



1. Identification of the substance/mixture and of the Company/undertaking:

1.1 Product identifier:

Product Names: Pola Night 10% Carbamide Peroxide Gel;
Pola Night 16% Carbamide Peroxide Gel.

1.2 Relevant identified use:

Relevant use: Dental Use:
To remove discoloration of teeth under the supervision of a dentist.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer / Supplier

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2. Hazard Identification

Classification of the substance/mixture:

Classification according to GHS for hazardous substances:

Pola Night 10% is NOT classified as a hazardous substance. Read directions before use and keep out of reach of children., and use personal protection as specified.

Pola Night 16% is classified HAZARDOUS as an eye irritant as follows:



2. Hazard Identification

Pola Night 16%:

Signal word: **WARNING**



Exclamation mark

GHS Classification:
Eye Irrit. 2

Precautionary phrases:

H319 Causes serious eye irritation

Prevention:

P264 Wash skin thoroughly after handling.
P280 Wear eye protection/face protection.

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.
P101 If medical advice is needed, have product packaging and leaflet at hand.
P102 Keep out of reach of children
P103 Read instructions before use.

3 Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>	<u>EC No.</u>	<u>Index No.</u>
Carbamide Peroxide Gel				
Carbamide peroxide	124-43-6	10.0 - 16.0	204-701-4	
<i>equivalent to:</i> hydrogen peroxide	7722-84-1	4.0 - 6.0	231-765-0	008-003-00-9

Hazard classification: Hydrogen peroxide: Eye Irrit 2; H319; 5% ≤ C < 8%



4. First Aid Measures

Eye (contact):	Flush opened eye with running water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing Seek medical attention.
Skin (contact):	Remove contaminated clothing. Wash skin with plenty of water.
Ingestion:	Do NOT induce vomiting, drink lots of water/milk. Seek medical attention.
Inhalation:	Side effects not expected.
Most important effects, acute and delayed:	The most important known symptoms and effects are described in section 2 and/or in section 11.
Indication of any immediate medical attention and special treatment needed:	No data available.

5. Fire Fighting Measures

Suitable extinguishing media:	Water spray, dry chemical, carbon dioxide, protein type air foams.
Unusual Fire and Explosion Hazards:	Heat may generate irritating vapours, e.g. CO, CO ₂ . acrylate monomers and hydrocarbons.
Unsuitable extinguishing media:	Do not use extinguishing media for organic compounds.
Specific hazards arising from the mixture:	The product itself does not burn. In the event of fire, product may decompose and release oxygen, irritating vapours, e.g. CO, CO ₂ . acrylate monomers and hydrocarbons. Incompatible materials: Avoid contact with metals, metallic salts, alkalis, flammable substances, and organic solvents.
Special protective equipment:	Wear approved respiratory and protective gear. Use spray to cool containers.
Advice for firefighters:	Wear self contained breathing apparatus for fire fighting if necessary.

6. Accidental Release Measures

Personal precautions:	Do not get into eyes, on skin or clothing. Use personal protective equipment. Wash thoroughly after handling. For personal protection see section 8.
Environmental precautions:	Prevent any spillage from entering waterways, drains or sewage system.
Methods for cleaning and containment:	Mop up using absorbent paper or towel. Wash the spillage area clean with water.
Removal of ignition sources, provision of sufficient ventilation, control of dust:	Remove sources of ignition.



7. Handling and storage

Precautions for safe handling: Care required when handling Carbamide Peroxide mixtures.

Conditions for safe storage, including any biocompatibilities:

Storage by the end user (Dental Clinic) is recommended to be at temperatures between 2 ° - 25°C (35° - 77°F) and should be kept away from direct sunlight.

Distribution:

During distribution, to our customers, this product can be transported in non-refrigerated conditions between 15° to 25° C. This product can also withstand temperatures up to 40° C for short periods (2 to 3 days) and intermittent peaks up to 50°C.

Specific end use:

Apart from the use mentioned in section 1.2, there are no other uses for the product.

