

Betadine Antiseptic Solution

Hazard Alert Code: MODERATE

Chemwatch Material Safety Data Sheet
Issue Date: 8-Jul-2008
A317LP

CHEMWATCH 14153
Version No:6.1.1.1
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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Betadine Antiseptic Solution

SYNONYMS

"povidone-iodine solution"

PRODUCT USE

Topical anti-infective antiseptic solution for antiseptics 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

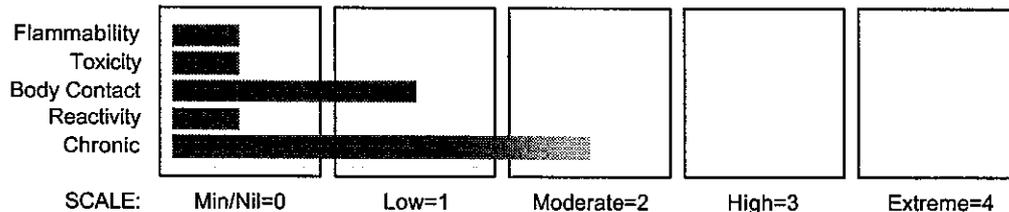
Company: Sanofi Consumer Healthcare Pty Ltd
Address:
87 Yarraman Place
Virginia
QLD, 4014
Australia
Telephone: +61 7 3212 8777
Emergency Tel: 1800 451 453
Fax: +61 7 3212 8643

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE

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

CHEMWATCH HAZARD RATINGS



RISK

•None under normal operating conditions.

SAFETY

•None under normal operating conditions.

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Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

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

Section 4 - FIRST AID MEASURES

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.
- 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

- 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.

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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 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.
- 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

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.
- Alert Fire Brigade and tell them location and nature of hazard.
- 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.

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Section 6 - ACCIDENTAL RELEASE MEASURES

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 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

Dropper bottles of 15mL. Bottles of 100mL, 500mL.

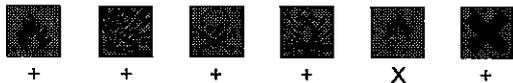
STORAGE INCOMPATIBILITY

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 storage and handling recommendations contained within this MSDS.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+: *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

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Source	Material	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	TWA F/CC	Notes
Australia Exposure Standards	glycerol (Glycerin mist (a))		10						(see Chapter 14)

The following materials had no OELs on our records

- povidone- iodine: CAS:25655- 41- 8
- water: CAS:7732- 18- 5

MATERIAL DATA

BETADINE ANTISEPTIC SOLUTION:

Not available

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:

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.

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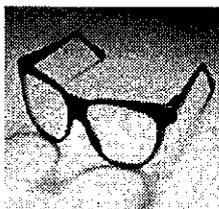
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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATOR

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

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

Liquid.

Mixes with water.

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

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.

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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.
In rare cases, skin contact may result in irritation during 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. Chronic use may increase blood iodine levels leading to altered thyroid function.

TOXICITY AND IRRITATION

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

BETADINE ANTISEPTIC SOLUTION:

- Not available. Refer to individual constituents.

POVIDONE-IODINE:

TOXICITY

Oral (rat) LD50:>8000 mg/k
Oral (rat) LD50:5990 mg/kg * [* = Manufacturer]
Dermal (human) TDLo: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.

IRRITATION

Skin (rabbit):500 mg Mild

GLYCEROL:

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Section 11 - TOXICOLOGICAL INFORMATION

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.

WATER:

■ No significant acute toxicological data identified in literature search.

SENSITISER

glycerol	IUCLID Photodegradation Data	Sensitiser	OH
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SKIN

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

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Section 12 - ECOLOGICAL INFORMATION

Algae IC50 (72hr.) (mg/l):	2900- 10000
log Kow (Sangster 1997):	- 1.76
log Pow (Verschueren 1983):	1.07692307
BOD5:	51%
COD:	95%
ThOD:	93%

For Glycerol: Log Kow: -2.66 to -2.47,

Atmospheric Fate: Glycerol is broken down in the air by hydroxyl radicals – the half-life for this process is 6.8 hours. However, only a negligible amount of the substance will move to the atmospheric compartment.
Terrestrial Fate: Only a negligible amount of glycerol will move into the soil compartment, if released into the environment.

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.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
povidone- iodine	No Data Available	No Data Available		
glycerol	LOW	No Data Available	LOW	HIGH

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 (ADG7)

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

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE

None

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Section 15 - REGULATORY INFORMATION

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"

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 National Pollutant Inventory", "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 - GESAMP Hazard Profiles", "IMO IBC Code Chapter 17: Summary of minimum requirements", "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", "International Council of Chemical Associations (ICCA) - High Production Volume List", "International Fragrance Association (IFRA) Survey: Transparency List", "OECD List of High Production Volume (HPV) Chemicals"

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

"Australia High Volume Industrial Chemical List (HVICL)", "Australia Inventory of Chemical Substances (AICS)", "IMO IBC Code Chapter 18: List of products to which the Code does not apply", "International Fragrance Association (IFRA) Survey: Transparency List", "OECD List of High Production Volume (HPV) Chemicals", "OSPAR National List of Candidates for Substitution - Norway"

No data for Betadine Antiseptic Solution (CW: 14153)

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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This is the end of the MSDS.