

DENTSPLY Tulsa Dental Specialties

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): Gutta Core Pink
Chemical Name/Classification: Polyisoprene Compound
Product Identifier (Part/Item Number): GuttaCore Pink Obturators 20 through 90
GuttaCore ProTaper X2 through X5
GuttaFusion Obturators 20 through 90
Guttafusion for RECIPROC
U.N. Number: 3077
U.N. Dangerous Goods Classification: 9
Recommended Use: Obturating root canals
Restrictions on Use: For use by Dental Professionals only. Latex sensitive people may experience a mild reaction.
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 (Product Information)
Emergency Contact Telephone Number: 1-800-262-8200
Email address: chemtrec@chemtrec.com

2. HAZARD(s) IDENTIFICATION

Gutta Core is a medical product according to Directive 93/42/EC and no hazardous substance or preparation according to Regulation 1272/2008 EC.

Gutta Percha contains less than 4.5% by weight titanium dioxide. Due to product's physical form (rubberlike pellets), exposure to this chemical is not likely. If user operations generate dust or fumes: The carcinogenic potential of inhaled titanium dioxide has been investigated in several inhalation carcinogenicity studies in rats and mice. Based on these studies; there was sufficient evidence that titanium dioxide is carcinogenic in experimental animals. IARC has reevaluated Titanium dioxide as pertaining to Group 2B: "possible carcinogenic to humans", based upon inadequate evidence in humans and sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. Under normal condition of use; inhalation of fine dust particles is not expected to occur.

Unknown Acute Toxicity (GHS-US) No data available

Hazard Statements	Precautionary Statements
H315, H319, H335, H400, H410	P273, P281, P302+352, P304+340, P305+351+338, P391, P501

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GHS07 GHS09

GHS Classification: Xi, Skin Irritant. 2; Eye Irritant. 2; STOT SE 3 – N

GHS Hazard (H) and Precautionary (P) Phrases: H315, H319, H335, H400, H410, P261, P273, P281, P302+352, P304+340, P305+351+338, P391, P501

Refer to Section 16 for the full text of the GHS Classifications and H/P Phrases

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Product: GuttaCore

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Paraffinic Petroleum Oil	64741-88-4 265-090-8	Olefin	Inorganic	<1
Zinc Stearate	557-05-1 209-151-9	OCTADECANOIC ACID ZINC SALT	Inorganic	<1
Zinc Oxide	1314-13-2 215-222-5	Zinc Oxide	Inorganic	>50
Bismuth Oxide	1304 76 3 215 134 7	Dibismuth trioxide	Inorganic	>30
2,5-dimethyl-2,5-di(tert-butylperoxy)hexane	78-63-7 201-128-1	peroxide, 1,4,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)]	Organic	<20
Non Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
1-Octadecanamine	124-30-1 204-695-3	n-Octadecylamine	Organic	<1
Stearic Acid	57-11-4 200-313-4	n-Octadecanoic acid	Organic	<1
Titanium Dioxide	13463-67-7	Titanium Dioxide	Inorganic	<20
para-aramid fiber	26125-61-1	Para-phenyleneterephtalamide	Organic	<20
Calcium carbonate	471-34-1 207-439-9	calcium carbonate	Inorganic	<5
Silica gel	63231-67-4	Silica	Inorganic	<5
Trimethylolpropane Trimethacrylate	3290-92-4 221-950-4	Trimethylolpropane Trimethacrylate (TMPTMA) Esters	Organic	<5
Silica, amorphous, precipitated	112926-00-8	Silica	Inorganic	<20

Product: Gutta Percha

Chemical Name	CAS Number	GHS-US Classification	Substance Classification	WT %
Titanium Dioxide	13463-67-7	Carc. 2, H351	Inorganic	<4.5
Propanoic acid	79-09-4	Flam. Liq. 3, H226 Skin Corr. 1B, H314 Acute Tox. 3 (Dermal), H311	Inorganic	<0.5

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Refer to Section 16 for the full text of the GHS and H phrases 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	Latex sensitive people may experience a mild reaction.
Note to Physicians (Treatment, Testing, and Monitoring) N/A	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Water, ABC, dry chemical or Protein type air foams.
Fire Fighting Procedures:	General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire
Specific Hazards Arising from the Chemical:	N/A
Precautions for Fire Fighters:	Firefighters should be equipped with self-contained breather apparatus and turn-out gear

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: N/A

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




Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES	SKIN	RESPIRATORY
		

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7. HANDLING AND STORAGE

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

Handling Product is intended for dental use only.
Precautions for safe handling Observe normal care for working with chemicals.
Information about fire and explosion protection: No special measures required.
Conditions for safe storage, including any incompatibilities
Storage Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
Information about storage in one common storage facility: Not required.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: 15mg/m3

Biological Exposure Limits: N/A

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.

Individual Protection Measures (PPE)
 Specific Eye/face Protection: safety glasses / face shield
 Specific Skin Protection: gloves
 Specific Respiratory Protection: face mask
 Specific Thermal Hazards: N/A

Recommended Personal Protective Equipment			
EYES/FACE	SKIN	RESPIRATORY	
			

Environmental Exposure Controls: see above

General Hygiene Considerations and Work Practices: see above

Protective Measures During Repair and Maintenance of Contaminated Equipment: see above

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pink coating and Pink Carrier	Explosive limits:	None
Odor:	Mild	Vapor pressure:	None
Odor threshold:	N/A	Vapor density:	None
pH:	Neutral	Relative density:	2g/cc
Melting/freezing point:	50°C	Solubility:	None
Initial boiling point and range:	None	Partition coefficient: n-octanol/water:	None
Flash point:	None	Auto-ignition temperature:	None
Evaporation rate:	None	Decomposition temperature:	300°C
Flammability:	None	Viscosity:	None
Explosive Properties:	None	Oxidizing Properties:	None

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10. STABILITY AND REACTIVITY

Reactivity: None

Chemical Stability: Stable

Possibility of Hazardous Reactions: None

Conditions to Avoid: None

Incompatible materials: None

Hazardous Decomposition Products: Smoke, fume, incomplete combustion products, oxides of carbon, flammable hydrocarbons, oxides of nitrogen, metallic oxides, hydrogen cyanide, ammonia

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: None

Emergency Overview: This vulcanized compound presents minimal risk since it precludes the possibility of air borne dust of the active ingredients. It is also the possibility of leaching of liquid additives under normal storage and use temperatures.

