atlas enta
Atlas-Enta Dişçilik Sanayi ve Ticaret A.Ş.

**MSDS Ref. No** : QS-MSDS-015
**Date Approved** : 12. June, 2017
**Revision Date** : -
**Revision No** : -

# MATERIAL SAFETY DATA SHEET G-CERAM PASTE OPAQUE

## 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

**1.1 Product name:** **PASTE OPAQUE FOR METAL FRAMEWORK RESTORATIONS**

**1.2 Trade name:** **G-CERAM**

**1.3 Application/Use of the product:** FOR FABRICATING DENTAL CROWNS AND BRIDGES

**1.4 Company/Manufacturer:** ATLAS-ENTA DİŞÇİLİK SANAYİ VE TİCARET A.Ş.
İzmir Pancar OSB. 9.Cadde no.10/A, 35865 Torbalı , İZMİR-TÜRKİYE
Tel: +90.232.433.7351 Fax: +90.232.469.6087

**1.5 Emergency information:** ATLAS-ENTA DİŞÇİLİK SANAYİ VE TİCARET A.Ş.
İzmir Pancar OSB. 9.Cadde no.10/A, 35865 Torbalı , İZMİR-TÜRKİYE
Tel: +90.232.433.7351 Fax: +90.232.469.6087

## 2. COMPOSITION / INFORMATION ON INGREDIENTS – main components

2.1 **Mixture:**

| Components | C.A.S. | Classification | WT % |
|---|---|---|---|
| Feldspar, Fused | 1332-58-7 | Not applicable | 65-70 |
| Tin Oxide | 21651-19-4 | Not applicable | 3-15 |
| Butylene Glycol | 107-88-0 | Not applicable | 10-27 |
| Glycerine | 56-81-5 | Not applicable | 10-20 |
| Diethylene Glycol | 21651-19-4 | AcuteTox.4,H302<br>STOT-RE 2, H373 | 3-10 |

## 3. HAZARDS IDENTIFICATION

3.1 **Classification of the Substance or Mixture:**

| GHS Classification: | | |
|---|---|---|
| Health | Environmental | Physical |
| Acute Toxicity Category 4 (H302) Specific Target Organ Toxicity - Repeated Exposure Category 2 (H373) | Not Hazardous | Not Hazardous |

3.2 **Label Elements:**

Signal Word: Warning!
Contains: Diethylene Glycol

| Hazard Phrases | Precautionary Phrases |
|---|---|
| H302 Harmful if swallowed.<br>H373 May cause damage to kidneys through prolonged or repeated exposure by oral route. | P260 Do not breathes dust, mist or vapors.<br>P264 Wash hands and skin thoroughly.<br>P270 Do not eat drink or smoke when using this product.<br>P301 + P312 IF Swallowed: Call a Poison CENTER or physician if you feel unwell.<br>P330 Rinse mouth.<br>P501 Dispose of contents and container in accordance with local and national regulations. |

3.2 **Other Hazards:** None known.

## 4. FIRST AID MEASURES

**4.1 Description of First Aid Measures**

| | |
|---|---|
| **Eyes contact with dust:** | Flush eyes with plenty of water; Get medical attention if irritation occurs and persists. |
| **Skin contact:** | Wash skin with soap and water. Get medical attention if irritation develops and persists. Remove and launder clothing before re-use. |
| **Ingestion:** | Seek immediate medical attention for large ingestions. Call local poison control center or go to an emergency department. Never give anything by mouth to or induce vomiting in an unconscious or drowsy person. |
| **Inhalation:** | Remove victim to fresh air. If symptoms persist, get medical attention. |

**4.2 Most Important Symptoms and Effects, Both Acute and Delayed:** May cause eye irritation. Inhalation of dust, mist, or vapors may cause nose and throat irritation and nervous system effects. Harmful if swallowed. Ingestion may cause abdominal discomfort or pain, nausea, vomiting, dizziness, drowsiness, malaise, blurring of vision, irritability, back pain, decrease in urine output, kidney failure, and central nervous system effects.

