

FAULDING BETADINE ANTISEPTIC SOLUTION

**Hazard Alert Code:  
MODERATE**

Chemwatch Material Safety Data Sheet  
Issue Date: 30-Mar-2006

Revision No: 2      Chemwatch 14153  
CD 2006/2

**Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: FAULDING BETADINE ANTISEPTIC SOLUTION

SYNONYMS

"povidone-iodine solution"

PRODUCT USE

Topical anti-infective antiseptic solution for antiseptis of minor cuts and abrasions and the treatment of minor infections. Application over large skin areas should be avoided. Use in pregnancy and lactation should be limited.

SUPPLIER

Company: Mayne

Address:

1538 Main North Road

Salisbury

SA, 5108






AUS

Telephone: +61 8 8209 2666

Telephone: 1800 802 777

Fax: +61 8 8281 0284

HAZARD RATINGS

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

**Section 2 - HAZARDS IDENTIFICATION**

STATEMENT OF HAZARDOUS NATURE

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

POISONS SCHEDULE

None

RISK

Cumulative effects may result following exposure\*.

\* (limited evidence).

SAFETY

Do not breathe gas/fumes/vapour/spray.

Avoid contact with skin.

**Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS**

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NAME	CAS RN	%
povidone-iodine	25655-41-8	10
buffer		<5
glycerol	56-81-5	<1
water	7732-18-5	>60

(equivalent to 1% available iodine)

## Section 4 - FIRST AID MEASURES

### SWALLOWED

If poisoning occurs, contact a doctor or Poisons Information Centre.

- 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.

### EYE

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.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

### SKIN

If skin or hair contact occurs:

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

### INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prosthesis 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

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- mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

### NOTES TO PHYSICIAN

Treat symptomatically.

## Section 5 - FIRE FIGHTING MEASURES

### EXTINGUISHING MEDIA

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

### FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- 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 to be a significant fire risk.
- Expansion or decomposition on heating may lead to violent rupture of containers.
- Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).
- May emit acrid smoke.

### FIRE INCOMPATIBILITY

None known.

### HAZCHEM

None

## Section 6 - ACCIDENTAL RELEASE MEASURES

### EMERGENCY PROCEDURES

#### MINOR SPILLS

- Clean up all spills immediately.
- Avoid breathing vapours and contact with skin and eyes.
- Control personal contact by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.
- Wipe up.

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- 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 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.
- Wash area and prevent runoff into drains or waterways.
- If contamination of drains or waterways occurs, advise emergency services.

EMERGENCY RESPONSE PLANNING GUIDELINES (ERPG)

The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour WITHOUT experiencing or developing

life-threatening health effects is:

povidone-iodine	125 mg/m <sup>3</sup>
water	500 mg/m <sup>3</sup>

irreversible or other serious effects or symptoms which could impair an individual's ability to take protective action is:

povidone-iodine	25 mg/m <sup>3</sup>
water	500 mg/m <sup>3</sup>

other than mild, transient adverse effects without perceiving a clearly defined odour is:

povidone-iodine	25 mg/m <sup>3</sup>
water	500 mg/m <sup>3</sup>

The threshold concentration below which most people will experience no appreciable risk of health effects:

povidone-iodine	12.5 mg/m <sup>3</sup>
water	500 mg/m <sup>3</sup>

American Industrial Hygiene Association (AIHA)

Ingredients considered according exceed the following cutoffs

Very Toxic (T+)	>= 0.1%	Toxic (T)	>= 3.0%
R50	>= 0.25%	Toxic (T)	>= 3.0%
R51	>= 2.5%	Corrosive (C)	>= 5.0%

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else  $\geq 10\%$   
where percentage is percentage of ingredient found in the mixture  
SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



*X: Must not be stored together*  
*O: May be stored together with specific preventions*  
*+: May be stored together*

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

## Section 7 - HANDLING AND STORAGE

### PROCEDURE FOR 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.
- Work clothes should be laundered separately.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

### SUITABLE CONTAINER

Dropper bottles of 15mL. Bottles of 100mL, 500mL and 4.5L.

### STORAGE INCOMPATIBILITY

None known.

### STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.

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- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

**Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION**

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m <sup>3</sup>	STEL ppm	STEL mg/m <sup>3</sup>	Peak ppm	Peak mg/m <sup>3</sup>
Australia Exposure Standards	povidone-iodine		10				
Australia Exposure Standards	glycerol		10				

The following materials had no OELs on our record under the following CAS or Chemwatch (CW) numbers

Faulding Betadine Antiseptic Solution: No data available for CW:14153

povidone-iodine: No data available for CAS:25655-41-8

water: No data available for CAS:7732-18-5

EMERGENCY EXPOSURE LIMITS

None assigned. Refer to individual constituents.

EXPOSURE STANDARDS FOR MIXTURE

"Worst Case" computer-aided prediction of spray/ mist or fume/ dust components and concentration:

Composite Exposure Standard for Mixture (TWA) :3.2039 mg/m<sup>3</sup>.

Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone.

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.

Component Breathing Zone ppm Breathing Zone mg/m<sup>3</sup> Mixture Conc (%)

Component	Breathing Zone (mg/m <sup>3</sup> )	Mixture Conc (%)
povidone-iodine	2.9126	10.0
glycerol	0.2913	1.0

INGREDIENT DATA

POVIDONE-IODINE:

These "dusts" have little adverse effect on the lungs and do not produce toxic effects or organic disease. Although there is no dust which does not evoke some cellular response at sufficiently high concentrations, the cellular response caused by P.N.O.C.s has the following characteristics:

- the architecture of the air spaces remain intact,
- scar tissue (collagen) is not synthesised to any degree,
- tissue reaction is potentially reversible.

Extensive concentrations of P.N.O.C.s may:

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- seriously reduce visibility,
- cause unpleasant deposits in the eyes, ears and nasal passages,
- contribute to skin or mucous membrane injury by chemical or mechanical action, per se, or by the rigorous skin cleansing procedures necessary for their removal. [ACGIH]

This limit does not apply:

- to brief exposures to higher concentrations
- nor does it apply to those substances that may cause physiological impairment at lower concentrations but for which a TLV has as yet to be determined.

This exposure standard applies to particles which

- are insoluble or poorly soluble\* in water or, preferably, in aqueous lung fluid (if data is available) and
- have a low toxicity (i.e.. are not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, and do not emit ionizing radiation, cause immune sensitization, or cause toxic effects other than by inflammation or by a mechanism of lung overload)

### GLYCEROL:

The mist is considered to be a nuisance particulate which appears to have little adverse effect on the lung and does produce significant organic disease or toxic effects. OSHA concluded that this limit would protect the worker from kidney damage and perhaps, testicular effects.

### WATER:

No exposure limits set by NOHSC or ACGIH.

### PERSONAL PROTECTION



### EYE

No special equipment for minor exposure i.e. when handling small quantities.

- OTHERWISE:
- Safety glasses with side shields.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens 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

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removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59]

HANDS/FEET

No special equipment needed when handling small quantities.

OTHERWISE: Wear chemical protective gloves, eg. PVC.

Stains may be removed with dilute sodium thiosulfate solution.

OTHER

- Overalls.
- Eyewash unit.

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:  
water, glycerol

Protective Material CPI \*.

NATURAL RUBBER C

\* 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.

RESPIRATOR

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.

Breathing Zone Level ppm (volume)	Maximum Protection Factor	Half-face Respirator	Full-Face Respirator
1000	10	-AUS P	-
1000	50	-	-AUS P
5000	50	Airline *	-
5000	100	-	-2 P
10000	100	-	-3 P
	100+		Airline**

\* - Continuous Flow \*\* - Continuous-flow or positive pressure demand.

The local concentration of material, quantity and conditions of use determine the type of personal

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protective equipment required.

For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

**ENGINEERING CONTROLS**

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood - local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

**Section 9 - PHYSICAL AND CHEMICAL PROPERTIES**

**APPEARANCE**

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Clear dark brown liquid with a slight odour of iodine; mixes with water.

### PHYSICAL PROPERTIES

Liquid.

Mixes with water.

Molecular Weight: Not applicable.	Boiling Range (°C): Not available.
Melting Range (°C): Not available.	Specific Gravity (water=1): 1.025-1.035
Solubility in water (g/L): Miscible	pH (as supplied): Not available
pH (1% solution): Not available.	Vapour Pressure (kPa): Not available.
Volatile Component (%vol): Not available.	Evaporation Rate: Not available
Relative Vapour Density (air=1): Not available.	Flash Point (°C): Not applicable
Lower Explosive Limit (%): Not applicable	Upper Explosive Limit (%): Not applicable
Autoignition Temp (°C): Not applicable	Decomposition Temp (°C): Not available.
State: Liquid	

### Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

#### CONDITIONS CONTRIBUTING TO INSTABILITY

Product is considered stable and hazardous polymerisation will not occur.

