

SAFETY DATA SHEET

Prep Creme 15%

1. MATERIAL AND SUPPLY COMPANY IDENTIFICATION

Product Name:	Prep Creme 15%
Product Codes:	DL0501- Endosure Prep Creme 15% 20g vial
Recommended Use:	Used in endodontic procedures.
Contact Information:	Dentalife Australia Pty. Ltd. Factory 9/505 Maroondah Highway Ringwood, VIC, 3134, Australia Phone: +61 3 9879 1226
Emergency Telephone Number:	+61 3 9879 1226
Poisons Information Centre:	24 hour, 7 days a week in an emergency call: 13 11 26

2. HAZARD IDENTIFICATION

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

Signal Word: Warning

Hazard Pictograms:



Hazard Classifications: Skin Corrosion/Irritation Category 1B, Serious Eye Damage/Eye Irritation Category 1, Acute Toxicity (Oral) Category 4, Chronic Aquatic Hazard Category 3

Hazard Statement: H314 Causes severe skin burns and eye damage.
H302 Harmful if swallowed.
H412 Harmful to aquatic life with long lasting effects.

Prevention Precautionary Statements: P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment



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Response Precautionary Statements:	P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. 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 CENTER/doctor/... P363 Wash contaminated clothing before reuse. P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Storage Precautionary Statements:	P403+P233 Store in a well-ventilated place. Keep container tightly closed. P403+P235 Store in a well-ventilated place. Keep cool.
Disposal Precautionary Statements:	P501 Dispose of contents/container in accordance with local, regional, national, and international regulations.
Poison Schedule:	Not Applicable

DANGEROUS GOOD CLASSIFICATION

Not classified as Dangerous Goods by the criteria of the "Australian Code for the Transport of Dangerous Goods by Road & Rail" and the "New Zealand NZS5433: Transport of Dangerous Goods on Land".

3. COMPOSITION INFORMATION

CHEMICAL ENTITY	CAS NO.	PROPORTION %
Cetyl Alcohol	36653-82-4	10-15
Edetic acid	60-00-4	15
Urea Hydrogen Peroxide	124-43-6	10
Balance of ingredients (non-hazardous)	-	60-65

4. FIRST AID MEASURES

If poisoning occurs, contact a doctor or Poisons Information Centre (Phone Australia 131 126, New Zealand 0800 764 766).

Inhalation:	If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Transport to hospital, or doctor.
Skin Contact:	Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre.

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Eye Contact:	If this product comes in contact with the eyes: Immediately hold eyelids apart and flush the eye continuously with 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. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. Transport to hospital or doctor without delay. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Ingestion:	For advice, contact a Poisons Information Centre or a doctor at once. Urgent hospital treatment is likely to be needed. 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. Transport to hospital or doctor without delay.
Indication of any immediate medical attention:	Treat symptomatically.

5. FIRE FIGHTING MEASURES

Extinguishing media:	Alcohol stable foam. Dry chemical powder. Carbon dioxide. Water spray or fog - large fires only.
Fire incompatibility:	Avoid contamination with oxidising agents i.e., nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
Hazchem Code:	Not applicable
Fire Fighting:	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 firefighting 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.

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Fire/Explosion Hazard:

Combustible. Will burn if ignited.

Combustion products include:

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- nitrogen oxides (NO_x)
- other pyrolysis products typical of burning organic material.

May emit poisonous fumes. May emit corrosive fumes.

6. ACCIDENTAL RELEASE MEASURES

Minor Spills:

Clean up all spills immediately.

Avoid breathing vapours and contact eyes.

Contain and absorb spill with sand, earth, inert material, or vermiculite. Wipe up.

Place in a suitable, labelled container for waste disposal.

Flush spill area with water.

**Dangerous Goods -Initial Emergency
Response Guide No:**

Not applicable

7. HANDLING AND STORAGE

Handling:

Avoid all personal contact, including inhalation.

Wear protective clothing when risk of exposure occurs.

Use in a well-ventilated area.

Prevent concentration in hollows and sumps.

DO NOT allow material to contact humans, exposed food or food utensils.

Avoid contact with incompatible materials.

When handling, DO NOT eat, drink or smoke.

Keep containers securely sealed when not in use.

Avoid physical damage to containers.

Always wash hands with soap and water after handling.

Work clothes should be laundered separately. Launder contaminated clothing before re-use.

Use good occupational work practice.

Observe manufacturer's storage and handling recommendations contained within this SDS.

Other information:

Store in original containers.

Keep containers securely sealed.

Store in a cool, dry, well-ventilated area.

Store away from incompatible materials and foodstuff containers.

Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS.

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Suitable container:

Check all containers are clearly labelled and free from leaks.



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X – Must not be stored together
0 – May be stored together with specific preventions
+ – May be stored together

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limits (OEL)

INGREDIENT DATA: Not Available

Emergency Limits:

Ingredient	TEEL-1	TEEL-2	TEEL-3
Cetyl Alcohol	1.6 mg/m ³	18 mg/m ³	110 mg/m ³
EDTA	4.1 mg/m ³	45 mg/m ³	200 mg/m ³
Urea Hydrogen Peroxide	1.2 mg/m ³	13 mg/m ³	79 mg/m ³

Ingredient	Original IDLH	Revised IDLH
Cetyl Alcohol	Not Available	Not Available
EDTA	Not Available	Not Available
Urea Hydrogen Peroxide	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
EDTA disodium salt	E	≤ 0.01 mg/ m ³
Cetrmidie	E	≤ 0.01 mg/ m ³

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.

