

BETADINE OINTMENT**Hazard Alert Code:
MODERATE**

Chemwatch Material Safety Data Sheet (REVIEW)

Revision No: 5

Chemwatch 24038

Issue Date: 4-Sep-2007

CD 2007/4

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**PRODUCT NAME:** BETADINE OINTMENT**SYNONYMS**

"povidone-iodine ointment"

PRODUCT USE

Bactericidal, sporicidal, fungicidal and virucidal antiseptic for the treatment of common skin infections e.g. infected nails, tinea, oralthrush, cold sores and prevention of infection of minor burns, cuts and abrasions. For external use only. Should be administered with caution to patients with a history of hypersensitivity to iodine. Use in pregnancy and lactation should be limited.

SUPPLIER

Company: Symbion Consumer

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:	1		
Toxicity:	0		
Body Contact:	1		Min/Nil=0
Reactivity:	0		Low=1
Chronic:	2		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

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

NAME	CAS RN	%
polyethylene glycol	25322-68-3	>60
povidone-iodine	25655-41-8	10
buffer		<1
water	7732-18-5	<30
(equivalent to 1% available iodine)		

Section 4 - FIRST AID MEASURES**SWALLOWED**

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

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.

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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**

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

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- 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.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.

FIRE/EXPLOSION HAZARD

- Combustible.
- Slight fire hazard when exposed to heat or flame.
- Heating may cause expansion or decomposition leading to violent rupture of containers.
- On combustion, may emit toxic fumes of carbon monoxide (CO).
- May emit acrid smoke.
- Mists containing combustible materials may be explosive.

FIRE INCOMPATIBILITY

Avoid contamination with strong oxidising agents as ignition may result.

HAZCHEM

None

Section 6 - ACCIDENTAL RELEASE MEASURES**EMERGENCY PROCEDURES****MINOR SPILLS**

Slippery when spilt.

- 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

Slippery when spilt.

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.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

X: Must not be stored together

O: May be stored together with specific preventions

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+: 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

7.5g Tube.

STORAGE INCOMPATIBILITY

Avoid storage with oxidisers.

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.

Store below 25 deg.C.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION**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	polyethylene glycol (Inspirable dust (not otherwise classified))		10					
Australia Exposure Standards	povidone-iodine (Inspirable dust (not otherwise classified))		10					

The following materials had no OELs on our records

- water: CAS:7732-18-5

MATERIAL DATA

None assigned. Refer to individual constituents.

INGREDIENT DATA**POLYETHYLENE GLYCOL:**

For powdered forms:

The polyethylene glycols are extremely low in oral toxicity, are not significantly irritating to the eyes or skin, and are not absorbed through the skin in toxic amounts. vapour pressures are extremely low and inhalation exposure is limited to mists. Based on experimental data and human experience, these substances do not present significant hazards to health in the workplace.

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.

WATER:

No exposure limits set by NOHSC or ACGIH.

PERSONAL PROTECTION

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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.

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

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 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**

Smooth, uniform dark brown ointment with a slight odour of iodine; dispersible in water. Viscosity 25000-70000 cps.

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

Molecular Weight: Not applicable.

Melting Range (°C): Not available.

Solubility in water (g/L): Miscible

pH (1% solution): Not available.

Volatile Component (%vol): Not available.

Relative Vapour Density (air=1): Not available.

Lower Explosive Limit (%): Not applicable

Autoignition Temp (°C): Not available

State: Liquid

Boiling Range (°C): Not available.

Specific Gravity (water=1): Not available

pH (as supplied): 2.5-6.0

Vapour Pressure (kPa): Not available.

Evaporation Rate: Not available

Flash Point (°C): Not applicable

Upper Explosive Limit (%): Not applicable

Decomposition Temp (°C): Not available.

Viscosity: Not available

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION**CONDITIONS CONTRIBUTING TO INSTABILITY**

Product is considered stable and hazardous polymerisation will not occur.

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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 material is discomforting to the gastro-intestinal tract.

Ingestion may result in nausea, abdominal irritation, pain and vomiting.

EYE

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

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

SKIN

The material may be capable of causing transient staining of the skin.

Not considered an irritant through normal use.

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.

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.

POLYETHYLENE GLYCOL:

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

TOXICITY

Oral (rat) LD50: 33750 mg/kg

IRRITATION

Skin (rabbit): 500mg/24h - mild.

Eye (rabbit): 500mg/24h - mild.

for molecular weights (200-8000) *

Oral (rat) LD50: 31000->50000 mg/kg

Oral (mice) LD50: 38000->50000 mg/kg

Oral (g.pig) LD50: 17000->50000 mg/kg

Oral (rabbit) LD50: 14000->50000 mg/kg * AIHA WEEL Guides

Intraperitoneal (mice) LD50: 3100-12900 mg/kg

POVIDONE-IODINE:

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

TOXICITY

Oral (rat) LD50: 8000 mg/k

Oral (rat) LD50: 5990 mg/kg *

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

IRRITATION

Skin (rabbit): 500 mg Mild

[* = Manufacturer]

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:

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

No significant acute toxicological data identified in literature search.

Section 12 - ECOLOGICAL INFORMATION

No data for Betadine Ointment.

Refer to data for ingredients, which follows:

POLYETHYLENE GLYCOL:

BOD 5 if unstated: 0-0.02,1%

COD: 1.62-1.74,98%

Toxicity Fish: TLM(96)>10000mg/L

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

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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.
DO NOT discharge into sewer or waterways.

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**Section 15 - REGULATORY INFORMATION****POISONS SCHEDULE**

None

REGULATIONS

Betadine Ointment (CAS: None):

No regulations applicable

polyethylene glycol (CAS: 25322- 68- 3) is found on the following regulatory lists;

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

Australia Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) -
Schedule 3

IMO IBC Code Chapter 17: Summary of minimum requirements

IMO MARPOL 73/78 (Annex II) - List of Other Liquid Substances

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

Australia Exposure Standards

Australia Illicit Drug Precursors/Reagents - Category II

Australia Inventory of Chemical Substances (AICS)

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

Australia Inventory of Chemical Substances (AICS)

IMO IBC Code Chapter 18: List of products to which the Code does not apply

OECD Representative List of High Production Volume (HPV) Chemicals

United Nations Convention Against Illicit Traffic in Narcotic Drugs and

Psychotropic Substances - Table II

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

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Issue Date: 4-Sep-2007

Print Date: 12-Mar-2008