

Safety Data Sheet

Date Issued: 1995
Document Number: SDSDNFCPO
Date Revised: 01/02/13
Revision Number: 03

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Densfil (20 through 40), Gutta Master (20 through 40), ProFile Vortex (20 through 40), ProTaper Universal (F1 through F4), ProTaper Next (X2, X3, X4), Thermafil (20 through 40), Thermafil Plus (20 through 40), Domino (20 through 40), WaveOne Obturators (Small, Primary, Large), GT Obturators (all sizes), GTX Obturators (all sizes)

Chemical Name/Classification: LIQUID CRYSTAL POLYMER-Carbomonocyclic Carbopolycyclic Polyester and Gutta Percha

Product Identifier (Part/Item Number): Liquid Crystal Polymer with 50% Tungsten and Gutta Percha

U.N. Number: Not Applicable

U.N. Dangerous Goods Classification: Not Applicable

Recommended Use: Obturating Root Canals

Restrictions on Use: None

Manufacturer/Supplier Name: DENTSPLY Tulsa Dental Specialties

Manufacturer/Supplier Address: 608 Rolling Hills Drive, Johnson City, Tn. 37604

Manufacturer/Supplier Telephone Number: 1-800-924-7393

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
Not Applicable	Not 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.

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3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Tungsten	7440-33-7	Tungsten	Inorganic	50
Zinc Oxide	1314-13-2	Zinc Oxide	Inorganic	77

Non Hazardous Components	C.A.S # EC#	IUPAC Name	Substance Classification	WT%
Gutta Percha	9003- 31-0	trans-1, 4-polyisoprene	Organic	20
Liquid Crystal Polymer	147310-94-9	Carbomonocyclic Carbopolycyclic Polyester	Organic	50

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	Rinse opened eye for several minutes under running water.
Skin	Flush skin with soap and water
Inhalation	Supply fresh air; consult a doctor in case of complaints.
Ingestion	If symptoms persist consult a doctor.
Other	Not Applicable
Note to Physicians (Treatment, Testing, and Monitoring) Not Applicable	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Water, ABC dry chemical, or Protein type air foams.
Fire Fighting Procedures:	Not Applicable
Specific Hazards Arising from the Chemical:	Carbon monoxide can be emitted at > 400°C
Precautions for Fire Fighters:	Firefighters should be equipped with self-contained breather apparatus and turn-out gear

DENTSPLY Maillefer

Recommended Protective Equipment for Fire Fighters: Wear positive pressure self-contained breathing apparatus (SCBA) during the attack phase of firefighting operations and during cleanup in enclosed or poorly ventilated areas immediately after a fire.

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Person related safety precautions- not required

Environmental Precautions: None

Methods and Materials for Containment and Clean-up: Placed in suitable containers for disposal by local, state, or federal waste disposal regulations.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY
		

7. HANDLING AND STORAGE

Precautions for Safe Handling: None

Conditions for Safe Storage: Control environmental maintaining a temperature range of 60°F to 86° F.




8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: 15mg/m³

Biological Exposure Limits: Not Applicable

Appropriate Engineering Controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

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Individual Protection Measures (PPE) Specific Eye/face Protection: Not Applicable Specific Skin Protection: Not Applicable Specific Respiratory Protection: Not Applicable Specific Thermal Hazards: Not Applicable			
Recommended Personal Protective Equipment			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			Not Applicable
Environmental Exposure Controls: Not Applicable			
General Hygiene Considerations and Work Practices: Not Applicable			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pink coating on Gray carrier	Explosive limits:	Not Available
Odor:	None reported	Vapor pressure:	Not Available
Odor threshold:	Not Applicable	Vapor density:	Not Available
pH:	7	Relative density:	1.3g/cc
Melting/freezing point:	<400°C	Solubility:	Negligible
Initial boiling point and range:	Not Applicable	Partition coefficient: n-octanol/water:	Not Available
Flash point:	Not Available	Auto-ignition temperature:	Not Available
Evaporation rate:	Not Available	Decomposition temperature:	540°C
Flammability:	Not Available	Viscosity:	Not Available
Explosive Properties:	Not Available	Oxidizing Properties:	Not Available

10. STABILITY AND REACTIVITY

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Reactivity: None

Chemical Stability: Stable

Possibility of Hazardous Reactions: No

Conditions to Avoid: Temperatures <400°C

Incompatible materials: None

Hazardous Decomposition Products: N/A

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: None

Emergency Overview: Liquid Crystal Polymer, and Tungsten are biocompatible. Gutta Percha is trans-1, 4-polyisoprene and Zinc Oxide.

