Betadine Antiseptic Spray

Chemwatch Material Safety Data Sheet (REVIEW)
Issue Date: 16-May-2013
A317LP

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Betadine Antiseptic Spray

SYNONYMS
"povidone-iodine solution"

PRODUCT USE
Anti-infective antiseptic spray for antisepsis of minor cuts, abrasions and minor burns and the treatment of minor infections. Application over large skin areas should be avoided. Use in pregnancy and lactation should be limited. Do not use if hypersensitive to iodine.

SUPPLIER
Company: Sanofi Consumer Healthcare Pty Ltd
Address:
87 Yarraman Place
Virginia
QLD, 4014
Australia
Telephone: +61 7 3212 8777
Emergency Tel: 1800 451 453
Fax: +61 7 3212 8643

Section 2 - HAZARDS IDENTIFICATION

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

CHEMWATCH HAZARD RATINGS

<table>
<thead>
<tr>
<th></th>
<th>Flammability</th>
<th>Toxicity</th>
<th>Body Contact</th>
<th>Reactivity</th>
<th>Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCALE:</td>
<td>Min/Nil=0</td>
<td>Low=1</td>
<td>Moderate=2</td>
<td>High=3</td>
<td>Extreme=4</td>
</tr>
</tbody>
</table>

RISK
• None under normal operating conditions.

SAFETY
• None under normal operating conditions.

continued...
Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>iodophore, as</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>povidone- iodine</td>
<td>25655-41-8</td>
<td>&lt;10</td>
</tr>
<tr>
<td>glycerol</td>
<td>56-81-5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>buffer</td>
<td></td>
<td>&gt;60</td>
</tr>
<tr>
<td>water</td>
<td>7732-18-5</td>
<td></td>
</tr>
</tbody>
</table>

(equivalent to 0.5% available iodine)

NOTE: Manufacturer has supplied full ingredient information to allow CHEMWATCH assessment.

Section 4 - FIRST AID MEASURES

SWALLOWED
• Immediately give a glass of water.
• First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

EYE
■ If this product comes in contact with eyes:
  • Wash out immediately with water.
  • If irritation continues, seek medical attention.
  • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN
■ 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, aerosols or combustion products are inhaled remove from contaminated area.
• Other measures are usually unnecessary.

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.
• Use extinguishing media suitable for surrounding area.

FIRE FIGHTING
• Alert Fire Brigade and tell them location and nature of hazard.
• Wear breathing apparatus plus protective gloves in the event of a fire.
• Prevent, by any means available, spillage from entering drains or water courses.
• Use fire fighting procedures suitable for surrounding area.
• DO NOT approach containers suspected to be hot.
• Cool fire exposed containers with water spray from a protected location.
• If safe to do so, remove containers from path of fire.

continued...
Section 5 - FIRE FIGHTING MEASURES

• Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD
• Non combustible.
• Not considered a significant fire risk, however containers may burn.

FIRE INCOMPATIBILITY
■ None known.

HAZCHEM
None

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
• Clean up all spills immediately.
• Avoid breathing vapours and contact with skin and eyes.
• Control personal contact with the substance, by using protective equipment.
• Contain and absorb spill with sand, earth, inert material or vermiculite.
• Wipe up.
• Place in a suitable, labelled container for waste disposal.

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

continued...
• Observe manufacturer's storage and handling recommendations contained within this MSDS.
• Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

SUITABLE CONTAINER
• Polyethylene or polypropylene container.
• Packing as recommended by manufacturer.
• Check all containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY
Avoid contamination of water, foodstuffs, feed or seed.
None known.

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 storage and handling recommendations contained within this MSDS.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

<table>
<thead>
<tr>
<th>+</th>
<th>+</th>
<th>+</th>
<th>X</th>
<th>+</th>
</tr>
</thead>
</table>
| + | May be stored together
| O | May be stored together with specific preventions
| X | Must not be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS
The following materials had no OELs on our records
• povidone- iodine: CAS:25655- 41- 8
• water: CAS:7732- 18- 5

MATERIAL DATA
BETADINE ANTISEPTIC SPRAY:
None assigned. Refer to individual constituents.

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
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

GLYCEROL:

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:
- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

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 the nuisance particulate limit would protect the worker from kidney damage and perhaps, testicular effects.

WATER:

No exposure limits set by NOHSC or ACGIH.

PERSONAL PROTECTION

EYE
- 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 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], [AS/NZS 1336 or national equivalent].

continued...
HANDS/FEET
- Wear general protective gloves, eg. light weight rubber gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact breakthrough time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:
- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

OTHER
- No special equipment needed when handling small quantities.

OTHERWISE:
- Overalls.
- Barrier cream.
- 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.

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

**RESPIRATOR**


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**

- Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

- Process controls which involve changing the way a job activity or process is done to reduce the risk.
- Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.

General exhaust is adequate under normal operating conditions. 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.