## 5. FIRE - FIGHTING MEASURES

**5.1 Extinguishing media:** Dry chemical, CO2, water spray or regular foam.

**5.2 Special hazards arising from the substance**

| | |
|---|---|
| **Hazardous combustion products:** | None |
| **General Hazard:** | Non-combustible. |
| **Properties contributing to Flammability:** | None |
| **Flashpoint:** | Not applicable |
| **Flammable limits in air:** | Upper: Not available Lower: Not available. |
| **Auto ignition temperature:** | Not applicable |
| **Sensitivity to static discharge:** | Not applicable |
| **Sensitivity to static impact:** | Not applicable |

5.3 **Advice for fire-fighters:** Use water to cool fire-exposed containers. Fight fire from a safe distance or protected location. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

## 6. ACCIDENTAL RELEASE MEASURES

**6.1 Person related safety precautions**: Avoid contact with skin, eyes or clothing. Do not breathe dust, mist or vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8

**6.2 Environmental Precautions :** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**6.3 Measures for cleaning :** Promptly wipe up or scoop up spills and place in appropriate containers for disposal. Wash spill site with water.

## 7. HANDLING AND STORAGE

**7.1 Precautions for safe handling :** Avoid contact with the eyes, skin and clothing. Do not breathe dust, mist or vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

**7.2 Conditions for safe storage :** Store in a cool, dry, well-ventilated area away from excessive heat, ignition sources and other incompatible materials. Keep containers closed when not in use.

**7.3 Specific end use (s) :** For professional use only.

# 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

| **8.1 Control Parameters:** | |
|---|---|
| Occupational Exposure Limits: | |
| Feldspar, Fused | 2 mg/m3 TWA ACGIH TLV (Respirable) 5 mg/m3 (Respirable fraction), 15 mg/m3 (Total dust) TWA OSHA PEL |
| | 2 mg/m3 TWA UK WEL (respirable aerosol) |
| | Belgium: 2 mg/m3 TWA |
| Diethylene Glycol | 10 mg/m3 TWA AIHA WEEL |
| | 44 mg/m3 TWA, 176 mg/m3 STEL DFG MAK |
| | 101 mg/m3 TWA UK WEL |
| Butylene Glycol | None Established |
| Glycerine | 5 mg/m3 (Respirable fraction), 15 mg/m3 (Total Dust) TWA OSHA PEL (As mist) |
| | 50 mg/m3 TWA (Inhalable), 100 mg/m3 STEL DFG MAK |
| | 10 mg/m3 TWA UK WEL |
| | Belgium: 10 mg/m3 TW |
| Tin Oxide | 2 mg/m3 TWA ACGIH TLV |
| | 4 mg/m3 TWA DFG MAK (Inhalable) (As Dust, general threshold limit value) |
| Biological Exposure Limits: None Established | |

| **8.2 Exposure Controls:** |
|---|
| **Appropriate Engineering Controls:** Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits. |
| **Individual Protection Measures (PPE):**<br>**Specific Eye/face Protection**: Chemical safety glasses are recommended if contact is possible.<br>**Specific Skin Protection:** Rubber, plastic or other impervious gloves should be worn to prevent prolonged skin contact. Specific **Respiratory Protection:** None should be needed for normal use. If the exposure limits are exceeded an approved dust/mist respirator or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.<br>**Specific Thermal Hazards**: None required. |

# 9. PHYSICAL AND CHEMICAL PROPERTIES

**9.1 Information on basic physical and chemical properties:**

| | | | |
|---|---|---|---|
| **Appearance:** | Finely divided powder in viscous carrier | **Explosive limits:** | LEL: Not determined<br>UEL: Not determined |
| **Odor:** | Not applicable | **Vapor pressure (mmHg):** | Not applicable |
| **Odor threshold:** | Not applicable | **Vapor density:** | Not applicable |
| **pH:** | Not applicable | **Relative density:** | 1.8-2.0 g/cc |
| **Melting/freezing point:** | Not applicable | **Solubility(ies):** | Not determined |
| **Initial boiling point and boiling range:** | Not determined | **Partition coefficient: noctanol / water:** | Not applicable |
| **Flash point:** | Not determined | **Auto-ignition temperature:** | Not applicable |
| **Evaporation rate:** | Partially evaporates | **Decomposition temperature:** | Not determined |
| **Flammability (solid, gas):** | Not applicable | **Viscosity:** | Not determined |
| **Explosive Properties:** | Not determined | **Oxidizing Properties:** | None |

**9.2 Other information**: None available

## 10. STABILITY AND REACTIVITY

.

| |
|---|
| **10.1 Reactivity:** None known |
| **10.2 Chemical Stability:** Stable, inorganic compound in organic carrier, does not degrade, partially evaporates. |
| **10.3 Possibility of Hazardous Reactions:** None known. |
| **10.4 Conditions to Avoid:** Avoid high temperatures, extreme heat, and ignition sources. |
| **10.5 Incompatible materials:** Strong oxidizing or reducing agents. |
| **10.6 Hazardous Decomposition Products:** Decomposition may release carbon monoxide and carbon dioxide. |

