



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

1.1 Product identifier:

Product Names: Pola Night 18% and Pola Night 22% Carbamide Peroxide Gel

1.2 Relevant identified use:

Relevant use:

Dental Use: To remove discoloration of teeth, to be performed by 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:

Hazard Classification according to GHS:

Pola Night 18% and Pola Night 22% are classified as hazardous as follows:

POLA NIGHT 18%

Signal word: WARNING



Exclamation mark

2. Hazard Identification

GHS Classification: Eye Irrit. (Category 2)

Precautionary phrases:

Hazard statement:

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 & leaflet at hand.

P102

Keep out of reach of children.

P103

Read instructions before use.

POLA NIGHT 22%

Signal word: DANGER



Corrosion

GHS Classification: Eye Dam. (Category 1)

Hazard statement:

H318 Causes serious eye damage.

Prevention:

P280 Wear eye protection/face protection.

P264 Wash skin thoroughly after handling

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.

P310

Immediately call a POISON CENTRE or doctor/physician.

P102

Keep out of reach of children.

P103

Read instructions before use.

Other: Pola Night 18% and Pola Night 22% are irritating/damaging to eyes, and may be irritating to skin and mucous membranes.



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 (urea peroxide)	124-43-6	18.0-22.0	204-701-4	-
<i>equivalent to:</i>				
Hydrogen peroxide	7722-84-1	7.0-8.0	231-765-0	008-003-00-9

Hazard classification (hydrogen peroxide): Eye Irrit 2; H319; $5\% \leq C < 8\%$
Eye Dam. 1; H318; $8\% \leq C < 50\%$

4. First Aid Measures

Eye (contact): Immediately flush open eyes with running water for at least 15 minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek urgent medical attention. Make sure the patient's, dentist's and auxiliary's eyes are protected.

Skin (contact): Remove contaminated clothing. If skin or hair contact occurs, wash skin and hair with running water. Skin may appear temporarily bleached white. Seek medical attention.

Ingestion: Do NOT induce vomiting, drink lots of water/milk. Seek immediate medical attention.

Inhalation: Side effects not expected. Remove victim from exposure to fresh air. If rapid recovery does not occur or if feeling unwell, seek urgent medical attention.

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, CO₂. acrylate monomers and hydrocarbons.

Unsuitable extinguishing media: Do not use extinguishing media for organic compounds.



5. Fire Fighting Measures

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. 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.

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: Follow

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

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



9. Physical and chemical properties

Solubility:	Soluble in water
Auto-ignition temperature:	Not established
Decomposition temperature:	> 25°C
Initial boiling point and boiling range:	Not established
pH:	5.9 - 6.9

10. Stability and Reactivity

Reactivity:	Product is stable under directed instructions for use and storage.
Chemical Stability:	Hydrogen Peroxide Liquid is easily decomposed. Stable under normal conditions of use and storage as indicated on label/instructions for use.
Conditions to avoid:	Heat and direct 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 18% is irritating to eyes, and Pola Night 22% is damaging to eyes. May be irritant to mucous membranes and skin.
Serious eye damage/irritation:	Pola Night 22% is damaging to the eyes. Pola Night 18% is irritating 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.
Respiratory or skin sensitisation:	None expected.
Germ cell mutagenicity:	No data available.



11. Toxicological information

Carcinogenicity:
(according to IARC, MAK, NTP, OSHA, and ACGIH):

Hydrogen peroxide – Group 3 – not classifiable as to its carcinogenicity to humans.

(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

IATA/ICAO: Carbamide peroxide, aqueous solution.

Proper shipping name Urea Hydrogen peroxide UN1511 Packing Group III Class 5.1 sub-risk Class 8.

If packed in Chemical kits the following classification may be considered if all ICAO/IATA transport requirements are met:

Chemical Kit UN3316 - Class 9.

Not classified as dangerous goods for sea transport.

15. Regulatory information

Pola Night 18% is classified according to the Australian SUSMP - *Standard for the Uniform Scheduling of Medicines and Poisons*, as follows:

Schedule 5 - CAUTION

Pola Night 22% is classified according to the Australian SUSMP - *Standard for the Uniform Scheduling of Medicines and Poisons*, as follows:

Schedule 6 - POISON

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

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