**Section 9 - PHYSICAL AND CHEMICAL PROPERTIES**

**APPEARANCE**

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

**PHYSICAL PROPERTIES**

<table>
<thead>
<tr>
<th>State</th>
<th>Liquid</th>
<th>Molecular Weight</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Range (°C)</td>
<td>Not Available</td>
<td>Viscosity</td>
<td>Not Available</td>
</tr>
<tr>
<td>Boiling Range (°C)</td>
<td>Not Available</td>
<td>Solubility in water (g/L)</td>
<td>Miscible</td>
</tr>
<tr>
<td>Flash Point (°C)</td>
<td>Not Applicable</td>
<td>pH (1% solution)</td>
<td>Not Available</td>
</tr>
<tr>
<td>Decomposition Temp (°C)</td>
<td>Not Available</td>
<td>pH (as supplied)</td>
<td>Not Available</td>
</tr>
<tr>
<td>Autoignition Temp (°C)</td>
<td>Not Applicable</td>
<td>Vapour Pressure (kPa)</td>
<td>Not Available</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
<td>Not Applicable</td>
<td>Specific Gravity (water=1)</td>
<td>1.03 approx.</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not Applicable</td>
<td>Relative Vapour Density (air=1)</td>
<td>Not Available</td>
</tr>
<tr>
<td>Volatile Component (%vol)</td>
<td>Not Available</td>
<td>Evaporation Rate</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

**Section 10 - STABILITY AND REACTIVITY**

**CONDITIONS CONTRIBUTING TO INSTABILITY**

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

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

continued...
Potentially Health Effects

Acute Health Effects

Swallowed
■ The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (eg. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

Eye
■ Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Skin
■ The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

Inhaled
■ The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product.

Chronic Health Effects
■ Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

Toxicity and Irritation
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

Water:
Betadine Antiseptic Spray:
■ No significant acute toxicological data identified in literature search.

Povidone-Iodine:
Toxicity
Oral (rat) LD50: >8000 mg/kg
Oral (rat) LD50: 5990 mg/kg [* = Manufacturer]
Dermal (human) TDL0: 3400 mg/Kg/24h
■ 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.

Continued...
Section 11 - TOXICOLOGICAL INFORMATION

GLYCEROL:

**TOXICITY**

- Oral (Rat) LD50: 12600 mg/kg
- Oral (Guinea pig) LD50: 7750 mg/kg
- Oral (Human) TDLo: 1428 mg/kg
- Intraperitoneal (Rat) LD50: 4420 mg/kg
- Subcutaneous (Rat) LD50: 100 mg/kg
- Intravenous (Rat) LD50: 5566 mg/kg
- Oral (Mouse) LD50: 4090 mg/kg
- Intraperitoneal (Mouse) LD50: 8700 mg/kg
- Subcutaneous (Mouse) LD50: 91 mg/kg
- Intravenous (Mouse) LD50: 4250 mg/kg

**IRRITATION**

At very high concentrations, evidence predicts that glycerol may cause tremor, irritation of the skin, eyes, digestive tract and airway. Otherwise it is of low toxicity. There is no significant evidence to suggest that it causes cancer, genetic, reproductive or developmental toxicity.

**SKIN**

glycerol GESAMP/EHS Composite List - GESAMP Hazard Profiles D1: skin 0 irritation/corrosion

Section 12 - ECOLOGICAL INFORMATION

GLYCEROL:

POVIDONE-IODINE:

DO NOT discharge into sewer or waterways.

POVIDONE-IODINE:

For Iodine: Iodine is an important element in studies of environmental protection and human health, global-scale hydrologic processes and nuclear non-proliferation. Inorganic and organic species that may be hydrophilic, atmophilic, and biophilic.

Terrestrial Fate: There was an appreciable iodate reduction to iodide, presumably mediated by the structural iron(II), in some clay minerals. Humic acid in soil promotes the electrochemical reduction of iodine(12) to ionic iodide. 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. Both soluble ferrous iron and sulfide, as well as iron monosulfide (FeS) were shown to abiotically 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. Iodine can be strongly retained in organic-rich surface soils and sediment. Soluble iodine may be associated with dissolved humic material. Iodine and iodate undergo a 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 (Verschueren 1983): 1.07692307
BOD5: 51%
COD: 95%

continued...
Section 12 - ECOLOGICAL INFORMATION

ThOD: 93%
For Glycerol: Log Kow: -2.66 to -2.47,
Aquatic Fate: Glycerol is considered to be readily biodegradable in the aquatic environment. Pre-adapted microorganisms can break glycerol down rapidly in oxygenated/low oxygen waters. The substance is not expected to react with water. When released to water, 100% of the substance will remain in the water compartment - only negligible amounts will be distributed to sediment.
Ecotoxicity: Glycerol is readily biodegradable. This substance is non-toxic to fish, including goldfish, algae, and bacteria, (Pseudomonas putida), and Daphnia magna water fleas. Glycerol is of low toxicity to aquatic organisms. Long-term aquatic toxicity data is not available. The substance is completely biodegradable and has a low potential to accumulate.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>povidone- iodine</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
<td>No Data</td>
</tr>
<tr>
<td>glycerol</td>
<td>LOW</td>
<td>No Data</td>
<td>LOW</td>
<td>HIGH</td>
</tr>
</tbody>
</table>

Section 13 - DISPOSAL CONSIDERATIONS

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common - the user should investigate:
• Reduction
• Reuse
• Recycling
• Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
• DO NOT allow wash water from cleaning or process equipment to enter drains.
• It may be necessary to collect all wash water for treatment before disposal.
• In all cases disposal to 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 licenced to accept chemical and / or pharmaceutical wastes or incineration in a licenced apparatus (after admixture with suitable combustible material).
• Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

continued...
Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:
None (ADG7)

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADG7, IATA, IMDG

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE
None

REGULATIONS

Regulations for ingredients

povidone-iodine (CAS: 25655-41-8) is found on the following regulatory lists;
"Australia - Victoria Drugs, Poisons and Controlled Substances (Precursor Chemicals) Regs 2007 - Schedule 1 - Precursor Chemicals and Quantities", "Australia Illicit Drug Precursors/Reagents - Category II", "Australia Inventory of Chemical Substances (AICS)", "Australia National Pollutant Inventory", "FisherTransport Information"

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

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

No data for Betadine Antiseptic Spray (CW: 63480)

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:
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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This is the end of the MSDS.