

DENTSPLY Tulsa Dental Specialties

Safety Data Sheet

Date Issued: August 14, 2008

Document Number: SDSCNGFP7/11

Date Revised: July 19, 2011

Revision Number: 01

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Glyde File Prep®/Root Canal Conditioner

Chemical Name/Classification: Ethylenediaminetetraacetic acid (EDTA), Carbamide peroxide and Propylene glycol

Product Identifier (Part/Item Number): 673021 – Syringe Kit, 5 – 3ml syringes, 50 tips
673022 – Tip Refill, 50 tips

U.N. Number: Not applicable

U.N. Dangerous Goods Classification: Not applicable

Recommended Use: Root canal treatment gel

Restrictions on Use: Not applicable

Manufacturer/Supplier Name: DENTSPLY Tulsa Dental Specialties

Manufacturer/Supplier Address: 608 Rolling Hills Dr., Johnson City, TN 37604

Manufacturer/Supplier Telephone Number: 1-800-263-1437 (Product Information)

Emergency Contact Telephone Number: 1-800-262-8200

Email address: chemtrec@chemtrec.com

2. HAZARD(s) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
Not applicable	Not applicable	Not applicable

Associated Hazards:

Hazard Statements	Precautionary Statements
Causes eye irritation. May be harmful if swallowed. May be harmful if swallowed and enters airways. May be harmful if inhaled	Wear eye protection/face protection. Wash hands thoroughly after handling. Wear protective gloves.

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EU Classification: Not applicable

EU Risk (R) and Safety (S) Phrases: Not applicable

Refer to Section 16 for the full text of the EU Classifications and R Phrases: Not applicable

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Hydrogen Peroxide-Urea	124-43-6	Not applicable	Not applicable	2.5-10

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	In case of contact immediately flush with running water for 15 minutes.
Skin	In case of contact immediately wash with soap and water, seek medical attention if necessary.
Inhalation	If inhalation occurs seek immediate medical attention.
Ingestion	If ingestion occurs seek immediate medical attention.
Most important symptoms of exposure	Not applicable
Other	Not applicable
Note to Physicians (Treatment, Testing, and Monitoring)	
Not applicable	

5. FIRE-FIGHTING MEASURES




Suitable Extinguishing Media:	Dry powder, CO ₂ , alcohol-resistant foam, water spray.
Fire Fighting Procedures:	Wear self-contained breathing apparatus.

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Specific Hazards Arising from the Chemical:	None known. This material is not flammable or combustible.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus for all fires involving chemicals.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Pick up mechanically. Must not be disposed together with household garbage.			
Environmental Precautions: Do not allow product to reach sewage system or any water course.			
Methods and Materials for Containment and Clean-up: Pick up mechanically. Absorb with liquid-binding material (e.g. inert absorbent sand universal binder). Dispose of absorbent material in accordance with local regulations.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			




7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with skin and eyes. Handle in accordance with good industrial hygiene and safety procedures.
Conditions for Safe Storage: Store only in the original receptacle under cool, dry conditions. Protect from heat and direct sunlight. Do not store together with oxidizing agents. Keep container tightly closed and in a well-ventilated space. Avoid exposure to temperatures > 50°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: Not applicable

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Biological Exposure Limits: Not applicable			
Appropriate Engineering Controls: Provide general or local exhaust ventilation.			
Individual Protection Measures (PPE) Specific Eye/face Protection: Safety glasses or goggles if eye contact is possible. Specific Skin Protection: Glove material must be impermeable and resistant to product, made of the following materials: rubber or plastic. Specific Respiratory Protection: Not applicable Specific Thermal Hazards: Not applicable			
Recommended Personal Protective Equipment			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			
Environmental Exposure Controls: Do not allow the product into the following: sewage water, stretches of water or drainage systems.			
General Hygiene Considerations and Work Practices: Observe normal care when working with chemicals. Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White/off white paste	Explosive limits:	Not applicable
Odor:	Odorless	Vapor pressure:	Not applicable
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH:	Ca. 10 (40 g/l) (20°C)	Relative density:	1.01 @ 30°C
Melting/freezing point:	Not applicable	Solubility:	Soluble
Initial boiling point and range:	Not applicable	Partition coefficient: n-octanol/water:	Not tested
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not applicable	Decomposition temperature:	Not applicable
Flammability:	Not applicable	Viscosity:	Not applicable

