SAFETY DATA SHEET

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

Product: Gutta Percha **Revision Date: 02/10/2015**

SECTION 1 - IDENTIFICATION

Product Identifier
Product Name: **Gutta Percha**
Product Form: **Mixture**

Recommended Use of the Chemical and Restrictions on Use
Recommended Use: Endodontic obturation material.

Restrictions on Use: The product is intended for professional use.

Details of the Supplier
Manufactured by: Integra York PA, Inc.
589 Davies Dr.
York, PA 17402 USA
1-866-854-8300

Emergency Phone Number
24-Hour Number: 1-800-535-5053
International: 1-352-323-3500

SECTION 2 – HAZARDS IDENTIFICATION

Classification

GHS-US classification – Not classified

Label Elements

GHS-US labeling
No labeling applicable

Other Hazards

This product contains less than 4.5% by weight titanium dioxide. Due to product's physical form (rubber-like 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 revaluated 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.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Mixture

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

Full text of H-phrases: see section 16

SECTION 4 – FIRST AID MEASURES

First Aid Measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Assure fresh air breathing. Get immediate medical advice/attention.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If burned by hot material, cool skin by quenching with large amounts of cool water. Burns caused by molten material must be treated clinically. Seek medical attention immediately.

First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

Most Important Symptoms and Effects (Acute and Delayed)

Symptoms/injuries after inhalation : Inhalation is unlikely a route of exposure at ambient temperature. Inhalation is unlikely due to physical form. If user operations generate dust or fumes, inhalation of dust may cause irritation of the respiratory system. Fumes are irritating to the respiratory system. If user operations generate dust, effects of excessive exposures are suspected of causing cancer

Symptoms/injuries after skin contact : Risk of thermal burns on contact with molten product.

Symptoms/injuries after eye contact : Not expected under normal conditions of use. If user operations generate dust. Dusts are mechanical irritants. may cause physical irritation upon direct contact. Risk of thermal burns on contact with molten product.

Symptoms/injuries after ingestion : Choking hazard.

Indication of any Immediate Medical Attention and Special Treatment Needed

No additional information available.

SECTION 5 – FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a water jet since it may cause the fire to spread.

Specific Hazards Arising from Substance or Mixture

No additional information available

Protective Equipment and Precautions for Firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protective equipment for firefighters : Do not enter fire area without proper personal protective equipment, including respiratory protection.

Other information : Hazardous combustion products are Carbon dioxide, carbon monoxide, smoke, fumes, unburned hydrocarbons and oxides of sulfur, phosphorus, zinc and/or nitrogen. Silicon oxide. Titanium dioxide. aluminium oxide smoke.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures

General measures : Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Eliminate all ignition sources if safe to do so.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : The low volatility of this product does not require ventilation. However depending on the condition an adequate ventilation might be required.

Environmental Precautions:
Prevent entry to sewers and public waters. Follow applicable federal, state, and/or local environmental disposal regulations.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials. Dispose in a safe manner in accordance with local/national regulations.

Reference to Other Sections

See Heading 8. Exposure controls and personal protection.

SECTION 7 – HANDLING AND STORAGE

Precautions for Safe Handling

Precautions for safe handling : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Work in a well-ventilated area. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Hygiene measures : Do not eat, drink or smoke when using this product.

Conditions for Safe Storage, Including any Incompatibilities

Technical measures : Provide local exhaust or general room ventilation. A washing facility/water for eye and skin cleaning purposes should be present.

Storage conditions : Keep out of reach of children. Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use. Store in a dark area. Keep away from heat and direct sunlight.

Incompatible materials : Strong acids, bases. Oxidizing agents.

Specific End Use(s)

No additional information available

SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION

Exposure Guidelines

Titanium dioxide (13463-67-7)		
USA ACGIH	ACGIH TWA (mg/m³)	10 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³

Propanoic acid (79-09-4)		
USA ACGIH	ACGIH TWA (ppm)	10 ppm

Appropriate Engineering Controls / Individual Protection Measures

Personal protective equipment : Avoid all unnecessary exposure. Gloves. Protective goggles. Protective clothing. For certain operations, additional Personal Protection Equipment (PPE) may be required.

Hand protection : Wear suitable protective gloves.

Eye protection : Wear chemical goggles or safety glasses.

Skin and body protection : Wear suitable protective clothing.

Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended.

Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Solid

Appearance : Rubber-like pellets.

