

DENTSPLY Tulsa Dental Specialties

Safety Data Sheet

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): QMix™ 2in1
Chemical Name/Classification: Ethylenediaminetetracetic acid disodium dehydrate,
Chlorhexidine Digluconate
Product Identifier (Part/Item Number):
U.N. Number: Not Applicable
U.N. Dangerous Goods Classification: Not Applicable
Recommended Use: Endodontic irrigant used to remove smear layer &
disinfect the root canal following instrumentation.
Restrictions on Use: Use as endodontic irrigant / root canal cleanser only
Manufacturer/Supplier Name: Manufactured for DENTSPLY Tulsa Dental Specialties
Manufacturer/Supplier Address: 5100 E. Skelly Drive Suite 300 Tulsa OK 74135-6546
Manufacturer/Supplier Telephone Number: 1-800-662-1202 (**Product Information**)
Emergency Contact Telephone Number: 1-631-419-1700
Email address: tulsquestions@dentsply.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 Causes skin irritation	Wear eye protection / face protection. Wash hands thoroughly after handling. Wear protective gloves.

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Include as applicable

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.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Ethylenediaminetetracetic acid disodium dihydrate	CAS: 6381-92-6 EC: 205-358-3	disodium 2-[carboxymethyl-[2-[carboxymethyl-(2-oxido-2-oxoethyl)amino]ethyl]amino]acetate	Chelating agent.	Less than 15

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	Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally.
Skin	Immediately flush skin with plenty of cool soapy water for at least 15 minutes.
Inhalation	Remove patient to fresh air.
Ingestion	If ingestion occurs, flush mouth with water and seek medical attention immediately.
Most important symptoms of exposure	Possible irritation of eyes, skin, breathing passages, mouth.
Other	Not Applicable
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically	

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Treat symptomatically

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Not Applicable
Fire Fighting Procedures:	Firefighters should wear self-contained respiratory protective devices.
Specific Hazards Arising from the Chemical:	Formation of toxic, irritating gases is possible from the decomposition of the ingredients. Product does not present an explosion hazard.
Precautions for Fire Fighters:	Firefighters should wear self-contained respiratory protective devices.


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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Environmental Precautions: Not Applicable.

Methods and Materials for Containment and Clean-up: For large spills dike area, spread absorbent material such as vermiculite or diatomaceous earth.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	
			

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7. HANDLING AND STORAGE

Precautions for Safe Handling: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Conditions for Safe Storage: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: Not Applicable

Biological Exposure Limits: Not Applicable

Appropriate Engineering Controls: Not Applicable

Individual Protection Measures (PPE)
Specific Eye/face Protection: Safety Glasses
Specific Skin Protection: The glove material has to be impermeable and resistant to the product.
Specific Respiratory Protection: Not Required
Specific Thermal Hazards: Not Applicable

Recommended Personal Protective Equipment			
EYES/FACE	SKIN		RESPIRATORY
	 		

Environmental Exposure Controls: Not Applicable

General Hygiene Considerations and Work Practices: Avoid prolonged skin contact with material. Wash hands thoroughly after handling this product.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Safety glasses, gloves, lab coat, personal respiratory equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, water white liquid.	Explosive limits:	Not Applicable
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Odor:	No odor	Vapor pressure:	Not Applicable
Odor threshold:	Not Applicable	Vapor density:	Not Applicable
pH:	7.5 - 8	Relative density:	Not listed (Relative gravity: approx. 1.085)
Melting/freezing point:	Not Tested (solution is not intended to be refrigerated)	Solubility:	Soluble
Initial boiling point and range:	Not Tested	Partition coefficient: n-octanol/water:	Not Tested
Flash point:	Not Applicable	Auto-ignition temperature:	Not Applicable
Evaporation rate:	Not Applicable	Decomposition temperature:	Not Tested (solution is intended to be stored at room temperature)
Flammability:	Not Applicable	Viscosity:	0.0013 – 0.0015 Pas
Explosive Properties:	Not Applicable.	Oxidizing Properties:	Not Tested

10. STABILITY AND REACTIVITY

Reactivity: None known
Chemical Stability: Stable
Possibility of Hazardous Reactions: May Not Occur
Conditions to Avoid: None known
Incompatible materials: Strong oxidizing agents (solution is aqueous).
Hazardous Decomposition Products: No dangerous decomposition products known if used according to DFU/IFU (Directions/Instructions for Use).

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: Product may irritate the skin and mucous membranes. On the eye the product has an irritating effect.							
Emergency Overview: Material may cause eye and skin irritation.							
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)

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Eye:	Eye contact may cause severe eye irritation and abrasion.	Single	Moderate	Irritation and possible corneal damage	Not Applicable	Not Listed	Not Listed
Skin:	May cause skin irritation	Single & Repeated	Mild	Reddening of skin	Not Applicable	Not Listed	Not Listed
Inhalation:	Direct inhalation may cause irritation to respiratory tract and mucous membranes. Symptoms may include coughing, shortness of breath.	Repeated	Moderate	Not Applicable	Not Applicable	Not Listed	Not Listed
Ingestion:	Ingestion may cause nausea, vomiting, diarrhea and difficulty in swallowing.	Single	Mild	Not Applicable	Not Applicable	Not Listed	Not Listed
Other:	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Listed	Not Listed
Medical Conditions Aggravated by Exposure: Individuals with known sensitivity to Chlorhexidine gluconate and/or EDTA (Ethylenediaminetetraacetic acid disodium dihydrate).							
Carcinogenicity: Not listed							

12. ECOLOGICAL INFORMATION

Toxicity: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.
Persistence and Degradability: Not Applicable.
Bio-accumulative Potential: Not Applicable
Mobility in Soil: Not Applicable
Other Adverse Effects: Not Applicable
Results of PBT/vPvB Assessment: Not Listed

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13. DISPOSAL CONSIDERATIONS

Regulations: Must not be disposed of together with household garbage. Dispose of in accordance with Federal, State and Local regulations.
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.
Waste Treatment Recommendations: Not Applicable

14. TRANSPORT INFORMATION

UN Identification Number: Not Applicable
UN Proper Shipping Name: Not Applicable
Transport hazard class(es): Not Applicable
Packing Group: Not Applicable
Special precautions for user: User must be a licensed clinician.

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): All of the components of this product are listed on the TSCA inventory.

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		

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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 contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

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.

16. OTHER INFORMATION

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

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU. The information contained herein is accurate to the best of our knowledge.

DENTSPLY Tulsa Dental Specialties makes no warranty of any kind, express or implied, concerning the safe use of this material.

Date of SDS Preparation/Revision: 22th October, 2010

Data Sources: Manufacturers' Data Sheets, PubChem, & sources listed therein.