## 11. TOXICOLOGICAL INFORMATION

**11.1 Information on toxicological effects**

**11.1.1 Potential Health Effects:**

**Eyes:** Direct contact with the paste may cause irritation with redness, burning and tearing.
**Skin:** Prolonged contact with the paste may cause irritation, reddening and drying of the skin.
**Ingestion:** Swallowing may cause gastrointestinal irritation, nausea, vomiting, diarrhea, and central nervous depression. Swallowing large amounts of diethylene glycol may cause lower back pain and kidney or liver damage.
**Inhalation:** Not expected to cause respiratory tract irritation.

**11.1.2 Chronic Health Effects:**

No adverse effects are expected under normal use conditions. Prolonged overexposure to diethylene glycol may cause adverse respiratory, cardiac, central nervous system effects, and damage to the bladder, kidney and liver based on animal data. Repeated excessive exposures to glycerine may cause increased fat levels in the blood and damage to the kidney and liver.

**11.1.3 Irritation:**

**Diethylene Glycol**: Not irritating to rabbit skin and rabbit eyes. Butylene Glycol: Not irritating to rabbit skin and slightly irritating to rabbit eyes.

**11.1.4 Corrosivity:**

This product is not expected to be corrosive.

**11.1.5 Sensitisation:**

No sensitizing effect known. This product showed no evidence of skin sensitizing.

**11.1.6 Carcinogenicity:**

None of the other components are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

**11.1.7 Mutagenicity:**

Diethylene glycol: Diethylene glycol was negative in the AMES test. CHO-cells were negative for a sister chromatid exchange test with and without metabolic activation at concentrations of 10-50 mg/mL, Butylene Glycol: Rats were fed butane-1, 3-diol in concentrations up to 24% of the diet and paired to produce F1A, F2A and F3A litters. Analysis of the femur bone marrow of at least two animals per sex and dose of these litters revealed no increase in chromosomal aberrations. Not mutagenic in vivo (rat dominant lethal and cytogenetic assays). Glycerine: Negative in AMES, in-vitro sister chromatid exchange and unscheduled DNA synthesis. This product is not expected to cause mutagenic activity.

**11.1.8 Aspiration Hazard:**

Not an aspiration hazard.

**11.1.9 Acute Toxicity:**

| | |
|---|---|
| Feldspar, Fused | : Oral rat LD50- >5000 mg/kg; Skin Rat LD50 - >5000 mg/kg |
| Diethylene Glycol | : Oral rat LD50 - 12,565 mg/kg; Skin rabbit LD50 – 11,890 mg/kg |
| Butylene Glycol | : Oral rat LD50 –18.6-30 g/kg |
| Glycerine | : Oral rabbit LD50- >12,600 mg/kg ; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >570 mg/m3/1hr |
| Tin Oxide | : No toxicity data available. |

**11.1.10 Reproductive Toxicity Data:**

Diethylene Glycol: In a reproductive study with mice and rats, diethylene glycol was administered for 6-15 days. The NOEL was 559 mg/kg/day with the mouse and 1,118 mg/kg/day with the rat for maternal toxicity, and 2,795 mg/kg/day with mice and 1,118 mg/kg/day with rats for developmental toxicity (fetotoxicity). Glycerine: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180 mg/kg or in rats or mice administered up to 1,310 mg/kg. Butylene Glycol: In a study of twenty five rats of both sexes were fed either control diet or diet supplemented with 1,3-butylene glycol at dose levels of 5, 10 or 24% of the diet (2500, 5000 or 12000 mg/kg by weight/day). 1,3-butylene glycol did not influence fertility in a five generation study with an embedded continuous breeding study in concentrations up to 10% in the diet (5000 mg/kg). In the highest concentration tested (24%, 12000 mg/kg) no offspring in the fifth litter of the F2 generation were produced. This product is not expected to cause adverse reproductive effects.

**11.1.11 Specific Target Organ Toxicity (STOT) --Single Exposure:**

Diethylene glycol: In an oral study with rats, doses of 1 and 5 mL/kg produced compensated metabolic acidosis, but doses greater than 10 mL/kg produced non-compensated metabolic acidosis, reduced or absence of urine output, kidney damage, and death. Glycerine: When place into the eye of a rabbit, glycerine will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells.

