SAFETY DATA SHEETS

This SDS packet was issued with item: 072055754

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

072055762 072055770 072055788 072055796 072055804 072055812 072055820 072055838 072055846 072055853 072055861 072055879 072055887 072055895 072055903 072055911 072055929 072055937 273034950



GRADIA OPAQUE MATERIAL SAFETY DATA SHEET

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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 OPAQUE

CHEMICAL NAME: N.A. **PRODUCT USE:** Dental crown and bridge work - opaque

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	41137-60-4	N.E.	N.E.	30-50%
2,2,4-trimethylhexamethylene				
dicarbamate				
Amorphous Precipitated Silica	112926-00-8	PEL=0.1mg/m ³	LD50=>10000mg/kg	20-30%
		TLV/TWA=10mg/m ³	(oral ratio)	
		(dust) (ACGIH)	LC50= N.E.	
Trietyleneglycol dimethacrylate	109-16-0	N.E.	N.E.	5-10%
Neopentylglycol dimethacrylate	126-30-7	N.E.	N.E.	1-5%

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:	Insoluble or difficult to dissolve	ODOR THRESHOLD:	N.E.
COEFFICIENT OF OIL/WAT	ER DISTRIBUTION: N.E.	APPEARANCE AND ODOR:	Paste and ester-like

SECTION 4 - FIRE AND EXPLOSION DATA

FLASH POINT: 101°C 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

Stable STABILITY: POLYMERIZATION: Will Not Occur

Unstable Will Occur

CONDITIONS TO AVOID: High heat, high humidity. INCOMPATIBILITY (MATERIALS TO AVOID): N.A. HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: N.E.



Other: N.A.

MS001420

GRADIA OPAQUE

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SECTION 6 - HEALTH HAZARD DATA and FIRST AID INFORMATION

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

ROUTES OF ENTRY: Inhalation Skin Ingestion

HEALTH HAZARD: (ACUTE AND CHRONIC):

SKIN: May cause irritation.

INGESTION: May cause toxic affects.

EMERGENCY FIRST AID PROCEDURES:

INHALATION: If irritation develops, 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: Dispose of waste 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.
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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:
 02 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 - 1	TOXICITY - 1	REACTIVITY - 1	SPECIAL- P

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Printing date 02/24/2015

Version US-EN-Rev 1

Reviewed on 02/20/2015

- · Product identifier
- · Trade name: GRADIA (Shade Group: Opaque)

 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

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



· Signal word Warning

- Hazard-determining components of labeling: urethane dimethacrylate (UDMA) dimethacrylate component**
- · Hazard statements
- May cause an allergic skin reaction.
- · Precautionary statements

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

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Trade name: GRADIA (Shade Group: Opaque)

(Contd. of page 1) Avoid breathing dust/fume/gas/mist/vapors/spray Wear protective gloves. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international regulations. • Additional information: 36 % of the mixture consists of component(s) of unknown toxicity. • Classification system: • NFPA ratings (scale 0 - 4))
Health = 1 Fire = 1 Reactivity = 0	
· HMIS-ratings (scale 0 - 4)	
HEALTH1FIRE1FIRE1REACTIVITY0	
 Other hazards Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable. 	
3 Composition/information on ingredients	

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 component**	10-20%
dimethacrylate**	1-5%
trimethacrylate**	1-5%
UV-light absorber**	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).

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.

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- After skin contact: Immediately wash with water and soap and rinse thoroughly. Seek medical treatment.
- After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.
- · 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 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. Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. 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. LISA

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Trade name: GRADIA (Shade Group: Opaque)

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7 Handling and storage

- · Handling:
- Precautions for safe handling
 Observe instructions for use.
 Ensure good ventilation/exhaustion at the workplace.
 Prevent formation of aerosols.
 Avoid contact with the eyes and skin.
- · Information about protection against explosions and fires: No special measures required.
- · 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:

trimethacrylate**

WEEL Long-term value: 1 mg/m³ Skin

• 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.

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.
- · 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

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Trade name: GRADIA (Shade Group: Opaque)

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9 Physical and chemical proper	ties
Information on basic physical and c	hemical properties
General Information	
· Appearance:	
Form:	Pasty
Color: · Odor:	Transparent Ester-like
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· 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 determined.
· Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
· Evaporation rate	Not determined.
 Solubility in / Miscibility with 	
Water:	Insoluble.
· Partition coefficient (n-octanol/wate	r): Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
Solids content:	100.0 %
Other information	No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability Stable at ambient temperature.

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Trade name: GRADIA (Shade Group: Opaque)

• 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: No irritant effect.
- on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- Additional toxicological information:

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)	
titanium dioxide	2B
poly(methyl methacrylate)	3
butylated hydroxytoluene (BHT)	3
iron(III) oxide	3
· 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:

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.

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Trade name: GRADIA (Shade Group: Opaque)

Danger to drinking water if even extremely small quantities leak into the ground.

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• 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

Void
Void
Void
Void
No
Not applicable.
of Not applicable.
-

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.

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Trade name: GRADIA (Shade Group: Opaque)

TSCA (Toxic Substances Control Act):	
urethane dimethacrylate (UDMA)	
surface-treated silica**	
dimethacrylate component**	
dimethacrylate**	
titanium dioxide	
trimethacrylate**	
poly(methyl methacrylate)	
UV-light absorber**	
Carcinogenic categories	
EPA (Environmental Protection Agency)	
None of the ingredients is listed.	
TLV (Threshold Limit Value established by ACGIH)	
titanium dioxide	
butylated hydroxytoluene (BHT)	
iron(III) oxide	
NIOSH-Ca (National Institute for Occupational Safety and Health)	
titanium dioxide	
The product is classified and labeled according to the Globally Harmonized System	າ (GHS).
The product is classified and labeled according to the Globally Harmonized System	ו (GHS).
Signal word Warning Hazard-determining components of labeling: urethane dimethacrylate (UDMA)	ו (GHS).
The product is classified and labeled according to the Globally Harmonized System Hazard pictograms GHS07 Signal word Warning Hazard-determining components of labeling: urethane dimethacrylate (UDMA) dimethacrylate component**	ו (GHS).
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Trade name: GRADIA (Shade Group: Opaque)

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· Contact:
Regulatory Affairs
Telephone No. +1 (708) 597-0900
sds@gcamerica.com
· Date of preparation / last revision 02/24/2015 / -
· 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
Skin Sens. 1: Sensitisation - Škin, 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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