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:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Skin:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Inhalation:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ingestion:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Other:	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Medical Conditions Aggravated by Exposure: None.

Carcinogenicity: None.

12. ECOLOGICAL INFORMATION

Toxicity: No hazards

Persistence and Degradability: Stable

Bio-accumulative Potential: None

Mobility in Soil: None

Other Adverse Effects: None

Results of PBT/vPvB Assessment: None

13. DISPOSAL CONSIDERATIONS

DENTSPLY Maillefer

Regulations: Dispose of container and unused contents in accordance with federal, state and local requirements.

Properties (Physical/Chemical) Affecting Disposal: None

Waste Treatment Recommendations: None required.

14. TRANSPORT INFORMATION

UN Identification Number: Not Applicable – Liquid Crystal Polymer, 3089 – Tungsten, 3077 - Zinc Oxide and Not Applicable - trans-1,4-polyisoprene

UN Proper Shipping Name: Not Applicable

Transport hazard class(es): Not regulated

Packing Group: III

Special precautions for user: None



Include as applicable

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Not regulated

Toxic Substances Control Act (TSCA): Not regulated

Clean Water Act (CWA): Not regulated

Clean Air Act (CAA): Not regulated

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

SARA Section 311/312 (40 CFR 370) Hazard Categories: None

Immediate Hazard:	None	Pressure Hazard:	None
Delayed Hazard:	None	Reactivity Hazard:	None
Fire Hazard:	None		

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

DENTSPLY Maillefer

Components	C.A.S. #	WT %
N/A	N/A	N/A

State Regulations

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

Components	C.A.S. #	WT %
Tungsten	7440-33-7	50
Zinc Oxide	1314-12-2	77

International Regulations

Canadian Environmental Protection Act: None

Canadian Workplace Hazardous Materials Information System (WHMIS): None

European Inventory of Existing Chemicals (EINECS): None

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3: None

Date of SDS Preparation/Revision: 01/02/2013

Data Sources: Supplier

Safety Data Sheet

Date Issued: 1995
Document Number: SDSDNFPFO
Date Revised: 01/02/13
Revision Number: 03

1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Densfil (45 through 140), Gutta Master(45 through 70), ProFile Vortex (45 and 50), ProTaper Universal F5, ProTaper Next X5, Therafil (45 through 140), Therafil Plus (45 through 140), Domino (45 through 70),

Chemical Name/Classification: POLYSULFONE and GUTTA PERCHA

Product Identifier (Part/Item Number): Polysulfone with 35% Tungsten and Gutta Percha

U.N. Number: Not Applicable

U.N. Dangerous Goods Classification: Not Applicable

Recommended Use: Obturating Root Canals

Restrictions on Use: None

Manufacturer/Supplier Name: DENTSPLY Tulsa Dental Specialties

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

Manufacturer/Supplier Telephone Number: 1-800-924-7393

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
Not Applicable	Not Applicable

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.

DENTSPLY Maillefer

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Tungsten	7440-33-7	Tungsten	Inorganic	35
Zinc Oxide	1314-13-2	Zinc Oxide	Inorganic	77
Non Hazardous Components	C.A.S # EC#	IUPAC Name	Substance Classification	WT%
Gutta Percha	9003-31-0	trans-1, 4-polyisoprene	Organic	20
Polysulfone	25135-51-7	4-[Hydrexghenyl)-Propan-2-yl]Phenol	Organic	65

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	Rinse opened eye for several minutes under running water
Skin	Flush skin with soap and water
Inhalation	Supply fresh air; consult a doctor in case of complaints.
Ingestion	If symptoms persist consult a doctor.
Other	Not Applicable
Note to Physicians (Treatment, Testing, and Monitoring) Not Applicable	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Water, ABC dry chemical, or Protein type air foams.
Fire Fighting Procedures:	Not Applicable
Specific Hazards Arising from the Chemical:	Carbon monoxide can be emitted at > 400°C
Precautions for Fire Fighters:	Firefighters should be equipped with self-contained breather apparatus and turn-out gear

