

SAFETY DATA SHEETS

This SDS packet was issued with item:

072057115

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072057107 072057123 072057131

SECTION 1 - SOURCE/IDENTITY/USE INFORMATION**DISTRIBUTOR**

GC AMERICA INC.

3737 West 127th St.

Alsip, Illinois, 60803

Telephone: 708-597-0900

Hours: Mon.- Fri. 8:00 am. - 5:00 pm. C.S.T.

Transportation Emergency No. 800-424-9300

COMMON NAME: GRADIA INTENSIVE COLOR AND MAMELON STAIN**CHEMICAL NAME:** N.A.**PRODUCT USE:** Used to add developmental grooves and characterizations to restorations.*The following information is provided with regard to the toxicity and hazards of the pure components present in this product.***SECTION 2 - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION**

COMPONENT	C.A.S.	EXPOSURE LIMITS	LD50/LC50	%
Di-2-Methacryloyloxyethyl 2,2,4-trimethylhexamethylene dicarbamate	41137-60-4	N.E.	N.E.	45-60
Neopentylglycol dimethacrylate	126-30-7	N.E.	N.E.	15-20
Amorphous Precipitated Silica	112926-00-8	PEL=0.1mg/m ³ TLV/TWA=10mg/m ³ (dust) (ACGIH)	LD50=>10000mg/kg (oral ratio) LC50= N.E.	5-15

SECTION 3 - PHYSICAL/CHEMICAL PROPERTIES**BOILING POINT:** N.E.**SPECIFIC GRAVITY:** N.E.**VAPOR PRESSURE:** N.E.**MELTING POINT:** N.E.**VAPOR DENSITY:** N.E.**EVAPORATION RATE:** N.E.**SOLUBILITY IN WATER:** N.E.**ODOR THRESHOLD:** N.E.**COEFFICIENT OF OIL/WATER DISTRIBUTION:** N.E.**APPEARANCE AND ODOR:** N.E.**SECTION 4 - FIRE AND EXPLOSION DATA****FLASH POINT:** N.E.**FLAMMABLE LIMITS:** N.E.**EXTINGUISHING MEDIA:** Water fog, carbon dioxide, dry chemical**SPECIAL FIRE FIGHTING PROCEDURES:** N.A.**UNUSUAL FIRE AND EXPLOSION HAZARDS:** N.A.**HAZARDOUS COMBUSTION PRODUCTS:** N.E.**SECTION 5 - REACTIVITY DATA****STABILITY:** Stable Unstable: **POLYMERIZATION:** Will Not Occur Will Occur: **CONDITIONS TO AVOID:** High heat, high humidity.**INCOMPATIBILITY (MATERIALS TO AVOID):** None.**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** N.E.

SECTION 6 - HEALTH HAZARD DATA and FIRST AID INFORMATION

	YES	NO	NE	NA	NTP	IARC	OSHA	OTHER
MUTAGENIC AFFECTS		X						
TERATOGENIC AFFECTS		X						
REPRODUCTIVE TOXIN		X						
CARCINOGENICITY		X						
SENSITIZER		X						

ROUTES OF ENTRY: Inhalation Skin Ingestion **HEALTH HAZARD (Acute and Chronic):****SKIN:** May cause irritation.**INGESTION:** May cause toxic affects.**SIGNS AND SYMPTOMS OF OVEREXPOSURE:** N.E.**CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:** N.E.**EMERGENCY FIRST AID PROCEDURES:****INHALATION:** If discomfort occurs, remove to fresh air.**EYES:** Flush with plenty of water. If irritation develops seek medical attention.**SKIN:** Wash with soap and water.**INGESTION:** Rinse and clear mouth and throat. Seek medical attention.**SECTION 7 - PRECAUTIONS FOR SAFE HANDLING AND USE****IN CASE OF RELEASE OR SPILL:** Absorb with inert material. Transfer to container for disposal.**WASTE DISPOSAL METHOD:** In accordance with local, state and federal regulations.**STORAGE, HANDLING, AND SPECIAL PRECAUTIONS:** Store at normal room temperature in a well ventilated area. Avoid direct sunlight.**SECTION 8 - CONTROL MEASURES****RESPIRATORY PROTECTION:** N.A.**VENTILATION:** Local Exhaust: Yes Mechanical: N.A. Special: N.A. Other: N.A.**PROTECTIVE GLOVES:** N.A.**EYE PROTECTION:** N.A.**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N.A.**WORK/HYGIENIC PRACTICE:** Observe good hygienic practices.**SECTION 9 - PREPARATION INFORMATION***This data is supplied to comply with OSHA Hazard Communication Standard 29 CFR 1910,1200 and W.H.M.I.S. CPR***DATE:** 09 January 2006**REVIEWED:** 03 April 2012**N.A. = NOT APPLICABLE****N.E. = NOT ESTABLISHED***The information herein is given in good faith but no warranty expressed or implied is made.*

