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, 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	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.		
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.		
Eye	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	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.		
Methylene Blue, 50mg in 5mL,	TOXICITY	IRRITATION	
Injection	Not Available	Not Available	
	ΤΟΧΙΟΙΤΥ	IRRITATION	
methylene blue	Oral (rat) LD50: 1180 mg/kg ^[2]	Not Available	
	ΤΟΧΙΟΙΤΥ	IRRITATION	
water	Not Available	Not Available	
Legend:	1. Value obtained from Europe ECHA Registered Substandata extracted from RTECS - Register of Toxic Effect of ch	ces - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified	

Methylene Blue, 50mg in 5mL, Injection	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.				
METHYLENE BLUE	The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited After i.v. administration Methylene Blue may cause nausea and hypertension; with very high doses methaemoglobiner system which reduces the methylene blue to leucomethyle absorbed from the gastrointestinal tract. It is believed to be with some unchanged drug. Methylene Blue imparts a blu Although intra-amniotic injection of Methylene Blue has be in twin pregnancies, there have been several reports of he Blue in the amniotic cavity. In most cases, exchange trans with caution in the treatment of toxic methemoglobinemia; (G6PD) deficiencies are particularly susceptible. A rapid of might not occur if the patient has erythrocyte G6PD or NA as aniline or dapsone. A second dose has been recomme study in animals and of a patient with aniline poisoning ind potentially dangerous in that it could enhance Heinz body should not be given by intrathecal injection as neural dam 6-phosphate dehydrogenase deficiency.	a, vomiting, abdominal and chest pain, hu nia and ahemolysis may occur. Methylen ene blue, which in turn is able to reduce n e reduced in the tissues to the leuco form e color to urine and faeces. In large dose sen used to diagnose premature rupture molytic anemia (Heinz-body anemia) and fusions and/or phototherapy are required high doses can cause hemolytic anemia lisappearance of cyanosis in response to .DPH-diaphorase deficiency or if methern nded if cyanosis does not disappear with licated that an increased dosage of Meth formation. Methylene Blue should not be	e Blue activates a normally dormant reductase enzyme nethaemoglobin to haemoglobin. Methylene Blue is n which is slowly excreted, mainly in the urine together es Methylene Blue can produce methaemoglobinaemia. of fetal membranes or to identify separate amniotic sacs d hyperbilirubinemia in neonates exposed to Methylene to control the jaundice. Methylene Blue should be used s and patients with glucose-6-phosphate dehydrogenase Methylene Blue would be expected within one hour but noglobinemia is due to the ingestion of compounds such in 1 hour of Methylene Blue administration but results of a ylene Blue might be of no additional benefit and could be e injected s.c. as it may cause necrotic abscesses. It		
Methylene Blue, 50mg in 5mL, Injection & WATER	No significant acute toxicological data identified in literatu	ure search.			
Acute Toxicity	\odot	Carcinogenicity	\odot		
Skin Irritation/Corrosion	×	Reproductivity	0		
Serious Eye Damage/Irritation	×	STOT - Single Exposure	\odot		
Respiratory or Skin sensitisation	\otimes				
Mutagenicity	\otimes	\odot			
		✓ - L	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

Methylene Blue, 50mg in 5mL, Injection	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Injection					

	Not Available	Not Available	Not Available	Not Available	Not Available
	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	1mg/L	4
methylene blue	EC50	48	Crustacea	2260mg/L	4
	NOEC	168	Fish	0.4mg/L	4
water	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1	. IUCLID Toxicity Data 2. Europe ECHA Registered S	Substances - Ecotoxicological Information - Aquatic To	xicity 3. EPIWII	V Suite V3.12
-	())	ic Toxicity Data (Estimated) 4. US EPA, Ecotox databa centration Data 7. METI (Japan) - Bioconcentration D	1 5 1	rd Assessment	Data 6. NITE

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

Product / Packaging disposal	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. • 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 sever 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.
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SECTION 14 TRANSPORT INFORMATION

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

METHYLENE BLUE(61-73-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

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 (methylene blue; water)
China - IECSC	Υ
Europe - EINEC / ELINCS / NLP	Υ
Japan - ENCS	Υ
Korea - KECI	Y
New Zealand - NZIoC	Υ
Philippines - PICCS	Y
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

Ingredients with multiple cas numbers

Name	CAS No
methylene blue	61-73-4, 7220-79-3, 1341-90-8, 6476-03-5, 12262-49-6, 97130-83-1, 105504-42-5, 121067-62-7, 167498-52-4, 122965-43-9

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chernwatch 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

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 This document is copyright.

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