**11.1.12 Specific Target Organ Toxicity (STOT) -- Repeated Exposure:**

Diethylene glycol: In a long term feeding study, rats given in 4% by weight in food showed an increase in mortality rates, a marked depression of growth rate, bladder stones, severe kidney damage, and moderate liver damage. Glycerine: In a 13 week sub-chronic inhalation study with rats, glycerine was found to cause mild irritation of mucous membranes. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerine in their feed. Butylene Glycol: No treatment related adverse effects were observed in a chronic feeding-study in rats which received up to 10% (5000 mg/kg/d) 1, 3-butylene glycol in food.

## 12. ECOLOGICAL INFORMATION

**12.1 Toxicity:**

Feldspar Fused: 24 hour and 48 hour LC50 Daphnia pulex ->1.1 g/L
Diethylene Glycol: 96 hour LC50 Lepomis macrochirus (Bluegill fish) - 1,000 mg/L
Butylene Glycol: 48hr EC50 Daphnia magna - >1000 mg/L; 72hr ErC50 Algae - >1070 mg/L
Glycerin: 24 hour LC50 Goldfish - >5000 mg/L; 48 hour EC50 Daphnia magna -10,000 mg/L

This product is not expected to present an environmental hazard.

**12.2 Persistence and degradability:**

Diethylene glycol is readily biodegradable -90% in 28 days. Butylene Glycol: Readily biodegradable – 81% after 29 days. Glycerien is readily biodegradable -96% in 24 hours.

**12.3 Bio accumulative potential:**

Diethylene glycol is not expected to bio accumulate in aquatic organisms. Glycerine is not expected to bio concentrate in fish and aquatic organisms.

**12.4 Mobility in soil:**

Diethylene glycol is expected to have a high rate of mobility in soil. Glycerine: Very high mobility in soil.

**12.5 Results of PBT and vPvB Assessment:**

Not required

**12.5 Other adverse effects:**

None

## 13. DISPOSAL CONSIDERATIONS

**13.1 Waste treatment methods:**

Use a qualified industrial waste disposal facility. Dispose of waste according to local laws and regulations.

## 14. TRANSPORT INFORMATION

| | 14.1 UN Number | 14.2 UN Proper Shipping Name | 14.3 Hazard Class(s) | 14.4 Packing Group | 14.5 Environmental Hazards |
|---|---|---|---|---|---|
| **DOT** | None | Not Regulated | None | None | Not applicable |
| **ADR/RID** | None | Not Regulated | None | None | Not applicable |
| **IMDG** | None | Not Regulated | None | None | Not applicable |
| **IATA/ICAO** | None | Not Regulated | None | None | Not applicable |

**14.6** **Special Precautions for User:** Not applicable.

**14.7** **Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable.

## 15. REGULATORY INFORMATION

**15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:**

**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 chemical notification requirements.

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act.

**Clean Air Act (CAA):** This material is not regulated under the Clean Air Act.

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:** Acute Health, Chronic Health

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):** None

**State Regulations:**

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None known

**International Regulations:**

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

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

**EU REACH:** This product is a medical device and not subject to chemical notification requirements.

**Australian Inventory of Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**China Inventory of Existing Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**Korean Existing Chemicals List:** This product is a medical device and not subject to chemical notification requirements.

**Philippine Inventory of Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**15.2 Chemical Safety Assessment:**
None required.

## 16. OTHER INFORMATION

**Warning for the reader: important**

This medical device has been studied and formulated for an exclusive professional dental use and must be used following instructions, procedures and precautions of use. The information disclosed in this Safety Data is believed to be correct to the best of our current knowledge and experience. It only relates to the specific product designated herein and it may not be valid when said product is used in combination with any other material or in any process, unless specified in the text. However, this document aims to provide the necessary health and safety information of the product and is not to be considered a warranty or quality specification and shall not establish any legally valid contractual relationship. Considering that used conditions and modes are not under our control we can't assume any responsibility for results that do not meet user's expectations. The manufacturer is not responsible for damages due to incorrect use or undue handlings. Furthermore, Atlas-Enta Dişçilik San ve Tic A.Ş. is not responsible for disposal or testing of this product for hazardous content, and will not be liable to any party for such disposal, testing, or content. This safety data sheet overrules and substitutes any previous edition.

**Further information on the product:**

For further information consult the product datasheet. Before use, operators must be sure that the product characteristics are suitable to their needs.

**REVISION SUMMARY:** Revision # 00.

This MSDS has been prepared to meet European Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EC) 2015/830), US 29CFR1910.1200, Canada Hazardous Products Regulation.