NFPA

FIRE - 0	TOXICITY - 1	REACTIVITY - 1	SPECIAL- P
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Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 03/14/2015

Version US-EN-Rev 1


Reviewed on 03/13/2015

1 Identification

- **Product identifier**
- **Trade name:** GRADIA (Shade Group: Mamelon Stain [MS2, MS3, and MS5])
- **Relevant identified uses of the substance or mixture and uses advised against**
Dental material
The product is intended for professional use.
To avoid risks for humans and environment obtain instructions.
- **Application of the substance / the mixture** Manufacture of dental prothesis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
USA

sds@gcamerica.com
- **Information department:** Regulatory Affairs
- **Emergency telephone number:**
During normal opening times (Mon.-Fri. 8:00 AM-5:00 PM CST): +1 (708) 597-0900
Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**
Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 4 H312 Harmful in contact with skin.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Additional information:**
The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS06
- **Signal word** Danger
- **Hazard-determining components of labeling:**
urethane dimethacrylate (UDMA)

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Trade name: GRADIA (Shade Group: Mamelon Stain [MS2, MS3, and MS5])

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- **Hazard statements**

Toxic if swallowed.
 Harmful in contact with skin.
 Causes skin irritation.
 Causes serious eye irritation.
 May cause an allergic skin reaction.

- **Precautionary statements**

Contaminated work clothing must not be allowed out of the workplace.
 Avoid breathing dust/fume/gas/mist/vapors/spray
 If swallowed: Immediately call a poison center/doctor.
 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:**

47 % of the mixture consists of component(s) of unknown toxicity.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 1
 Fire = 1
 Reactivity = 1

- **HMIS-ratings (scale 0 - 4)**



Health = 1
 Fire = 1
 Reactivity = 1

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

72869-86-4	urethane dimethacrylate (UDMA)	25-50%
	dimethacrylate**	10-20%
	UV-light absorber**	1-5%
13463-67-7	titanium dioxide	1-5%

- **Additional information:**

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

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4 First-aid measures

- **Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
If symptoms persist consult doctor.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
Do not use mouth to mouth or mouth to nose resuscitation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
- **After eye contact:**
Protect unharmed eye.
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Do not induce vomiting; immediately call for medical help.
Rinse out mouth and then drink plenty of water.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** Allergic reactions
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid formation of dust.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.

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- **Methods and material for containment and cleaning up:**
 - Pick up mechanically.
 - Prevent formation of dust.
 - Dispose of the collected material according to 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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
 - Observe instructions for use.
 - Ensure good ventilation/exhaustion at the workplace.
 - Prevent formation of dust.
 - Any deposit of dust which cannot be avoided must be regularly removed.
 - Avoid contact with the eyes and skin.
- **Information about protection against explosions and fires:**
 - Dust can combine with air to form an explosive mixture.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
 - Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Observe instructions for use / storage.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

Components with limit values that require monitoring at the workplace:

13463-67-7 titanium dioxide

PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³ withdrawn from NIC

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - The usual precautionary measures for handling chemicals should be followed.
 - Do not inhale dust / smoke / mist.
 - Avoid contact with the eyes and skin.
 - Wash hands before breaks and at the end of work.
 - Immediately remove all soiled and contaminated clothing.
- **Breathing equipment:** Suitable respiratory protective device recommended.