Colour : Pink

Odour : Mild odor

Odour threshold : No data available

pH : No data available

Relative evaporation rate (butyl acetate=1) : No data available

Melting point : Approximately 98.88 °C (210 °F)

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Density	:	2.55 - 2.6 Specific Gravity
Solubility	:	No data available
Log Pow	:	No data available
Log Kow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: No additional information available.

Chemical stability: Stable at normal conditions.

Possibility of hazardous reactions: Hazardous polymerization will not occur.

Conditions to avoid: Direct sunlight. Extremely high or low temperatures.

Incompatible materials: Strong acids. Strong bases. Oxidizing agents.

Hazardous decomposition products: Thermal decomposition generates : On burning: release of (titanium oxides). Hazardous combustion products are Carbon dioxide, carbon monoxide, smoke, fumes, unburned hydrocarbons and oxides of sulfur, phosphorus, zinc and/or nitrogen. Fume. Silicon dioxide.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute toxicity	:	Not classified

Titanium dioxide (13463-67-7)	
LD50 oral rat	> 10000 mg/kg

Propanoic acid (79-09-4)	
LD50 oral rat	2600 mg/kg
LD50 dermal rabbit	496 mg/kg
LC50 inhalation rat (ppm)	4650 ppm (Exposure time: 8 h)
ATE US (oral)	2600.00 mg/kg bodyweight
ATE US (dermal)	496.00 mg/kg bodyweight

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met.

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation : Not classified
Based on available data, the classification criteria are not met.

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met.

Carcinogenicity : Not classified

(Based on available data, the classification criteria are not met. No significant exposure to primary particles of titanium dioxide is thought to occur during the use of products in which titanium dioxide is bound to other materials).

Due to product's physical form,(rubber-like pellets), exposure to this chemical is not likely.

Gutta Percha	
IARC group	This product contains less than 4.5% by weight titanium dioxide. Due to product's physical form (rubber-like 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 revaluated 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.

Titanium dioxide (13463-67-7)	
IARC group	2B - Possibly carcinogenic to humans

Reproductive toxicity	:	Not classified Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure)	:	Not classified Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure)	:	Not classified Based on available data, the classification criteria are not met.
Aspiration hazard	:	Not classified Based on available data, the classification criteria are not met.
Potential Adverse human health effects and symptoms	:	Based on available data, the classification criteria are not met.
Symptoms/injuries after inhalation	:	Inhalation is unlikely a route of exposure at ambient temperature. Inhalation is unlikely due to physical form. If user operations generate dust or fumes, . Inhalation of dust may cause irritation of the respiratory system. Fumes are irritating to the respiratory system.
Symptoms/injuries after skin contact	:	Risk of thermal burns on contact with molten product.
Symptoms/injuries after eye contact	:	Not expected under normal conditions of use. If user operations generate dust. Dusts are mechanical irritants. may cause physical irritation upon direct contact. Risk of thermal burns on contact with molten product.
Symptoms/injuries after ingestion	:	Choking hazard.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity

Propanoic acid (79-09-4)	
LC50 fishes 1	> 1 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
LC50 fish 2	73 - 99.7 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

Persistence and degradability

Gutta Percha	
Persistence and degradability	Not established.

Bioaccumulative potential

Gutta Percha	
Bioaccumulative potential	Not established.

Propanoic acid (79-09-4)	
Log Pow	0.25 - 0.33

Mobility in soil
No additional information available.

Other adverse effects

Effect on ozone layer : No additional information available

Effect on the global warming : No known ecological damage caused by this product.

Other information : Avoid release to the environment.

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to comply with applicable local, national and international regulations.

Ecology - waste materials : Avoid release to the environment.

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SECTION 14 – TRANSPORT INFORMATION

In accordance with DOT
Not regulated for transport

Additional Information

Other information : No supplementary information available.

ADR

Transport document description : No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15 – REGULATORY INFORMATION

US Federal Regulations

Propanoic acid (79-09-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
RQ (Reportable quantity, section 304 of EPA's List of Lists) :	5000 lb

International Regulations

CANADA

Titanium dioxide (13463-67-7)	
Listed on the Canadian DSL (Domestic Sustances List)	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects

Propanoic acid (79-09-4)	
Listed on the Canadian DSL (Domestic Sustances 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

EU-Regulations
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

National Regulations
No additional information available

US State Regulations

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

SECTION 16 – OTHER INFORMATION

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Revision Date: 10/27/2014

Full text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Carc. 2	Carcinogenicity, Category 2
Flam. Liq. 3	Flammable liquids Category 3

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Skin Corr. 1B	Skin corrosion/irritation Category 1B
H226	Flammable liquid and vapour
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H351	Suspected of causing cancer

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