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Explosive Properties:	Not applicable	Oxidizing Properties:	Not applicable
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10. STABILITY AND REACTIVITY

Reactivity:	Reaction with strong oxidants.
Chemical Stability:	light sensitivity, heat sensitivity
Possibility of Hazardous Reactions:	Reaction with strong oxidants
Conditions to Avoid:	None known
Incompatible materials:	None known
Hazardous Decomposition Products:	No hazardous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: Not applicable							
Emergency Overview: Not applicable							
Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye:	Eye contact may cause eye irritation and abrasion.	Single	Mild	Not applicable	Not applicable	Not listed	Not listed
Skin:	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not listed	Not listed
Inhalation:	Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing and shortness of breath.	Single	Mild	Not applicable	Not applicable	Not listed	>5.1 mg/l/4h

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Ingestion:	Ingestion may cause nausea, choking, vomiting and difficulty swallowing.	Single	Mild	Not applicable	Not applicable	1525 mg/kg	Not listed
Other:	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not listed	Not listed
Medical Conditions Aggravated by Exposure: Not applicable							
Carcinogenicity: None known							

12. ECOLOGICAL INFORMATION

Toxicity: Product is not cytotoxic.
Persistence and Degradability: This product is biodegradable.
Bio-accumulative Potential: Not applicable
Mobility in Soil: Not applicable
Other Adverse Effects: Not applicable
Results of PBT/vPvB Assessment: Not listed

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose of container and unused contents in accordance with federal, state and local requirements.
Properties (Physical/Chemical) Affecting Disposal: Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Waste Treatment Recommendations: Not applicable

14. TRANSPORT INFORMATION

UN Identification Number: Not applicable
UN Proper Shipping Name: Not applicable
Transport hazard class(es): Not classified as dangerous in transport regulations.
Packing Group: Not applicable
Special precautions for user: Not applicable

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15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to TSCA requirements.

Clean Water Act (CWA): Not applicable

Clean Air Act (CAA): Not applicable

Superfund Amendments and Reauthorization Act (SARA) Title III Information: None

SARA Section 311/312 (40 CFR 370) Hazard Categories: Not applicable

Immediate Hazard:	Not applicable	Pressure Hazard:	Not applicable
Delayed Hazard:	Not applicable	Reactivity Hazard:	Not applicable
Fire Hazard:	Not applicable		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Not applicable	Not applicable	Not applicable

State Regulations

California: This product does not contain chemical(s) known to the State of California at this time to cause developmental toxicity, reproductive harm or birth defects.

Components	C.A.S. #	WT %
Not applicable	Not applicable	Not applicable

International Regulations

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

Canadian Workplace Hazardous Materials Information System (WHMIS): Not applicable

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

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16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

Hazard/Danger Classification:

Health - Not applicable

Environmental - Not applicable

Physical - Not applicable

Associated Hazards:

Hazard Statements:

- Causes eye irritation
- May be harmful if swallowed
- May be harmful if swallowed and enters airways
- May be harmful if inhaled

Precautionary Statements:

- Wear eye protection/face protection
- Wash hands thoroughly after handling
- Wear protective gloves

EU Classification - Not applicable

EU Risk (R) and Safety (S) Phrases - Not applicable

Hazardous Components - Hydrogen Peroxide-Urea

C.A.S.#, EC# - 124-43-6

IUPAC Name - Not applicable

Substance Classification - Not applicable

WT% - 2.5-10

Date of SDS Preparation/Revision:

July 19, 2011 – Rev 01

Data Sources:

Manufacturer's Safety Data Sheet and DENTSPLY Canada LTD. Material Safety Data Sheet