### Section 11 - TOXICOLOGICAL INFORMATION

#### POTENTIAL HEALTH EFFECTS

##### ACUTE HEALTH EFFECTS

###### SWALLOWED

Considered an unlikely route of entry in commercial/industrial environments.

The liquid is discomforting to the gastro-intestinal tract.

Ingestion may result in nausea, abdominal irritation, pain and vomiting if swallowed in large quantity.

###### EYE

The liquid may produce eye discomfort causing smarting, pain and redness.

###### SKIN

The liquid may be slightly discomforting to the skin if exposure is prolonged and is capable of causing transient staining of the skin and skin reactions which may lead to dermatitis from repeated exposures over long periods.

Not considered an irritant through normal use.

###### INHALED

Not normally a hazard due to non-volatile nature of product.

#### CHRONIC HEALTH EFFECTS

Primary route of exposure is usually by skin contact.

Iodine and iodides cause goitre and diminished as well as increased activity of the thyroid gland. A toxic syndrome resulting from chronic iodide overdose and from repeated administration of small amounts of iodine is characterised by excessive saliva production, head cold, sneezing, conjunctivitis, headache, fever, laryngitis, inflammation of the bronchi and mouth cavity, inflamed parotid gland, and various skin rashes. Swelling and inflammation of the throat, irritated and swollen eyes and lung swelling may also occur. Swelling of the glottis, necessitating a tracheotomy has been reported. Use of iodides in frequency can cause foetal death, severe goitre, hypothyroidism and the cretinoid appearance of the newborn.

#### TOXICITY AND IRRITATION

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Not available. Refer to individual constituents.

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances

### TOXICITY

### IRRITATION

#### POVIDONE-IODINE:

Oral (rat) LD50: > 8000 mg/k

Skin (rabbit): 500 mg Mild

Oral (rat) LD50: 5990 mg/kg \*

[\* = Manufacturer]

Dermal (human) TDLo: 3400 mg/Kg/24h

#### GLYCEROL:

Oral (Rat) LD50: 12600 mg/kg

#### WATER:

No significant acute toxicological data identified in literature search.

## Section 12 - ECOLOGICAL INFORMATION

No data for Faulding Betadine Antiseptic Solution.

Refer to data for ingredients, which follows:

#### GLYCEROL:

"Algae IC50 (72hr.) (mg/l):" 2900-10000

"log Kow (Sangster 1997):" -1.76

"log Pow (Verschuereen 1983):" 1.07692307

BOD5: 51%

COD: 95%

ThOD: 93%

log Kow: -2.66- -2.47

BOD 5 if unstated: 0.617-0.87,31-51%

COD: 1.16,82-95%

ThOD: 1.217-1.56

Completely biodegradable.

Fish LC50: >5000 mg/l

Algae IC50: >2900 mg/l

Bacteria EC50: .10000 mg/l (Pseudomonas putida)

## Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Bury residue in an authorised landfill.
- Recycle containers if possible, or dispose of in an authorised landfill.

## Section 14 - TRANSPORTATION INFORMATION

### HAZCHEM

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:UN,IATA,IMDG

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**Section 15 - REGULATORY INFORMATION**

**POISONS SCHEDULE**

None

**REGULATIONS**

povidone-iodine (CAS: 25655-41-8) is found on the following regulatory lists;

Australia Inventory of Chemical Substances (AICS)

Australia Poisons Schedule

glycerol (CAS: 56-81-5) is found on the following regulatory lists;

Australia High Volume Industrial Chemical List (HVICL)

Australia Inventory of Chemical Substances (AICS)

International Council of Chemical Associations (ICCA) - High Production Volume List

OECD Representative List of High Production Volume (HPV) Chemicals

water (CAS: 7732-18-5) is found on the following regulatory lists;

Australia Inventory of Chemical Substances (AICS)

OECD Representative List of High Production Volume (HPV) Chemicals

**Section 16 - OTHER INFORMATION**

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