



# Pola Night 16% Carbamide Peroxide Gel

## SDI Limited

Version No: 9.1.1.1  
Safety Data Sheet according to WHS and ADG requirements

Issue Date: 01/11/2019  
Print Date: 02/10/2020  
L.GHS.AUS.EN

### SECTION 1 Identification of the substance / mixture and of the company / undertaking

#### Product Identifier

Product name	Pola Night 16% Carbamide Peroxide Gel
Synonyms	Not Available
Other means of identification	Not Available

#### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	To remove discoloration of teeth under the supervision of a dentist.
--------------------------	--

#### Details of the supplier of the safety data sheet

Registered company name	SDI Limited	SDI (North America) Inc.	SDi
Address	3-15 Brunsdon Street Bayswater VIC 3153 Australia	1279 Hamilton Parkway Itasca IL 60143 United States	Rua Dr. Virgílio de Carvalho Pinto, 612 Pinheiros, Sao Paulo 05415-020 Brazil
Telephone	+61 3 8727 7111 (Business Hours)	+1 630 361 9200 (Business hours) 1 800 228 5166	+55 11 3092 7100 (Business Hours)
Fax	+61 3 8727 7222	+1 630 361 9222	+55 11 3092 7101
Website	<a href="http://www.sdi.com.au">www.sdi.com.au</a>	<a href="http://www.sdi.com.au">http://www.sdi.com.au</a>	<a href="http://www.sdi.com.au/">http://www.sdi.com.au/</a>
Email	info@sdi.com.au	USA.Canada@sdi.com.au	Brasil@sdi.com.au

Registered company name	SDI Dental Limited
Address	Block 8, St Johns Court Santry Dublin 9 Ireland
Telephone	+353 1 886 9577 (Business Hours) 800 0225 5734
Fax	Not Available
Website	<a href="http://www.sdi.com.au/">http://www.sdi.com.au/</a>
Email	Ireland@sdi.com.au

#### Emergency telephone number


Association / Organisation	SDI Limited	SDi	SDI Dental Limited
Emergency telephone numbers	+61 3 8727 7111	+61 3 8727 7111	+61 3 8727 7111
Other emergency telephone numbers	ray.cahill@sdi.com.au	Not Available	Not Available

### SECTION 2 Hazards identification

#### Classification of the substance or mixture

Poisons Schedule	Not Applicable
Classification [1]	Eye Irritation Category 2A
Legend:	1. Classification by vendor; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### Label elements

Hazard pictogram(s)	
Signal word	Warning

#### Hazard statement(s)

H319	Causes serious eye irritation.
------	--------------------------------

#### Precautionary statement(s) Prevention

## Pola Night 16% Carbamide Peroxide Gel

<b>P280</b>	Wear protective gloves/protective clothing/eye protection/face protection.
-------------	--

### Precautionary statement(s) Response

<b>P305+P351+P338</b>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
<b>P337+P313</b>	If eye irritation persists: Get medical advice/attention.

### Precautionary statement(s) Storage

Not Applicable

### Precautionary statement(s) Disposal

Not Applicable

## SECTION 3 Composition / information on ingredients

### Substances

See section below for composition of Mixtures

### Mixtures

CAS No	%[weight]	Name
124-43-6	16	<u>urea hydrogen peroxide</u>
Not Available		equivalent to:
7722-84-1	5.3	<u>hydrogen peroxide</u>

## SECTION 4 First aid measures

### Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Immediately hold eyelids apart and flush the eye continuously with running water.</li> <li>▶ 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.</li> <li>▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>▶ Transport to hospital or doctor without delay.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately remove all contaminated clothing, including footwear.</li> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>If swallowed do NOT induce vomiting.</b></li> <li>▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>▶ Observe the patient carefully.</li> <li>▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>▶ Seek medical advice.</li> </ul>

### Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5 Firefighting measures

### Extinguishing media

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

### Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	None known.
-----------------------------	-------------

### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Non combustible.</li> <li>▶ Not considered a significant fire risk, however containers may burn.</li> </ul> <p>Decomposition may produce toxic fumes of:</p>

Continued...

