

Paraldehyde Injection BP

Phebra Pty Ltd

Chemwatch: 4750-15

Version No: 2.1.1.1

Material Safety Data Sheet according to NOHSC and ADG requirements

Chemwatch Hazard Alert Code: 3

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	Paraldehyde Injection BP
Chemical Name	paraldehyde
Synonyms	Not Available
Proper shipping name	PARALDEHYDE
Other means of identification	Not Available

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

Relevant identified uses	Paraldehyde has been used as a sedative and hypnotic in a variety of clinical situations, although it has been largely replaced by safer and/ or more effective agents. It may also be used in the treatment of convulsive episodes arising from tetanus, status epilepticus and poisoning by convulsive drugs, when other agents are inappropriate or ineffective. Paraldehyde may be effective in reducing the anxiety associated with withdrawal from drugs such as narcotics or barbiturates, as well as in the management of acute agitation or delirium tremens due to alcohol withdrawal. Paraldehyde is only recommended for use in these conditions when other treatments are ineffective or deemed inappropriate.
--------------------------	---

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

HAZARDOUS SUBSTANCE. DANGEROUS GOODS. According to the Criteria of NOHSC, and the ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	3	
Toxicity	2	
Body Contact	2	
Reactivity	1	
Chronic	0	

0 = Minimum
 1 = Low
 2 = Moderate
 3 = High
 4 = Extreme

Poisons Schedule	S4
Risk Phrases [1]	<p>R11 Highly flammable.</p> <p>R22 Harmful if swallowed.</p> <p>R36 Irritating to eyes.</p>

Legend: 1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Paraldehyde Injection BP



Relevant risk statements are found in section 2

Indication(s) of danger	Xn
SAFETY ADVICE	
S02	Keep out of reach of children.
S09	Keep container in a well ventilated place.
S13	Keep away from food, drink and animal feeding stuffs.
S16	Keep away from sources of ignition. No smoking.
S23	Do not breathe gas/fumes/vapour/spray.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S29	Do not empty into drains.
S33	Take precautionary measures against static discharges.
S35	This material and its container must be disposed of in a safe way.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water and detergent.
S41	In case of fire and/or explosion, DO NOT BREATHE FUMES.
S43	In case of fire use the extinguishing media detailed in section 5 of this SDS.
S46	If swallowed, seek medical advice immediately and show this container or label.
S51	Use only in well ventilated areas.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

Other hazards

Inhalation may produce health damage*.

Cumulative effects may result following exposure*.

May produce discomfort of the respiratory system*.

Possible skin sensitizer*.

May possibly be harmful to the foetus/ embryo*.

Repeated exposure potentially causes skin dryness and cracking*.

Vapours potentially cause drowsiness and dizziness*.

HARMFUL: may cause lung damage if swallowed

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS**Substances**

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
123-63-7	99.9	paraldehyde
123-31-9	0.01	hydroquinone

SECTION 4 FIRST AID MEASURES**Description of first aid measures**

Eye Contact	If this product comes in contact with the eyes: <ul style="list-style-type: none"> ► 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: <ul style="list-style-type: none"> ► 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	<ul style="list-style-type: none"> ► If fumes or combustion products are inhaled remove from contaminated area. ► Lay patient down. Keep warm and rested. ► Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ► Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ► Transport to hospital, or doctor.

Continued...

Paraldehyde Injection BP**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.
- Avoid giving milk or oils.
- Avoid giving alcohol.
- If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus.

Indication of any immediate medical attention and special treatment needed

Any material aspirated during vomiting may produce lung injury. Therefore emesis should not be induced mechanically or pharmacologically. Mechanical means should be used if it is considered necessary to evacuate the stomach contents; these include gastric lavage after endotracheal intubation. If spontaneous vomiting has occurred after ingestion, the patient should be monitored for difficult breathing, as adverse effects of aspiration into the lungs may be delayed up to 48 hours.

Treat symptomatically.

For simple aldehydes:

BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 l/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.
- Give activated charcoal.

ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Consider intubation at first sign of upper airway obstruction resulting from oedema.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

EMERGENCY DEPARTMENT

- Laboratory analysis of complete blood count, serum electrolytes, BUN, creatinine, glucose, urinalysis, baseline for serum aminotransferases (ALT and AST), calcium, phosphorus and magnesium, may assist in establishing a treatment regime. Other useful analyses include anion and osmolar gaps, arterial blood gases (ABGs), chest radiographs and electrocardiographs.
- Positive end-expiratory pressure (PEEP)-assisted ventilation may be required for acute parenchymal injury or adult respiratory distress syndrome.
- Treat bronchospasm in a similar manner to that employed for reactive airway disease. Severe exposures may require inhaled corticosteroids.
- Sodium bicarbonate may correct acidosis.
- Haemodialysis may assist in severely symptomatic patients.
- Consult a toxicologist as necessary.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

SECTION 5 FIREFIGHTING MEASURES**Extinguishing media**

- Alcohol stable foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

Special hazards arising from the substrate or mixture

Fire Incompatibility	► Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
-----------------------------	--

Advice for firefighters**Fire Fighting**

- Alert Fire Brigade and tell them location and nature of hazard.
- May be violently or explosively reactive.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- If safe, switch off electrical equipment until vapour fire hazard removed.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- Avoid spraying water onto liquid pools.
- **DO NOT** approach containers suspected to be hot.

Fire/Explosion Hazard

- Liquid and vapour are flammable.
- Moderate fire hazard when exposed to heat or flame.
- Vapour forms an explosive mixture with air.
- Moderate explosion hazard when exposed to heat or flame.
- Vapour may travel a considerable distance to source of ignition.
- Heating may cause expansion or decomposition leading to violent rupture of containers.
- On combustion, may emit toxic fumes of carbon monoxide (CO).

Combustion products include:

Paraldehyde Injection BP

carbon monoxide (CO)
 carbon dioxide (CO₂)
 other pyrolysis products typical of burning organic material.

HAZCHEM

•2Y

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	<ul style="list-style-type: none"> ► Remove all ignition sources. ► 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 small quantities with vermiculite or other absorbent material. ► Wipe up. ► Collect residues in a flammable waste container.
Major Spills	<ul style="list-style-type: none"> ► Clear area of personnel and move upwind. ► Alert Fire Brigade and tell them location and nature of hazard. ► May be violently or explosively reactive. ► Wear breathing apparatus plus protective gloves. ► Prevent, by any means available, spillage from entering drains or water course. ► Consider evacuation (or protect in place). ► No smoking, naked lights ignition sources. ► Increase ventilation.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ► Containers, even those that have been emptied, may contain explosive vapours. ► Do NOT cut, drill, grind, weld or perform similar operations on or near containers. ► DO NOT allow clothing wet with material to stay in contact with skin ► Avoid all personal contact, including inhalation. ► Wear protective clothing when risk of overexposure occurs. ► Use in a well-ventilated area. ► Prevent concentration in hollows and sumps. ► DO NOT enter confined spaces until atmosphere has been checked. ► Avoid smoking, naked lights or ignition sources. ► Avoid generation of static electricity. ► DO NOT use plastic buckets.
Other information	<ul style="list-style-type: none"> ► Store in original containers in approved flammable liquid storage area. ► Store away from incompatible materials in a cool, dry, well-ventilated area. ► DO NOT store in pits, depressions, basements or areas where vapours may be trapped. ► No smoking, naked lights, heat or ignition sources. ► Storage areas should be clearly identified, well illuminated, clear of obstruction and accessible only to trained and authorised personnel - adequate security must be provided so that unauthorised personnel do not have access. ► Store according to applicable regulations for flammable materials for storage tanks, containers, piping, buildings, rooms, cabinets, allowable quantities and minimum storage distances. ► Use non-sparking ventilation systems, approved explosion proof equipment and intrinsically safe electrical systems. ► Have appropriate extinguishing capability in storage area (e.g. portable fire extinguishers - dry chemical, foam or carbon dioxide) and flammable gas detectors. <p>Rotate all stock to prevent ageing. Use on FIFO (First In-First Out) basis</p>

