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Version US-EN-Rev 1

Reviewed on 09/19/2017

1 Identification

- · Product identifier
- Trade name: GRADIA PLUS MODELLING LIQUID

 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 Auxiliary for 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.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· 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: dimethacrylate component** urethane dimethacrylate (UDMA) UV-light absorber**

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(Contd. of page 1) · Hazard statements May cause an allergic skin reaction. Harmful to aquatic life. Harmful to aquatic life with long lasting effects. Precautionary statements Avoid breathing dust/fume/gas/mist/vapors/spray Contaminated work clothing must not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves. Wash contaminated clothing before reuse. Dispose of contents/container in accordance with local/regional/national/international regulations. · Hazard not otherwise classified (HNOC): · Classification system: NFPA ratings (scale 0 - 4) Health = 0Fire = 1 Reactivity = 0 · HMIS-ratings (scale 0 - 4) HEALTH 0 Health = 0 FIRE Fire = 11 REACTIVITY 0 Reactivity = 0 · 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:

•	•	
CAS: 41637-3	38-1 ethoxylated bisphenol-A dimethacrylate (Bis-EMA)	50 - 70%
	dimethacrylate component**	10 - 20%
CAS: 72869-8	B6-4 urethane dimethacrylate (UDMA)	5 - 10%
CAS: 128-37-	0 butylated hydroxytoluene (BHT)	< 1%
	UV-light absorber**	< 0.5%

· 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.

- 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.
 Do not allow to penetrate the ground/soil.
 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
 Description:
 Description:
 Description:
 Description:
 Description:
 Description:
 Description:
 Description:
 Absorb liquid components with liquid-binding material.
 Dispose of the collected material according to regulations.
 Description:
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- Reference to other sections
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.

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Protective Action Protective Action C * indicates the PA ** indicates the PA *** indicates the PA	disposal information. Criteria for Chemicals Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Lim AC value is between 10% and up to 50% of the LEL (10% LEL \leq PAC \leq AC value is between 50% and up to 100% of the LEL (50% LEL \leq PAC AC value is at 100% or more of the LEL (PAC \geq LEL). Iuction to PAC Table 2 – PAC Rev. 29 – May 2016	< 50% ĹEL).
· PAC-1:		
	dimethacrylate component**	33 mg/m3
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	120 mg/m3
CAS: 112945-52-5	silicon dioxide, amorphous	18 mg/m3
· PAC-2:		
	dimethacrylate component**	360 mg/m3
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	1,300 mg/m3
CAS: 112945-52-5	silicon dioxide, amorphous	100 mg/m3
· PAC-3:		
	dimethacrylate component**	2,100 mg/m3
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	7,900 mg/m3
CAS: 112945-52-5	silicon dioxide, amorphous	630 mg/m3

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.
- · Conditions for safe storage, including any incompatibilities
- · 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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists that were valid during the creation were used as basis.

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(Contd. of page 4) 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

9 Physical and chemical properties

General Information		
Appearance: Form:	Liquid	
	Liquid	
Color:	Light yellow	
Odor:	Odorless	
Odor threshold:	Not determined.	
pH-value at 20°C (68 °F):	3.5	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
	100%0 (%E)	
Flash point:	123°C (°F)	
Flammability (solid, gaseous):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not self-igniting.	

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Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure: Not determined.		
Density at 20°C (68 °F):	1.2 g/cm ³ (lbs/gal)	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic: Not determined.		
Kinematic:	Not determined.	
Solvent content:		
VOC content:	0.00 %	
Solids content:	5.0 %	
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:

CAS: 128-37-0 butylated hydroxytoluene (BHT)

- Oral LD50 10,700 mg/kg (guinea pig)
 - 1,040 mg/kg (mouse)

2,930 mg/kg (rat (f+m))

Dermal LD50 890 mg/kg (rat (f+m))

Primary irritant effect:

• on the skin: No irritant effect.

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 on the eye: No irritating effect. Sensitization: Sensitization possible through skin contact. 	
 Additional toxicological information: Carcinogenic categories 	
· IARC (International Agency for Research on Cancer)	
silicon dioxide, amorphous	3
butylated hydroxytoluene (BHT)	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 2B. The agent is not classifiable as to its carcinogenicit	ty 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.	
• Repeated dose toxicity. No further relevant information available	
CMR effects (carcinogenity, mutagenicity and toxicity for repr	
No further relevant information available.	
No further relevant information available.	
_	
12 Ecological information	
· Toxicity	
· Aquatic toxicity:	
CAS: 128-37-0 butylated hydroxytoluene (BHT)	
NOEC-value Ecol. other effects 0.07 mg/l (daphnia magna) 21 day, reproductive effects	
Persistence and degradability No further relevant information av	vailable.
 Behavior in environmental systems: Bioaccumulative potential No further relevant information availal 	ble
• Mobility in soil No further relevant information available.	ble.
· Ecotoxical effects:	
Remark: Harmful to fish	
 Additional ecological information: General notes: 	
Water hazard class 1 (Self-assessment): slightly hazardous for wa Do not allow undiluted product or large quantities of it to reach gr system.	
Harmful to aquatic organisms	
Results of PBT and vPvB assessment	
PBT: Not applicable.	
· vPvB: Not applicable.	(Contd. on page 8)

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Safety Data Sheet acc. to OSHA HCS 29 CFR 1910.1200

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· 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.

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
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex	
MARPOL73/78 and the IBC Code	Not applicable.

15 Regulatory information

 $^{\cdot}$ Safety, health and environmental regulations/legislation specific for the substance or mixture $^{\cdot}$ SARA (Superfund Amendments and Reauthorization Act)

• Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

• TSCA (Toxic Substances Control Act):

ethoxylated bisphenol-A dimethacrylate (Bis-EMA)

dimethacrylate component**

methacrylate**

urethane dimethacrylate (UDMA)

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butylated hydroxytoluene (BHT) svnergist**

UV-light absorber**

photoinitiator**

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

butylated hydroxytoluene (BHT)

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

None of the ingredients is listed.

· 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: dimethacrylate component** urethane dimethacrylate (UDMA) UV-light absorber**
- Hazard statements
 May cause an allergic skin reaction.
 Harmful to aquatic life.
 Harmful to aquatic life with long lasting effects.

Precautionary statements
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Contaminated work clothing must not be allowed out of the workplace.
 Avoid release to the environment.
 Wear protective gloves.
 Wash contaminated clothing before reuse.
 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 09/19/2017 / -

• **Abbreviations and acronyms:** GHS: Globally Harmonized System of Classification and Labelling of Chemicals HCS: Hazard Communication Standard (USA)

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(Contd. of page 9) 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) PAC: Protective Action Criterion (USA) PACs: Protective Action Criteria (USA) HNOC: Hazard Not Otherwise Classified (USA) LEL: Lower Explosive Limit UEL: Upper Explosive Limit 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) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit **REL: Recommended Exposure Limit** Skin Sens. 1: Skin sensitisation - Category 1 Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard - Category 3 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 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.

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

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