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:	Discomfort	Single	Mild	None	None	None	None
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:
Aquatic Life

Ecotoxicological effects:

Remark: *Very toxic for fish*

Persistence and Degradability: Stable

Bio-accumulative Potential: None

Mobility in Soil: None

Other Adverse Effects: None

Results of PBT/vPvB Assessment:

PBT: Not applicable.

vPvB: Not applicable.

Additional ecological information:

Poisonous for fish and plankton in water bodies.

Water hazard class 2 (German Regulation) (Self-assessment):

Hazardous for water.


Very toxic for aquatic organisms

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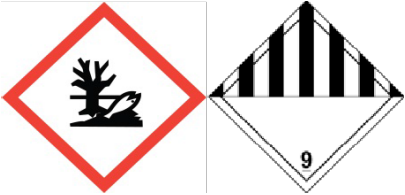
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13. DISPOSAL CONSIDERATIONS

<p>Regulations: Regulations: Waste resulting from this product as supplied is not known to be classified as a hazardous waste. It is the user's responsibility to determine, per the regulations of state, local or other governmental agency, the proper disposal technique.</p> <ul style="list-style-type: none"> • <i>Waste treatment methods</i> • <i>Recommendation</i>
<div style="text-align: center;">  </div> <p>Must not be disposed together with household garbage. Do not allow product to reach sewage system.</p>
<p>Properties (Physical/Chemical) Affecting Disposal: None</p> <p>Uncleaned packaging: <i>Recommendation: Disposal must be made according to official regulations.</i></p>
<p>Waste Treatment Recommendations: N/A</p>

14. TRANSPORT INFORMATION

<p>UN Identification Number: (zinc oxide,3077)</p>
<p>UN Proper Shipping Name: (3077 - Environmentally hazardous substance, solid, n.o.s. (not including waste)) (3089 - Metal powder, flammable, n.o.s.) (3108- Organic peroxide type E, solid)</p>
<p>Transport hazard class(es): 9</p>
<p>Packing Group: III</p>
<p>Special markings: Symbol (fish and tree)</p>
<p>Maritime transport IMDG: IMDG Class: 9 UN Number: 3077 Label: 9 Packaging group: III EMS Number: F-A,S-F Marine pollutant: Yes Special marking: Symbol (fish and tree) Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)</p>
<p>Air transport ICAO-TI and IATA-DGR:-</p> <div style="text-align: center; margin: 10px 0;">  </div> <p>Above markings are applicable to EU ADR/ RID and AND/ADNR only.</p> <p>UN Number: 3077 IMDG Class: 9 Label: 9 Special marking: Symbol (fish and tree) Packaging group: III EMS Number: F-A,S-F</p>

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15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): N/A
Toxic Substances Control Act (TSCA): N/A
Clean Water Act (CWA): N/A
Clean Air Act (CAA): N/A
Superfund Amendments and Reauthorization Act (SARA) Title III Information: N/A
SARA Section 311/312 (40 CFR 370) Hazard Categories: N/A
<p>Canadian Regulations: Titanium dioxide (13463-67-7) Listed on the Canadian DSL (Domestic Substances List) WHMIS Classification: Class D Division 2 Subdivision A - Very toxic material causing other toxic effects</p> <p>Propanoic acid (79-09-4) Listed on the Canadian DSL (Domestic Substances List) WHMIS Classification Class B Division 3 - Combustible Liquid Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects Class E - Corrosive Material</p>
<p>European Union Regulations: EC # 215-222-5 Zinc oxide is not considered environmentally hazardous outside of the EU. ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide) UN 3077, Class 9, PG III. Ingredients listed on the European inventory of existing commercial Chemical substances (EINECS).....Yes, on inventory WARNING. H410: Very toxic to aquatic life with long lasting effects. P273: Avoid release to the environment. P391: Collect spillage. P501: Disposal of contents/ container as hazardous or special waste in accordance with applicable law.</p> <p>EU-Regulations- Gutta Percha - No additional information available Classification according to Regulation (EC) No. 1272/2008 [CLP]-No additional information available Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD] -No additional information available</p> <p>National Regulations - No additional information available</p>

State Regulations

California: T This product contains the following chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm: Titanium dioxide (13463-67-7)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significance risk level (NSRL)
Yes	No	No	No	No

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16. OTHER INFORMATION

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

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects

P281: Use personal protective equipment as required P302+352: IF ON SKIN: Wash with soap and water

P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Disposal of contents/ container as hazardous or special waste in accordance with applicable law.

N - Dangerous to Environment

Xi - Irritant

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide) UN 3077, Class 9, PG III.

Gutta Core is a medical product according to Directive 93/42/EC and no hazardous substance or preparation according to Regulation 1272/2008 EC.

Date of SDS Preparation/Revision: 03/23/2015 rev. 03

Data Sources: Manufacturing Supplier