## Pola Night 16% Carbamide Peroxide Gel

	nitrogen oxides (NOx) May emit poisonous fumes. May emit corrosive fumes.
<b>HAZCHEM</b>	Not Applicable

### SECTION 6 Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

See section 8

#### Environmental precautions

See section 12

#### Methods and material for containment and cleaning up

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid contact with skin and eyes.</li> <li>▶ Wear impervious gloves and safety goggles.</li> <li>▶ Trowel up/scrape up.</li> <li>▶ Place spilled material in clean, dry, sealed container.</li> <li>▶ Flush spill area with water.</li> </ul>
<b>Major Spills</b>	<p>Minor hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Control personal contact with the substance, by using protective equipment as required.</li> <li>▶ Prevent spillage from entering drains or water ways.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.</li> <li>▶ Wash area and prevent runoff into drains or waterways.</li> <li>▶ If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

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

### SECTION 7 Handling and storage

#### Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Other information</b>	<p>Store in a dry and well ventilated-area, away from heat and sunlight.  <b>Do not store in direct sunlight.</b>            Store between 2 and 25 deg C.</p>

#### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	▶ <b>DO NOT repack.</b> Use containers supplied by manufacturer only.
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid storage with reducing agents.</li> <li>▶ Avoid strong bases.</li> </ul>

### SECTION 8 Exposure controls / personal protection

#### Control parameters

##### Occupational Exposure Limits (OEL)

##### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	hydrogen peroxide	Hydrogen peroxide	1 ppm / 1.4 mg/m3	Not Available	Not Available	Not Available

##### Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
urea hydrogen peroxide	Urea peroxide; (Urea hydrogen peroxide)	1.2 mg/m3	13 mg/m3	79 mg/m3
hydrogen peroxide	Hydrogen peroxide	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH

Continued...

## Pola Night 16% Carbamide Peroxide Gel

Ingredient	Original IDLH	Revised IDLH
urea hydrogen peroxide	Not Available	Not Available
hydrogen peroxide	75 ppm	Not Available

## Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
urea hydrogen peroxide	E	≤ 0.01 mg/m <sup>3</sup>

**Notes:** Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

## MATERIAL DATA

## Exposure controls

Appropriate engineering controls	<p>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:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, wear 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.</p> <table border="1"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air).</td> <td>0.25-0.5 m/s (50-100 f/min)</td> </tr> <tr> <td>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)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min.)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td> <td>2.5-10 m/s (500-2000 f/min.)</td> </tr> </tbody> </table> <p>Within each range the appropriate value depends on:</p> <table border="1"> <thead> <tr> <th>Lower end of the range</th> <th>Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only.</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood-local control only</td> </tr> </tbody> </table> <p>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.</p>	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.)	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
	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.)																				
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																				
Personal protection																					
Eye and face protection	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles.</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses 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]</li> </ul>																				
Skin protection	See Hand protection below																				
Hands/feet protection	<ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> <li>▶ Rubber Gloves</li> </ul>																				
Body protection	See Other protection below																				
Other protection	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C apron.</li> <li>▶ Barrier cream.</li> <li>▶ Skin cleansing cream.</li> <li>▶ Eye wash unit.</li> </ul>																				

## Respiratory protection

## Pola Night 16% Carbamide Peroxide Gel

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

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	B-AUS	-	B-PAPR-AUS / Class 1
up to 50 x ES	-	B-AUS / Class 1	-
up to 100 x ES	-	B-2	B-PAPR-2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

### SECTION 9 Physical and chemical properties

#### Information on basic physical and chemical properties

<b>Appearance</b>	Clear gel with spearmint odour, mixes with water.		
<b>Physical state</b>	Gel	<b>Relative density (Water = 1)</b>	1.1
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	5.9-6.9	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Available
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Available	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Miscible	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available

### SECTION 10 Stability and reactivity

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	Product is considered stable and hazardous polymerisation will not occur.
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

### SECTION 11 Toxicological information

#### Information on toxicological effects

<b>Inhaled</b>	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.
<b>Ingestion</b>	The material has <b>NOT</b> 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 (e.g 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.
<b>Skin Contact</b>	Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