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- **Protection of hands:** Protective gloves
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

- | | |
|------------------------|---------------------------------|
| Form: | Pasty |
| Color: | Different according to coloring |
| Odor: | Characteristic |
| Odor threshold: | Not determined. |

- | | |
|------------------|-----------------|
| pH-value: | Not applicable. |
|------------------|-----------------|

· Change in condition

- | | |
|-------------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

- | | |
|---------------------|-----------------|
| Flash point: | Not applicable. |
|---------------------|-----------------|

- | | |
|---------------------------------------|-----------------|
| Flammability (solid, gaseous): | Not determined. |
|---------------------------------------|-----------------|

- | | |
|------------------------------|---------------|
| Ignition temperature: | Undetermined. |
|------------------------------|---------------|

- | | |
|-----------------------------------|-----------------|
| Decomposition temperature: | Not determined. |
|-----------------------------------|-----------------|

- | | |
|-----------------------|------------------------------|
| Auto igniting: | Product is not selfigniting. |
|-----------------------|------------------------------|

- | | |
|-----------------------------|---|
| Danger of explosion: | Product does not present an explosion hazard. |
|-----------------------------|---|

· Explosion limits:

- | | |
|---------------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |

- | | |
|------------------------|-----------------|
| Vapor pressure: | Not applicable. |
|------------------------|-----------------|

- | | |
|-------------------------|-----------------|
| Density: | Not determined. |
| Relative density | Not determined. |
| Vapour density | Not applicable. |
| Evaporation rate | Not applicable. |

· Solubility in / Miscibility with

- | | |
|---------------|------------|
| Water: | Insoluble. |
|---------------|------------|

- | | |
|---|-----------------|
| Partition coefficient (n-octanol/water): | Not determined. |
|---|-----------------|

· Viscosity:

- | | |
|-----------------|-----------------|
| Dynamic: | Not applicable. |
|-----------------|-----------------|

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Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
· Solids content:	85.1 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable at ambient temperature.
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **LD/LC50 values that are relevant for classification:** No further relevant information available.
 - **Primary irritant effect:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Irritating effect.
 - **Sensitization:** Sensitization possible through skin contact.
 - **Experience with humans:**
May cause damage to kidneys.
May cause damage to liver.
 - **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
 - **Carcinogenic categories**
 - **IARC (International Agency for Research on Cancer)**
- | | |
|------------------|----|
| titanium dioxide | 2B |
|------------------|----|
- **NTP (National Toxicology Program)**
 - None of the ingredients is listed.
 - **OSHA-Ca (Occupational Safety & Health Administration)**
 - None of the ingredients is listed.
 - **Carcinogenic categories' legend:**

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IARC Group 1: The agent is carcinogenic to humans.
 IARC Group 2A: The agent is probably carcinogenic to humans.
 IARC Group 2B: The agent is possibly carcinogenic to humans.
 IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.
 IARC Group 4: The agent is probably not carcinogenic to humans.
 NTP K: Known to be human carcinogen.
 NTP R: Reasonably anticipated to be human carcinogen.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
 Water hazard class 3 (Self-assessment): extremely hazardous for water
 Do not allow product to reach ground water, water course or sewage system, even in small quantities.
 Danger to drinking water if even extremely small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
 Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|-------------------------------------|------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |

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- | | |
|--|-----------------|
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendments and Reauthorization Act)

- **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

urethane dimethacrylate (UDMA)

dimethacrylate**

UV-light absorber**

titanium dioxide

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

titanium dioxide

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

titanium dioxide

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS06

- **Signal word** Danger

- **Hazard-determining components of labeling:**

urethane dimethacrylate (UDMA)

- **Hazard statements**

Toxic if swallowed.

Harmful in contact with skin.

Causes skin irritation.

Causes serious eye irritation.

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May cause an allergic skin reaction.

· **Precautionary statements**

Contaminated work clothing must not be allowed out of the workplace.

Avoid breathing dust/fume/gas/mist/vapors/spray

If swallowed: Immediately call a poison center/doctor.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

· **Department issuing SDS:** Regulatory Affairs

· **Contact:**

Regulatory Affairs

Telephone No. +1 (708) 597-0900

sds@gcamerica.com

· **Date of preparation / last revision** 03/14/2015 / -

· **Abbreviations and acronyms:**

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HCS: Hazard Communication Standard (USA)

MSDS: Material Safety Data Sheet

SDS: Safety Data Sheet

ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways)

ECHA: European Chemicals Agency

OSHA: Occupational Safety and Health Administration (USA)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· **Sources**

· Manufacturers' MSDSs/SDSs

· OSHA (<https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html>)

· TOXNET (<http://toxnet.nlm.nih.gov/>)

· ECHA (<http://echa.europa.eu/>)

· EnviChem (www.echemportal.org)

· **Notes:**

CAS Registry Number is a Registered Trademark of the American Chemical Society.

CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

· * **Data compared to the previous version altered.** This version replaces all previous versions.

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