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ► Glass container is suitable for laboratory quantities ► Packing as supplied by manufacturer. ► Plastic containers may only be used if approved for flammable liquid. ► Check that containers are clearly labelled and free from leaks. ► For low viscosity materials (i) : Drums and jerry cans must be of the non-removable head type. (ii) : Where a can is to be used as an inner package, the can must have a screwed enclosure. ► For materials with a viscosity of at least 2680 cSt. (23 deg. C) ► For manufactured product having a viscosity of at least 250 cSt. (23 deg. C) ► Manufactured product that requires stirring before use and having a viscosity of at least 20 cSt (25 deg. C): (i) Removable head packaging; (ii) Cans with friction closures and (iii) low pressure tubes and cartridges may be used. ► Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages ► In addition, where inner packagings are glass and contain liquids of packing group I there must be sufficient inert absorbent to absorb any spillage, unless the outer packaging is a close fitting moulded plastic box and the substances are not incompatible with the plastic.
Storage incompatibility	<ul style="list-style-type: none"> ► Flammable and/or toxic gases are generated by the combination of aldehydes with azo, diazo compounds, dithiocarbamates, nitrides, and strong reducing agents. ► Many aldehydes are incompatible with strong acids, amines, strong oxidisers, and alkaline materials. ► Several medium range aldehydes ignite in air, particularly if exposure is increased by sorption on paper or cloth - ignition often occurs within 2 hours ► Segregate from alcohol, water. ► Avoid strong acids, acid chlorides, acid anhydrides and chloroformates. ► Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Continued...

Paraldehyde Injection BP

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	hydroquinone	Hydroquinone	2 mg/m3	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
paraldehyde	Paraldehyde	14 mg/m3	150 mg/m3	930 mg/m3
hydroquinone	Hydroquinone	3 mg/m3	20 mg/m3	120 mg/m3

Ingredient	Original IDLH	Revised IDLH
paraldehyde	Not Available	Not Available
hydroquinone	50 mg/m3	Not Available

Exposure controls

Appropriate engineering controls	<p>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.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>For flammable liquids and flammable gases, local exhaust ventilation or a process enclosure ventilation system may be required.</p>
Personal protection	   
Eye and face protection	<ul style="list-style-type: none"> ▶ 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	<p>See Hand protection below</p> <ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber <p>NOTE:</p> <ul style="list-style-type: none"> ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. <p>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.</p> <p>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.</p> <p>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.</p> <p>Suitability and durability of glove type is dependent on usage.</p>
Hands/feet protection	<p>See Other protection below</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. ▶ Eyewash unit. ▶ Ensure there is ready access to a safety shower. <ul style="list-style-type: none"> ▪ Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity. <ul style="list-style-type: none"> ▪ For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets). ▪ Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds. Electrical resistance must range between 0 to 500,000 ohms. <p>Conductive shoes should be stored in lockers close to the room in which they are worn. Personnel who have been issued conductive footwear should not wear them from their place of work to their homes and return.</p>
Body protection	<p>See Other protection below</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. ▶ Eyewash unit. ▶ Ensure there is ready access to a safety shower. <ul style="list-style-type: none"> ▪ Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity. <ul style="list-style-type: none"> ▪ For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets). ▪ Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds. Electrical resistance must range between 0 to 500,000 ohms. <p>Conductive shoes should be stored in lockers close to the room in which they are worn. Personnel who have been issued conductive footwear should not wear them from their place of work to their homes and return.</p>
Other protection	<p>Not Available</p>
Thermal hazards	<p>Not Available</p>

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:

Respiratory protection

Type AX Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Continued...

Paraldehyde Injection BP

Paraldehyde Injection BP

Material	CPI
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
PVC	C

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	AX-AUS	-	AX-PAPR-AUS / Class 1
up to 50 x ES	-	AX-AUS / Class 1	-
up to 100 x ES	-	AX-2	AX-PAPR-2 ^

* 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.

^ - Full-face

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)

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Paraldehyde Injection is a clear, colourless to pale yellow, solution.		
Physical state	Liquid	Relative density (Water = 1)	0.991-0.996
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	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)	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

Information on toxicological effects

Inhaled	<p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo.</p> <p>Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.</p> <p>There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.</p> <p>Inhalation hazard is increased at higher temperatures.</p> <p>Persons exposed to this material at work are liable to the same side effects as those taking this material in supervised conditions. Persons with a psychiatric history taking drugs should be monitored carefully as they are more prone to dependence and addiction.</p>
---------	---

Continued...

Paraldehyde Injection BP

Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. Swallowing of the liquid may cause aspiration into the lungs with the risk of chemical pneumonitis; serious consequences may result. (ICSC13733)	
Skin Contact	Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions. Repeated exposure may cause skin cracking, flaking or drying following normal handling and use. 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 evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation. Severe inflammation may be expected with pain.	
Chronic	There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Based on experience with animal studies, there is a possibility that exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Exposure to Aliphatic aldehydes can cause irritation of the skin. Babies born to mothers taking sedatives/hypnotics may show withdrawal symptoms from the drug in the weeks after birth. Loss of muscle tone in these babies has also been noted.	
Paraldehyde Injection BP	TOXICITY Not Available	IRRITATION Not Available
paraldehyde	TOXICITY Dermal (rabbit) LD50: 14000 mg/kg ^[2] Oral (rat) LD50: 1530 mg/kg ^[2]	IRRITATION Eye (rabbit): 5 mg SEVERE Skin (rabbit): 500 mg open mild
hydroquinone	TOXICITY Dermal (rabbit) LD50: >2000 mg/kg ^[2] Oral (rat) LD50: 302 mg/kg ^[2]	IRRITATION Skin (human): 2% - mild Skin (human): 5% - SEVERE
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