## Pola Night 16% Carbamide Peroxide Gel

<b>Eye</b>	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.	
<b>Chronic</b>	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.	
<b>Pola Night 16% Carbamide Peroxide Gel</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
<b>urea hydrogen peroxide</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Eye: adverse effect observed (irreversible damage) <sup>[1]</sup> Skin: adverse effect observed (irritating) <sup>[1]</sup>
<b>hydrogen peroxide</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	50 mg/kg <sup>[2]</sup>	Not Available
	500 mg/kg <sup>[2]</sup>	
	Dermal (rabbit) LD50: 4060 mg/kg <sup>[2]</sup>	
	Inhalation (rat) LC50: 2 mg/l/4H <sup>[2]</sup>	
	Oral (rat) LD50: =1193-1270 mg/kg <sup>[2]</sup>	
	Oral (rat) LD50: >225 mg/kg <sup>[2]</sup>	
	Oral (rat) LD50: >5000 mg/kg <sup>[2]</sup> Oral (rat) LD50: 1270 mg/kg <sup>[1]</sup>	
<b>Legend:</b>	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

<b>UREA HYDROGEN PEROXIDE</b>	No chronic human exposure data is available
<b>HYDROGEN PEROXIDE</b>	<p>For hydrogen peroxide: Hazard increases with peroxide concentration, high concentrations contain an additive stabiliser.</p> <p><b>Pharmacokinetics</b> Hydrogen peroxide is a normal product of metabolism. It is readily decomposed by catalase in normal cells. In experimental animals exposed to hydrogen peroxide, target organs affected include the lungs, intestine, thymus, liver, and kidney, suggesting its distribution to those sites. Hydrogen peroxide has been detected in breath.</p> <ul style="list-style-type: none"> <li>▶ Absorption: Hydrogen peroxide is decomposed in the bowel before absorption. When applied to tissue, solutions of hydrogen peroxide have poor penetrability.</li> <li>▶ Distribution: Hydrogen peroxide is produced metabolically in intact cells and tissues. It is formed by reduction of oxygen either directly in a two-electron transfer reaction, often catalysed by flavoproteins, or by an initial one-electron step to O<sub>2</sub> followed by dismutation to hydrogen peroxide.</li> <li>▶ Hydrogen peroxide has been detected in serum and in intact liver. based on the results of toxicity studies, the lungs, intestine, thymus, liver, and kidney may be distribution sites. In rabbits and cats that died after intravenous administration of hydrogen peroxide, the lungs were pale and emphysematous. Following intraperitoneal injection of hydrogen peroxide in mice, pyknotic nuclei were induced in the intestine and thymus (IARC 1985). Degeneration of hepatic and renal tubular epithelial tissue was observed following oral administration of hydrogen peroxide to mice.</li> <li>▶ Metabolism: Glutathione peroxidase, responsible for decomposing hydrogen peroxide, is present in normal human tissues (IARC 1985). When hydrogen peroxide comes in contact with catalase, an enzyme found in blood and most tissues, it rapidly decomposes into oxygen and water.</li> <li>▶ Excretion: Hydrogen peroxide has been detected in human breath at levels ranging from 1.0+/-0.5 g/L to 0.34+/-0.17 g/L.</li> </ul> <p><b>Carcinogenicity</b> Gastric and duodenal lesions including adenomas, carcinomas, and adenocarcinomas have been observed in mice treated orally with hydrogen peroxide. Marked strain differences in the incidence of tumors have been observed. Papilloma development has been observed in mice treated by dermal application.</p> <p><b>Genotoxicity</b> Hydrogen peroxide induced DNA damage, sister chromatid exchanges and chromosomal aberrations in mammalian cells <i>in vitro</i>. Hydrogen peroxide induced DNA damage in bacteria (<i>E. coli</i>), and was mutagenic to bacteria (<i>Salmonella typhimurium</i>) and the fungi, <i>Neurospora crassa</i> and <i>Aspergillus chevallieri</i>, but not to <i>Streptomyces griseoflavus</i>. It was not mutagenic to <i>Drosophila melanogaster</i> or to mammalian cells <i>in vitro</i>.</p> <p><b>Developmental Toxicity</b> Malformations have been observed in chicken embryos treated with hydrogen peroxide, but experiments with mice and rats have been negative. Female rats that received 0.45% hydrogen peroxide (equivalent to approximately 630 mg/kg/day)<sup>7</sup> as the sole drinking fluid for five weeks produced normal litters when mated with untreated males. Doses of 1.4 to 11 mol/egg hydrogen peroxide (purity 30%) dissolved in water were injected into the airspace of groups of 20-30 white leghorn chicken eggs on day 3 of incubation. Embryos were examined on day 14. The incidence of embryonic deaths and malformations was dose-related and detected at doses of 2.8 mol/egg and above. The combined ED50 was 2.7 mol/egg.</p> <p><b>Reproductive Toxicity</b> A 1% solution of hydrogen peroxide (equivalent to 1900 mg/kg/day) given as the sole drinking fluid to three-month-old male mice for 7-28 days did not cause infertility. The substance is classified by IARC as Group 3: <b>NOT</b> classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.</p>
<b>UREA HYDROGEN PEROXIDE &amp; HYDROGEN PEROXIDE</b>	No significant acute toxicological data identified in literature search.  Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt

## Pola Night 16% Carbamide Peroxide Gel

onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Acute Toxicity	✗	Carcinogenicity	✗
Skin Irritation/Corrosion	✗	Reproductivity	✗
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
 ✓ – Data available to make classification

## SECTION 12 Ecological information

## Toxicity

Pola Night 16% Carbamide Peroxide Gel	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

urea hydrogen peroxide	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	9-100mg/L	2
	EC50	48	Crustacea	2mg/L	2
	EC0	24	Crustacea	0.9mg/L	2
	NOEC	48	Crustacea	1.5mg/L	2

hydrogen peroxide	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	16.4mg/L	2
	EC50	48	Crustacea	2mg/L	2
	EC50	72	Algae or other aquatic plants	0.85mg/L	2
	NOEC	72	Algae or other aquatic plants	=0.1mg/L	1

**Legend:** *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

**DO NOT** discharge into sewer or waterways.

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
hydrogen peroxide	LOW	LOW

## Bioaccumulative potential

Ingredient	Bioaccumulation
hydrogen peroxide	LOW (LogKOW = -1.571)

## Mobility in soil

Ingredient	Mobility
hydrogen peroxide	LOW (KOC = 14.3)

## SECTION 13 Disposal considerations

## Waste treatment methods

Product / Packaging disposal	
	Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill.

## SECTION 14 Transport information

## Labels Required

Marine Pollutant	
	NO
HAZCHEM	
	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Continued...

## Pola Night 16% Carbamide Peroxide Gel

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

### SECTION 15 Regulatory information

#### Safety, health and environmental regulations / legislation specific for the substance or mixture

##### urea hydrogen peroxide is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals  
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 10 / Appendix C  
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6  
Australian Inventory of Industrial Chemicals (AIIC)

##### hydrogen peroxide is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals  
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 10 / Appendix C  
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6  
Australian Inventory of Industrial Chemicals (AIIC)  
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

#### National Inventory Status

National Inventory	Status
Australia - AIIC	Yes
Australia - Non-Industrial Use	No (urea hydrogen peroxide; hydrogen peroxide)
Canada - DSL	No (urea hydrogen peroxide)
Canada - NDSL	No (hydrogen peroxide)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (urea hydrogen peroxide)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	No (urea hydrogen peroxide)
Vietnam - NCI	Yes
Russia - ARIPS	Yes
<b>Legend:</b>	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

### SECTION 16 Other information

<b>Revision Date</b>	01/11/2019
<b>Initial Date</b>	09/11/2015

#### SDS Version Summary

Version	Issue Date	Sections Updated
8.1.1.1	16/08/2017	Ingredients
9.1.1.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by SDI Limited using available literature references.

The 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.

#### Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average  
PC—STEL: Permissible Concentration-Short Term Exposure Limit  
IARC: International Agency for Research on Cancer  
ACGIH: American Conference of Governmental Industrial Hygienists  
STEL: Short Term Exposure Limit  
TEEL: Temporary Emergency Exposure Limit.  
IDLH: Immediately Dangerous to Life or Health Concentrations  
OSF: Odour Safety Factor  
NOAEL :No Observed Adverse Effect Level

Continued...



**Pola Night 16% Carbamide Peroxide Gel**

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

The information contained in the Safety Data Sheet is based on data considered to be accurate, however, no warranty is expressed or implied regarding the accuracy of the data or the results to be obtained from the use thereof.

**Other information:**

Prepared by: SDI Limited

3-15 Brunson Street, Bayswater Victoria, 3153, Australia

Phone Number: +61 3 8727 7111

Department issuing SDS: Research and Development

Contact: Technical Director