



Pola Night 18% Carbamide Peroxide Gel

SDI Limited

Version No: 6.1.1.1

Safety Data Sheet (Conforms to Regulation (EC) No 2015/830)

Issue Date: 24/05/2016

Print Date: 31/05/2016

Initial Date: Not Available

L.REACH.GBR.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Product name	Pola Night 18% Carbamide Peroxide Gel
Synonyms	Not Available
Other means of identification	Not Available

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	To remove discoloration of teeth, to be performed by a dentist.
Uses advised against	Not Applicable

1.3. Details of the supplier of the safety data sheet

Registered company name	SDI Limited	SDI Brazil Industria E Comercio Ltda	SDI Germany GmbH
Address	3-15 Brunsdon Street VIC Bayswater 3153 Australia	Rua Dr. Virgilio de Carvalho Pinto, 612 São Paulo CEP 05415-020 Brazil	Hansestrasse 85 Cologne D-51149 Germany
Telephone	+61 3 8727 7111 (Business Hours)	+55 11 3092 7100	+49 0 2203 9255 0
Fax	+61 3 8727 7222	+55 11 3092 7101	+49 0 2203 9255 200
Website	www.sdi.com.au	www.sdi.com.au	www.sdi.com.au
Email	info@sdi.com.au	brasil@sdi.com.au	germany@sdi.com.au

Registered company name	SDI (North America) Inc.
Address	1279 Hamilton Parkway IL Itasca 60143 United States
Telephone	+1 630 361 9200 (Business hours)
Fax	Not Available
Website	Not Available
Email	USA.Canada@sdi.com.au

1.4. Emergency telephone number

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

Association / Organisation	Not Available
Emergency telephone numbers	+61 3 8727 7111
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes.


DSD classification	In case of mixtures, classification has been prepared by following DPD (Directive 1999/45/EC) and CLP Regulation (EC) No 1272/2008 regulations
DPD classification [1]	R36 Irritating to eyes.
Legend:	1. Classification by vendor; 2. Classification drawn from EC Directive 67/548/EEC - Annex I ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

Continued...

Pola Night 18% Carbamide Peroxide Gel

Classification according to regulation (EC) No 1272/2008 [CLP] ^[1]	Eye Irritation Category 2
Legend:	1. Classification by vendor; 2. Classification drawn from EC Directive 67/548/EEC - Annex I ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

2.2. Label elements

CLP label elements	
SIGNAL WORD	WARNING

Hazard statement(s)

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

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P280	Wear protective gloves/protective clothing/eye protection/face protection.
-------------	--

Precautionary statement(s) Response

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

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

2.3. Other hazards

Ingestion may produce health damage*.

Cumulative effects may result following exposure*.

RECh - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances

See 'Composition on ingredients' in Section 3.2

3.2. Mixtures

1.CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to directive 67/548/EEC [DSD]	Classification according to regulation (EC) No 1272/2008 [CLP]
1.124-43-6 2.204-701-4 3.Not Available 4.Not Available	18	urea <u>hydrogen</u> <u>peroxide</u>	R8, R20/22, R34, R41 ^[1]	Oxidizing Solid Category 3, Metal Corrosion Category 1, Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4, Skin Corrosion/Irritation Category 1B, Serious Eye Damage Category 1; H272, H290, H302, H332, H314, H318 ^[1]
		equivalent to:		
1.7722-84-1 2.231-765-0 3.008-003-00-9 4.01-2119485845-22-XXXX	6	<u>hydrogen</u> <u>peroxide</u>	R5, R8, R20/22, R35 ^[2]	Oxidizing Liquid Category 1, Acute Toxicity (Inhalation) Category 4, Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 1A; H271, H332, H302, H314 ^[3]
Legend:	1. Classification by vendor; 2. Classification drawn from EC Directive 67/548/EEC - Annex I ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI 4. Classification drawn from C&L			

SECTION 4 FIRST AID MEASURES

4.1. Description of first aid measures

General	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation. <p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ 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. ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
----------------	---

Continued...

Pola Night 18% Carbamide Peroxide Gel

	<ul style="list-style-type: none"> ▶ 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 Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ 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 Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ 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.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid any contamination of this material as it is very reactive and any contamination is potentially hazardous
-----------------------------	--

5.3. Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. <p>Decomposition may produce toxic fumes of; nitrogen oxides (NOx) carbon monoxide (CO) carbon dioxide (CO2)</p>

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	Wipe with absorbent towel. Wash with water (15 mins).
Major Spills	<p>Minor hazard.</p> <ul style="list-style-type: none"> ▶ 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 if risk of overexposure exists. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Contain spill/secure load if safe to do so. ▶ Bundle/collect recoverable product and label for recycling. ▶ Collect remaining product and place in appropriate containers for disposal. ▶ Clean up/sweep up area. Water may be required. ▶ If contamination of drains or waterways occurs, advise emergency services.