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Personal Protection:



Eye and Face Protection:

Chemical goggles.
Full face shield may be required for supplementary but never for primary protection of eyes.
Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.
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 (Hands/Feet):

Wear chemical protective gloves, e.g. PVC.
When handling corrosive liquids, wear trousers or overalls outside of boots, to avoid spills entering boots.
The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
· Contaminated gloves should be replaced.

Other Protection:

Overalls.
PVC Apron.
PVC protective suit may be required if exposure severe.
Eyewash unit.
Ensure there is ready access to a safety shower.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	Non-Slump Paste
Colour:	Not available
Odour:	Not available
Solubility:	Partially soluble in water
Specific gravity:	Not available
Relative Vapor Density (water=1)	>1
Vapour Pressure (20 °C):	Not available
Flash Point (°C):	Not available
Flammability Limits (%):	Not flammable
Autoignition Temperature (°C):	Not available
Melting Point/Range (°C):	Not available

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Boiling Point/Range (°C):	Not available
pH:	Not available
Viscosity:	Not available
Total VOC (g/Litre):	Not available

10. STABILITY AND REACTIVITY

Chemical Stability:	Unstable in the presence of incompatible material. Product is considered stable. Hazardous polymerisation will not occur.
Conditions to Avoid:	See section 7
Incompatible Materials:	See section 7
Hazardous Decomposition Products:	See section 5
Hazardous Reactions:	See section 7

11. TOXICOLOGICAL INFORMATION

No adverse health effects expected if the product is handled in accordance with this Safety Data Sheet and the product label. Symptoms or effects that may arise if the product is mishandled and overexposure occurs are:

Inhalation:	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.
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.
Ingestion:	Accidental ingestion of the material may be harmful.
Eye Contact:	The material can produce chemical burns to the eye following direct contact. Vapours or mists may be extremely irritating.

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Chronic: Repeated or prolonged exposure to corrosives may result in the erosion of teeth, inflammatory and ulcerative changes in the mouth and necrosis (rarely) of the jaw. Bronchial irritation, with cough, and frequent attacks of bronchial pneumonia may ensue. Gastrointestinal disturbances may also occur. Chronic exposures may result in dermatitis and/or conjunctivitis. Minor reactions resembling those produced by histamine or the common cold are sometimes seen. Parenteral administration of EDTA and its salts in high doses may produce severe renal lesions with tubular necrosis, internal haemorrhage, transient bone marrow depression and life-threatening hypocalcaemia. Prolonged parenteral exposures produce electrolyte imbalance and possible cardiac arrhythmias. Prolonged or repeated skin contact may result in irritation.

Toxicity:

Canal Prep 15%:

Not available

Cetyl alcohol:

Dermal (rabbit) LD50: >1660 mg/kg
Inhalation(Rat) LC50: >0.237 mg/l4h
Oral (Rat) LD50: >6.098 mg/kg

EDTA:

Oral(Rat) LD50: >2000 mg/kg

Urea hydrogen peroxide:

Dermal (rabbit) LD50: 700 mg/kg
Oral (Mouse) LD50: 11500 mg/kg

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.

Acute Toxicity:

Skin irritation/Corrosion:

May produce severe skin irritation after prolonged or repeated exposure

Respiratory or Skin Sensitisation:

Carcinogenicity:

Not considered to be carcinogenic.

Mutagenicity:

Not considered to be mutagenic.

Reproductivity:

Not considered to be toxic to reproduction.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No information available

Persistence and Degradability:

No data available

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Bioaccumulation Potential:	Cetyl alcohol: HIGH (LogKOW=6.7342) EDTA: LOW(BCF=123)
Mobility:	Cetyl alcohol: LOW (KOC=3786) EDTA: LOW (KOC = 1046)
Environmental Protection:	Prevent this material entering waterways, drains and sewers.

13. DISPOSAL CONSIDERATIONS

Disposal Method:	Dispose of in accordance with all local, state and federal regulations. All empty packaging should be disposed of in accordance with Local, State, and Federal Regulations or recycled/reconditioned at an approved facility.
Disposal of Contaminated Packaging:	Recycle /reconditioned at an approved facility.
Environmental Regulations:	Not relevant

14. TRANSPORT INFORMATION

Road and Rail Transport:	Not classified as Dangerous Goods by the criteria of the "Australian Code for the Transport of Dangerous Goods by Road & Rail" and the "New Zealand NZS5433: Transport of Dangerous Goods on Land".
Marine Transport:	Not classified as Dangerous Goods by the criteria of the International Maritime Dangerous Goods Code (IMDG Code) for transport by sea.
Air Transport:	Not classified as Dangerous Goods by the criteria of the International Air Transport Association (IATA) Dangerous Goods Regulations for transport by air.

15. REGULATORY INFORMATION

Regulatory Information:	Not classified as a Scheduled Poison according to the Standard for the Uniform Scheduling of Medicines and Poisons. (SUSMP).
This material/constituent(s) is covered by the following requirements:	All components of this product are listed or exempt from the Australian Inventory of Industrial Chemicals (AIIC)

Product is regulated by the TGA in Australia. This product complies under ARTG No. 160241.



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16. OTHER INFORMATION

Product is considered safe if used as intended.
Product is intended for professional dental/medical use only.

This information was prepared in good faith from the best information available at the time of issue. It is based on the present level of research and to this extent we believe it is accurate. However, no guarantee of accuracy is made or implied and since conditions of use are beyond our control, all information relevant to usage is offered without warranty. The manufacturer will not be held responsible for any unauthorised use of this information or for any modified or altered versions.

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