8. Exposure controls / personal protection

Control parameters:

Occupational exposure limits (NOHSC, NIOSH, OSHA,):

Standard name	Cas No	TWA (ppm)	TWA (mg/m ³)	STEL (ppm)	STEL (mg/m ³)
Urea hydrogen peroxide (carbamide peroxide)	124-43-6	Not listed	Not listed	Not listed	Not listed
Hydrogen peroxide	7722-84-1	1	1.4	-	-

NOHSC – National Occupation Health and Safety Commission

NIOSH – National Institute for Occupation Safety and Health

OSHA – Occupational Health and Safety Authority

TWA – Time weighted average

STEL – Short term exposure limit

Appropriate engineering controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at end of workday.

Personal protective equipment:

Respiratory protection: Not required under normal conditions of use.

Hand protection: Rubber, latex or PVC gloves.

Eye protection: Safety glasses, goggles or face shield.

General safety and hygiene measures: Eye bath Wash thoroughly after handling. Wash contaminated clothing before re-use.
Follow good housekeeping practices and good industrial hygiene in handling this material.



9. Physical and chemical properties

Appearance:	Clear gel
Odour:	Spearmint
Boiling point:	Not applicable
Melting point:	Not applicable
Specific gravity:	1.1
Flash point:	Not applicable
Flammable:	Not flammable
Autoflammability:	Does not self ignite
Explosive properties:	Does not present an explosion hazard
Oxidising properties:	Strong oxidiser
Vapour pressure (@ 20°C):	Not established
Relative density:	Not established
Solubility:	Soluble in water
Auto-ignition temperature:	Not established
Decomposition temperature:	> 25°C
pH:	5.9 – 6.9

10. Stability and Reactivity

Reactivity:	Product is stable under directed Instructions for use and storage.
Chemical Stability:	Carbamide peroxide Liquid is easily decomposed. Stable under normal conditions of storage and use as per label/instructions.
Conditions to avoid:	Heat and sunlight
Materials to avoid:	Metals, strong bases and organic solvents
Hazardous decomposition products:	None under normal conditions.
Hazardous reactivity (polymerization):	Will not occur.

11. Toxicological information

LD50/LC50 Carbamide peroxide:	No data available.
Acute toxicity:	Pola Night 16% is an irritant/damaging to eyes. May be irritant to mucous membranes and skin.
Serious eye damage/irritation:	Pola Night 16% is irritant to eyes.
Skin corrosion/irritation:	No side effects expected for small amounts. May be irritant to mucous membranes and skin.
Ingestion:	No side effects expected for small amounts.



11. Toxicological information

Respiratory or skin sensitisation:	None expected.
Germ cell mutagenicity:	No data available.
Carcinogenicity:	
IARC:	Urea Hydrogen peroxide – Not listed as a carcinogen by IARC.. (IARC: International Agency for Research on Cancer, by the World Health Organisation (WHO)).
Reproductive toxicity:	No data available.
Specific target organ toxicity – single exposure:	May cause irritation to eyes, skin and inhalation.
Specific target organ toxicity – repeated exposure:	No data available.
Aspiration hazard:	No data available.

12. Ecological information

Self assessment:	Slightly hazardous for water. Do not allow large quantities to reach sewage systems and waterways.
Ecotoxicity:	No data available.
Persistence and biodegradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and VPvB assessment:	PBT/VPvB assessment not available as chemical safety assessment not required/not conducted.
Other adverse effects (such as hazardous to ozone layer):	No data available.

13. Disposal considerations

Dispose of in accordance with local official regulations.	
Contaminated packaging:	Dispose of contaminated packaging as hazardous waste in accordance with local official regulations.



14. Transport information

Not classified as a dangerous good for transport by road/rail, air and sea.

15. Regulatory information

Pola Night 10% and 16% are classified according to the Australian SUSMP - *Standard for the Uniform Scheduling of Medicines and Poisons*, as follows:

Schedule 5 - CAUTION

16. Other information

The information provided herein is given in good faith, but no warranty expressed or implied is made.

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Department issuing SDS: Research and Development

Contact: R&D Director