6.4. Reference to other sections

Pola Night 18% Carbamide Peroxide Gel

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

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ When handling DO NOT eat, drink or smoke. ▶ Always wash hands with soap and water after handling. ▶ Avoid physical damage to containers. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.
Fire and explosion protection	See section 5
Other information	Store between 2 and 25 deg C. Do not store in direct sunlight. Store in a dry and well ventilated-area, away from heat and sunlight.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	▶ DO NOT repack. Use containers supplied by manufacturer only.
Storage incompatibility	▶ Avoid strong bases.

7.3. Specific end use(s)

See section 1.2

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

DERIVED NO EFFECT LEVEL (DNEL)

Not Available

PREDICTED NO EFFECT LEVEL (PNEC)

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs)	hydrogen peroxide	Hydrogen peroxide	1.4 mg/m ³ / 1 ppm	2.8 mg/m ³ / 2 ppm	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/m ³	13 mg/m ³	79 mg/m ³
hydrogen peroxide	Hydrogen peroxide	Not Available	Not Available	Not Available
hydrogen peroxide	Hydrogen peroxide - 30%	33 ppm	170 ppm	330 ppm

Ingredient	Original IDLH	Revised IDLH
urea hydrogen peroxide	Not Available	Not Available
hydrogen peroxide	75 ppm	75 [Unch] ppm


MATERIAL DATA

8.2. Exposure controls

8.2.1. 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.</p> <p>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" style="width: 100%;"> <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> </tbody> </table>	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.)
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.)						

Continued...

Pola Night 18% Carbamide Peroxide Gel

	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)
Within each range the appropriate value depends on:		
Lower end of the range		Upper end of the range
1: Room air currents minimal or favourable to capture		1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.		2: Contaminants of high toxicity
3: Intermittent, low production.		3: High production, heavy use
4: Large hood or large air mass in motion		4: Small hood-local control only
<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>		
8.2.2. Personal protection		
Eye and face protection	<ul style="list-style-type: none"> ▶ 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 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] 	
Skin protection	See Hand protection below	
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber ▶ Rubber Gloves 	
Body protection	See Other protection below	
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. ▶ Eyewash unit. ▶ Ensure there is ready access to a safety shower. 	
Thermal hazards	Not Available	

Respiratory protection

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(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

8.2.3. Environmental exposure controls

See section 12

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Clear gel with spearmint odour, soluble in water.		
Physical state	Gel	Relative density (Water = 1)	1.1
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	5.9-6.9	Decomposition temperature	Not Available

Continued...

Pola Night 18% Carbamide Peroxide Gel

Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

9.2. Other information

Not Available

SECTION 10 STABILITY AND REACTIVITY

10.1.Reactivity	See section 7.2
10.2.Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Inhaled	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
Skin Contact	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.
Eye	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.
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Pola Night 18% Carbamide Peroxide Gel	TOXICITY	IRRITATION
	Not Available	Not Available
urea hydrogen peroxide	TOXICITY	IRRITATION
	Not Available	Not Available
hydrogen peroxide	TOXICITY	IRRITATION
	dermal (rat) LD50: 3000-5480 mg/kg ^[1]	Nil reported
	Inhalation (rat) LC50: 2 mg/L/4H ^[2]	
	Oral (rat) LD50: 75 mg/kg ^[1]	

Legend:

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

UREA HYDROGEN PEROXIDE	<p>No significant acute toxicological data identified in literature search.</p> <p>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 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. No chronic human exposure data is available</p>
------------------------	---

Continued...

Pola Night 18% Carbamide Peroxide Gel

HYDROGEN PEROXIDE	No significant acute toxicological data identified in literature search.	
	<p>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 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.</p> <p>For hydrogen peroxide: Hazard increases with peroxide concentration, high concentrations contain an additive stabiliser.</p> <p>Pharmacokinetics 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"> ▶ Absorption: Hydrogen peroxide is decomposed in the bowel before absorption. When applied to tissue, solutions of hydrogen peroxide have poor penetrability. ▶ 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 O₂ followed by dismutation to hydrogen peroxide. ▶ 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. ▶ 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. ▶ Excretion: Hydrogen peroxide has been detected in human breath at levels ranging from 1.0+/- .5 g/L to 0.34+/-0.17 g/L. <p>Carcinogenicity 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>Genotoxicity 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>Developmental Toxicity 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) 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>Reproductive Toxicity 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: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.</p>	

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 available but does not fill the criteria for classification
✔ – Data required to make classification available
☹ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
hydrogen peroxide	LC50	96	Fish	0.020mg/L	3
hydrogen peroxide	EC50	3	Algae or other aquatic plants	0.27mg/L	4
hydrogen peroxide	EC50	48	Crustacea	2.32mg/L	4
hydrogen peroxide	EC50	72	Algae or other aquatic plants	0.71mg/L	4
hydrogen peroxide	NOEC	192	Fish	0.028mg/L	4

Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - 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.

12.2. Persistence and degradability

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

Continued...