HYDROQUINONE	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested. The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration. Animal testing shows that hydroquinone is rapidly and extensively absorbed from the gut and lung. Absorption via the skin is slow, but may be accelerated with alcohols. Hydroquinone distributes rapidly and widely among tissues. It is rapidly excreted from the body, mostly via the urine. In animals, hydroquinone has moderate oral acute toxicity. Limited data suggests that in animals, hydroquinone may cause temporary eye irritation and cloudiness of the cornea; in rabbits, hydroquinone caused slight irritation of the eye. Hydroquinone may be a skin sensitizer in animals. Repeated dosing in animals caused tremors and reduced activity, reduced weight gain, convulsions, and kidney disease. 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 in animal testing.		
Paraldehyde Injection BP & PARALDEHYDE	The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.		
Paraldehyde Injection BP & PARALDEHYDE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.		
Acute Toxicity	✓	Carcinogenicity	✗
Skin Irritation/Corrosion	✗	Reproductivity	✗
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

Legend: – 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

Paraldehyde Injection BP	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

Continued...

Paraldehyde Injection BP

	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
paraldehyde	Not Available	Not Available	Not Available	Not Available	Not Available
hydroquinone	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	0.044mg/L	4
	EC50	48	Crustacea	0.061mg/L	2
	EC50	72	Algae or other aquatic plants	<0.033mg/L	2
	BCF	24	Algae or other aquatic plants	0.05mg/L	4
	NOEC	72	Algae or other aquatic plants	0.0015mg/L	2

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
paraldehyde	HIGH	HIGH
hydroquinone	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
paraldehyde	LOW (BCF = 4.8)
hydroquinone	LOW (BCF = 65)

Mobility in soil

Ingredient	Mobility
paraldehyde	HIGH (KOC = 1)
hydroquinone	LOW (KOC = 434)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. <p>Otherwise:</p> <ul style="list-style-type: none"> If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. <p>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.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> Reduction Reuse Recycling Disposal (if all else fails)
	<p>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.</p> <ul style="list-style-type: none"> 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

Labels Required



Continued...

Paraldehyde Injection BP

Marine Pollutant	NO
HAZCHEM	•2Y

Land transport (ADG)

UN number	1264
UN proper shipping name	PARALDEHYDE
Transport hazard class(es)	Class 3 Subrisk Not Applicable
Packing group	III
Environmental hazard	Not Applicable
Special precautions for user	Special provisions Not Applicable Limited quantity 5 L

Air transport (ICAO-IATA / DGR)

UN number	1264
UN proper shipping name	Paraldehyde
Transport hazard class(es)	ICAO/IATA Class 3 ICAO / IATA Subrisk Not Applicable ERG Code 3L
Packing group	III
Environmental hazard	Not Applicable
Special precautions for user	Special provisions Not Applicable Cargo Only Packing Instructions 366 Cargo Only Maximum Qty / Pack 220 L Passenger and Cargo Packing Instructions 355 Passenger and Cargo Maximum Qty / Pack 60 L Passenger and Cargo Limited Quantity Packing Instructions Y344 Passenger and Cargo Limited Maximum Qty / Pack 10 L

Sea transport (IMDG-Code / GGVSee)

UN number	1264
UN proper shipping name	PARALDEHYDE
Transport hazard class(es)	IMDG Class 3 IMDG Subrisk Not Applicable
Packing group	III
Environmental hazard	Not Applicable
Special precautions for user	EMS Number F-E , S-D Special provisions Not Applicable Limited Quantities 5 L

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

PARALDEHYDE(123-63-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

HYDROQUINONE(123-31-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

Australia Hazardous Substances Information System - Consolidated Lists

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

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (paraldehyde; hydroquinone)

Continued...

Paraldehyde Injection BP

China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
Legend:	<i>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)</i>

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

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.

Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH.

TEL (+61 3) 9572 4700.

Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, Australia.