

BETADINE ANTISEPTIC SOLUTION

Hazard Alert Code:
MODERATE

Chemwatch Material Safety Data Sheet

Revision No: 6

Chemwatch 14153

Issue Date: 8-Jul-2008

CD 2009/1

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

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: sanofi-aventis Consumer Healthcare

Address:

87 Yarraman Place

Virginia

QLD, 4014

AUS

Telephone: +61 1800 451 453

Telephone: +61 7 3212 8777

Fax: +61 7 3212 8688

HAZARD RATINGS

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

Min/Nil=0
Low=1
Moderate=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

None under normal operating conditions.

SAFETY

None under normal operating conditions.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
iodophore, as		10
povidone-iodine	25655-41-8	
buffer		<5
glycerol	56-81-5	<1
water	7732-18-5	>60
(equivalent to 1% available iodine)		

Section 4 - FIRST AID MEASURES

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SWALLOWED

» For advice, contact a Poisons Information Centre or a doctor.

- 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.
- 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.

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

»

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- 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.
- 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.

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.

STORAGE INCOMPATIBILITY

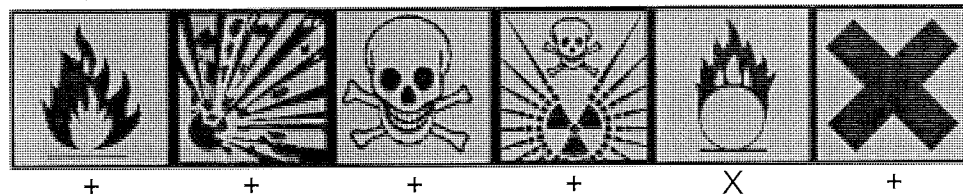
» None known.

STORAGE REQUIREMENTS

»

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



X: Must not be stored together

O: May be stored together with specific precautions

+: May be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	TWA F/CC
Australia Exposure Standards	glycerol (Glycerin mist (a))		10					
The following materials had no OELs on our records								
• povidone-iodine: CAS:25655-41-8								
• water: CAS:7732-18-5								

MATERIAL DATA

» Not available. Refer to individual constituents.

INGREDIENT DATA

POVIDONE-IODINE:

» It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

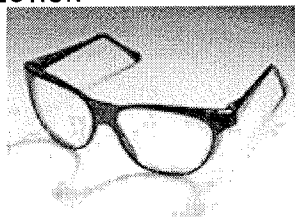
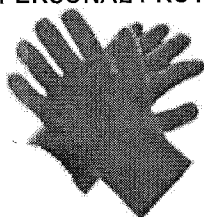
GLYCEROL:

The mist is considered to be a nuisance particulate which appears to have little adverse effect on the lung and does not 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 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.

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	A-AUS P	-
1000	50	-	A-AUS P
5000	50	Airline *	-
5000	100	-	A-2 P
10000	100	-	A-3 P
	100+		Airline**

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

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

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

Viscosity: Not Available

Material

Value

log Kow

-2.66- -2.47

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

» Product is considered stable and hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

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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 pregnancy can cause foetal death, severe goitre, hypothyroidism and the cretinoid appearance of the newborn.

TOXICITY AND IRRITATION

» Not available. Refer to individual constituents.

GLYCEROL:

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

TOXICITY

Oral (Rat) LD50: 12600 mg/kg

» The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

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.

WATER:

» No significant acute toxicological data identified in literature search.

IRRITATION

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

POVIDONE-IODINE:

» Iodine is an important element in studies of environmental protection and human health, global-scale hydrologic processes and nuclear nonproliferation. Biogeochemical cycling of iodine is complex, because iodine occurs in multiple oxidation states and as inorganic and organic species that may be hydrophilic, atmophilic, and biophilic. Experiments illustrate complex behavior with various processes occurring, including iodate reduction, irreversible retention or mass loss of iodide, and rate-limited and nonlinear sorption. There was an appreciable iodate reduction to iodide, presumably mediated by the structural Fe(II) in some clay minerals; therefore, careful attention must be given to potential interconversion among species when interpreting the biogeochemical behavior of iodine in the environment.

Iodine (I₂) is electrochemically reduced to ionic iodide by natural processes but humic acid appears to promote the reaction. The different oxidation species of iodine have markedly different sorption properties. Hence, changes in iodine redox states can greatly affect the mobility of iodine in the environment. A major microbial role has been suggested in the past to account for at least some of these redox changes. Both soluble ferrous iron and sulfide, as well as iron monosulfide (FeS) were shown to abiologically reduce iodate to iodide. These results indicate that ferric iron and/or sulfate reducing bacteria are capable of mediating both direct, enzymatic, as well as abiotic reduction of iodate in natural anaerobic environments.

Environmental and geological evidence indicates that iodine can become associated with natural organic matter (NOM) in soils and sediments. Previous studies have shown that iodine (including I₂) can be strongly retained in organic-rich surface soils and sediment and that soluble iodine may be associated with dissolved humic material. Iodine and iodate undergo an abiotic pseudo first-order reaction with peat leading to either reduction of iodate or iodine to iodide or incorporation of the iodine atoms into the organic matrix. Iodine appears to be incorporated in sphagnum peat by aromatic substitution for hydrogen on phenolic constituents of the peat.

GLYCEROL:

» Algae IC50 (72hr.) (mg/l):

2900- 10000

» log Kow (Sangster 1997):

- 1.76

» log Pow (Verschuereen 1983):

1.07692307

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» 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)
WATER:

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 (ADG6)
NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE

None

REGULATIONS

Betadine Antiseptic Solution (CAS: None);
No regulations applicable
Regulations for ingredients
povidone- iodine (CAS: 25655- 41- 8) is found on the following regulatory lists;
Australia Illicit Drug Precursors/Reagents - Category II
Australia Inventory of Chemical Substances (AICS)
glycerol (CAS: 56- 81- 5) is found on the following regulatory lists;
Australia Exposure Standards
Australia High Volume Industrial Chemical List (HVICL)
Australia Inventory of Chemical Substances (AICS)
Australia Therapeutic Goods Administration (TGA) Substances that may be used as active ingredients in Listed medicines
CODEX General Standard for Food Additives (GSFA) - Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP
GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships
IMO IBC Code Chapter 18: List of products to which the Code does not apply
IMO MARPOL 73/78 (Annex II) - List of Other Liquid Substances
IMO Provisional Categorization of Liquid Substances - List 1: Pure or technically pure products
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)
GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships
IMO IBC Code Chapter 18: List of products to which the Code does not apply
OECD Representative List of High Production Volume (HPV) Chemicals

Section 16 - 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.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

» The (M)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

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Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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