Pola Night 18% Carbamide Peroxide Gel

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
hydrogen peroxide	LOW (LogKOW = -1.571)

12.4. Mobility in soil

Ingredient	Mobility
hydrogen peroxide	LOW (KOC = 14.3)

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT Criteria fulfilled?	Not Available	Not Available	Not Available

12.6. Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product / Packaging disposal	Consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Decontaminate empty containers.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

14.1. UN number	Not Applicable
14.2. Packing group	Not Applicable
14.3. UN proper shipping name	Not Applicable
14.4. Environmental hazard	Not Applicable
14.5. Transport hazard class(es)	Class : Not Applicable Subrisk : Not Applicable
14.6. Special precautions for user	Hazard identification (Kemler) : Not Applicable Classification code : Not Applicable Hazard Label : Not Applicable Special provisions : Not Applicable Limited quantity : Not Applicable

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

14.1. UN number	Not Applicable
14.2. Packing group	Not Applicable
14.3. UN proper shipping name	Not Applicable
14.4. Environmental hazard	Not Applicable
14.5. Transport hazard class(es)	ICAO/IATA Class : Not Applicable ICAO / IATA Subrisk : Not Applicable ERG Code : Not Applicable
14.6. Special precautions for user	Special provisions : Not Applicable Cargo Only Packing Instructions : Not Applicable Cargo Only Maximum Qty / Pack : Not Applicable Passenger and Cargo Packing Instructions : Not Applicable

Pola Night 18% Carbamide Peroxide Gel

	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable

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

14.1. UN number	Not Applicable	
14.2. Packing group	Not Applicable	
14.3. UN proper shipping name	Not Applicable	
14.4. Environmental hazard	Not Applicable	
14.5. Transport hazard class(es)	IMDG Class	Not Applicable
	IMDG Subrisk	Not Applicable
14.6. Special precautions for user	EMS Number	Not Applicable
	Special provisions	Not Applicable
	Limited Quantities	Not Applicable

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. Packing group	Not Applicable	
14.3. UN proper shipping name	Not Applicable	
14.4. Environmental hazard	Not Applicable	
14.5. Transport hazard class(es)	Not Applicable	Not Applicable
14.6. Special precautions for user	Classification code	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Equipment required	Not Applicable
	Fire cones number	Not Applicable

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

Not Applicable

SECTION 15 REGULATORY INFORMATION**15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture****UREA HYDROGEN PEROXIDE(124-43-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

European Customs Inventory of Chemical Substances ECICS (English)

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

HYDROGEN PEROXIDE(7722-84-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

EU REACH Regulation (EC) No 1907/2006 - Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

European Customs Inventory of Chemical Substances ECICS (English)

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances - updated by ATP: 31

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Air Transport Association (IATA) Dangerous Goods Regulations - Prohibited List Passenger and Cargo Aircraft

UK Workplace Exposure Limits (WELs)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments as well as the following British legislation: - The Control of Substances Hazardous to Health Regulations (COSHH) 2002 - COSHH Essentials - The Management of Health and Safety at Work Regulations 1999

15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier	
urea hydrogen peroxide	124-43-6	Not Available	Not Available	
Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)		Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Ox. Sol. 3, Skin Corr. 1B		GHS05, GHS03, Dgr	H272, H314
2	Ox. Sol. 3, Skin Corr. 1B, Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, STOT SE 3, Ox. Sol. 2		GHS05, GHS03, Dgr	H272, H314, H302, H318, H335

Continued...

Pola Night 18% Carbamide Peroxide Gel

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
hydrogen peroxide	7722-84-1	008-003-00-9	01-2119485845-22-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Ox. Liq. 1, Acute Tox. 4, Skin Corr. 1A	GHS07, GHS05, GHS03, Dgr	H271, H302, H314, H332
2	Ox. Liq. 1, Acute Tox. 4, Skin Corr. 1A, Eye Dam. 1, STOT SE 3, Aquatic Chronic 3, Ox. Liq. 2, Acute Tox. 3, Flam. Liq. 2, Skin Corr. 1B, Acute Tox. 2, Met. Corr. 1, Aquatic Chronic 2, Not Classified, Skin Irrit. 2, Eye Irrit. 2	GHS05, GHS03, Dgr, GHS02, GHS06, GHS09, Wng	H271, H314, H335, H318, H225, H301, H330, H290

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (urea hydrogen peroxide)
Canada - NDSL	N (hydrogen peroxide)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (urea hydrogen peroxide)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y

Legend:
 Y = All ingredients are on the inventory
 N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Full text Risk and Hazard codes

H225	Highly flammable liquid and vapour.
H271	May cause fire or explosion; strong oxidiser.
H272	May intensify fire; oxidiser.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
R20/22	Harmful by inhalation and if swallowed.
R34	Causes burns.
R35	Causes severe burns.
R41	Risk of serious damage to eyes.
R5	Heating may cause an explosion.
R8	Contact with combustible material may cause fire.

Other information

DSD / DPD label elements



Relevant risk statements are found in section 2.1

Indication(s) of danger	Xi

SAFETY ADVICE

S02	Keep out of reach of children.
S23	Do not breathe the gas/fumes/vapour/spray.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.

Continued...

Pola Night 18% Carbamide Peroxide Gel

S35	This material and its container must be disposed of in a safe way.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water.
S46	If swallowed, seek medical advice immediately and show this container or label.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

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
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