DENTSPLY Maillefer

Recommended Protective Equipment for Fire Fighters: Wear positive pressure self-contained breathing apparatus (SCBA) during the attack phase of firefighting operations and during cleanup in enclosed or poorly ventilated areas immediately after a fire.			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: N/A

Environmental Precautions: N/A

Methods and Materials for Containment and Clean-up: Place in suitable containers for disposal by local, state, or federal waste disposal regulations.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling: None

Conditions for Safe Storage: Control environmental maintaining a temperature range of 60°F to 86° F.




8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: Not Applicable

Biological Exposure Limits: Not Applicable

Appropriate Engineering Controls: N/A

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Individual Protection Measures (PPE) Specific Eye/face Protection: Not Applicable Specific Skin Protection: Not Applicable Specific Respiratory Protection: Not Applicable Specific Thermal Hazards: Not Applicable			
Recommended Personal Protective Equipment			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			N/A
Environmental Exposure Controls: Not Applicable			
General Hygiene Considerations and Work Practices: Not Applicable			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pink coating on Gray carrier	Explosive limits:	Not Available
Odor:	None reported	Vapor pressure:	Not Available
Odor threshold:	Not Applicable	Vapor density:	Not Available
pH:	7	Relative density:	1.5g/cc
Melting/freezing point:	<400°C	Solubility:	Negligible
Initial boiling point and range:	Not Applicable	Partition coefficient: n-octanol/water:	Not Available
Flash point:	Not Available	Auto-ignition temperature:	Not Available
Evaporation rate:	Not Available	Decomposition temperature:	400°C
Flammability:	Not Available	Viscosity:	Not Available
Explosive Properties:	Not Available	Oxidizing Properties:	Not Available

10. STABILITY AND REACTIVITY

DENTSPLY Maillefer

Reactivity: None
Chemical Stability: Stable
Possibility of Hazardous Reactions: No
Conditions to Avoid: Temperatures > 400°C
Incompatible materials: None
Hazardous Decomposition Products: N/A

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: None							
Emergency Overview: Polysulfone and Tungsten are biocompatible. Gutta Percha is trans-1,4-polyisoprene and Zinc Oxide.							
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:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Skin:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Inhalation:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ingestion:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Other:	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medical Conditions Aggravated by Exposure: None.							
Carcinogenicity: None.							

12. ECOLOGICAL INFORMATION

Toxicity: No hazards
Persistence and Degradability: Stable
Bio-accumulative Potential: None
Mobility in Soil: None
Other Adverse Effects: None
Results of PBT/vPvB Assessment: None

DENTSPLY Maillefer

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose of container and unused contents in accordance with federal, state and local requirements.

Properties (Physical/Chemical) Affecting Disposal: None

Waste Treatment Recommendations: None required.

14. TRANSPORT INFORMATION

UN Identification Number: Not Applicable – Polysulfone, 3089 – Tungsten, 3077 - Zinc Oxide and Not Applicable - trans-1, 4-polyisoprene

UN Proper Shipping Name: Not Applicable

Transport hazard class(es): Not regulated

Packing Group: III

Special precautions for user: None



Include as applicable

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): Not regulated

Toxic Substances Control Act (TSCA): Not regulated

Clean Water Act (CWA): Not regulated

Clean Air Act (CAA): Not regulated

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

SARA Section 311/312 (40 CFR 370) Hazard Categories: None

Immediate Hazard:	None	Pressure Hazard:	None
Delayed Hazard:	None	Reactivity Hazard:	None

DENTSPLY Maillefer

Fire Hazard:	None
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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 %
N/A	N/A	N/A

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 %
Tungsten	7440-33-7	35
Zinc Oxide	1314-3-2	77

International Regulations

Canadian Environmental Protection Act: None

Canadian Workplace Hazardous Materials Information System (WHMIS): None

European Inventory of Existing Chemicals (EINECS): None

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3: None

Date of SDS Preparation/Revision: 01/02/13

Data Sources: Supplier