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

1.1 Product identifier:

Product Name: PolaZing

1.2 Relevant identified use:

Relevant use: Dental use: For whitening of teeth by dental professionals.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer / Supplier

SDI Limited 3-13 Brunsdon Street, Bayswater Victoria, 3153, Australia SDI (North America) Inc. 1279 Hamilton Parkway Itasca, IL 60143, USA

Telephone:

+61 3 8727 7111 (Business hours)

<u>Telephone</u>:

+1 630 361 9200 (Business hours)

Southern Dental Industries Ltd Block 8, St Johns Court Swords Road

Santry, Dublin 9, Ireland

SDI Brasil Indústria e Comércio Ltda Rua Dr. Virgílio de Carvalho Pinto, 612 Pinheiros, São Paulo, 05415-020

Brasil

Telephone:

<u>Telephone</u>:

+353 1 886 9577 (Business Hours) + 55 11 3092 7100 (Business Hours)

Emergency contact number: +61 3 8727 7111

Email: ray.cahill@sdi.com.au (Technical Director, SDI Limited)

2. Hazard Identification

Classification of the substance/mixture:

Hazard classification according to GHS as follows:

Signal word: DANGER



Corrosion

GHS Classification: Eye Dam. (Category 1)

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2. Hazard Identification

Precautionary statements:

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.

-____

3. Composition / Information on ingredients

Composition:	<u>CAS No.</u>	Wt. %	EC No.	I <u>ndex No.</u>
Carbamide peroxide (urea peroxide) equivalent to:	124-43-6	350	-	-
hydrogen peroxide	7722-84-1	13.0	231-765-0	008-003-00-9
			4 11240 00	· · · · · · · · · · · · · · · · · · ·

Hazard classification: Hydrogen peroxide: Eye Dam. 1; H318: $8\% \le C < 50\%$

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 if irritation develops.

Ingestion: Do NOT induce vomitiing, drink plenty 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.

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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.

Specific hazards arising from the

mixture (i.e. Nature of any combustion products):

The product itself does not burn. In the event of fire, product may decompose and release oxygen and irritating

vapours, e.g. CO, CO₂. acrylate monomers and

hydrocarbons..

Incompatible materials: Avoid contact with metals, metallic salts, alkalis, flammable substances, and organic solvents.

Special protective equipment: Wear approved self-contained breathing apparatus, full

protective clothing long with protective equipment.

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

<u>Precautions for safe handling:</u> Replace caps immediately after use.

Care required when handling carbamide

peroxide mixtures.

Conditions for safe storage, including any biocompatibilities:

Store in a cool, dry place at temperatures between 2° and

8°C (35° - 45°F). Keep away from direct sunlight.

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

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Control parameters:

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

Standard name	Cas No	TWA (ppm)	TWA (mg/m ³)	STEL (ppm)	STEL (mg/m³)
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

OHSA – 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

9. Physical and chemical properties

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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: Stable under normal conditions.

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: May be irritating/harmful to skin and mucous membrane.

Serious damage to eyes.

Serious eye damage/irritation: Serious damage to eyes.

Skin corrosion/irritation: May be irritating to skin.

Respiratory or skin sensitisation: No side effects expected.

Ingestion: May be harmful to mucous membrane.

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

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Self assessment: Slightly hazardous for water. Do not allow large quantities to

reach sewage systems and waterways.

Ecotoxicity: No data available.

Persistence and biodegradeability: 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

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 good for transport by sea.

15. Regulatory information

This product is regulated by: Medical Devices Directive 93/42/EEC

National regulations

16. Other information

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

Prepared by: SDI Limited Phone Number: 3-13 Brunsdon Street, Bayswater +61 3 8727 7111

Victoria 21E2 Australia

Victoria, 3153, Australia

Australia

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Department issuing SDS: Research and Development

Contact: R&D Director