

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

1 Identification

- **Product identifier**
- **Trade name:** G-æniel Bulk Injectable
- **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** Dental filling material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803

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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**
bismethacrylate**
UV-light absorber**
urethane dimethacrylate (UDMA)
dimethacrylate component**
- **Hazard statements**
May cause an allergic skin reaction.

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 1)

- **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray
 Contaminated work clothing must not be allowed out of the workplace.
 Wear protective gloves.
 If skin irritation or rash occurs: Get medical advice/attention.
 Wash contaminated clothing before reuse.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

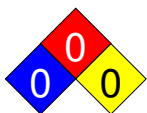
- **Hazard not otherwise classified (HNOC):** None

- **Additional information:**

9.8 % of the mixture consists of component(s) of unknown toxicity.

- **Classification system:**

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



Health = 0
 Fire = 0
 Reactivity = 0

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



HEALTH 0 Health = 0
 FIRE 0 Fire = 0
 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: 41637-38-1	ethoxylated bisphenol-A dimethacrylate (Bis-EMA)	10 - < 25%
	bismethacrylate**	2.5 - < 5%
	dimethacrylate**	2.5 - < 5%
	UV-light absorber**	0.2 - < 0.5%
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	0.2 - < 0.5%
	dimethacrylate component**	0.2 - < 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).

4 First-aid measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 2)

- 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, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water
- **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**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**
Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)
* indicates the PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ PAC < 50% LEL).
** indicates the PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC < 100% LEL).
*** indicates the PAC value is at 100% or more of the LEL (PAC ≥ LEL).
excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-ænia Bulk Injectable

(Contd. of page 3)

· PAC-1:		
CAS: 65997-17-3	glass, oxide, chemicals	15 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	120 mg/m ³
	dimethacrylate component**	33 mg/m ³
· PAC-2:		
CAS: 65997-17-3	glass, oxide, chemicals	170 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	1,300 mg/m ³
	dimethacrylate component**	360 mg/m ³
· PAC-3:		
CAS: 65997-17-3	glass, oxide, chemicals	990 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	7,900 mg/m ³
	dimethacrylate component**	2,100 mg/m ³

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:** Protect against electrostatic charges.
- **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.
- **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.
 - Immediately remove all soiled and contaminated clothing.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 4)

- **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:**

Manufacturing sites:

Wear safety glasses with side shields (or goggles).

Distribution, Workplace, and Household Settings:

No special protective equipment required

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:

Pasty

Color:

According to product specification

- **Odor:**

Odorless

- **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 self-igniting.

- **Danger of explosion:**

Product does not present an explosion hazard.

- **Explosion limits:**

Lower:

Not determined.

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 5)

Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC content:	0.00 %
· Solids content:	< 67.0 %
· 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:** 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)	
glass, oxide, chemicals	65997-17-3
butylated hydroxytoluene (BHT)	3
· NTP (National Toxicology Program)	
None of the ingredients is listed.	

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 6)

· **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.

· **Repeated dose toxicity.** No further relevant information available.

· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**

No further relevant information available.

No further relevant information available.

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 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **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:**

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

· **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

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 7)

· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	Not applicable.
· 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":	Void

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 ingredients is listed.

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

None of the ingredients is listed.

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

glass, oxide, chemicals

ethoxylated bisphenol-A dimethacrylate (Bis-EMA)

bismethacrylate**

dimethacrylate**

surface-treated silica**

UV-light absorber**

urethane dimethacrylate (UDMA)

dimethacrylate component**

photoinitiator**

- **TSCA new (21st Century Act) (Substances not listed)**

CAS: 41637-38-1 ethoxylated bisphenol-A dimethacrylate (Bis-EMA)

bismethacrylate**

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

butylated hydroxytoluene (BHT)

A4

- **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).

(Contd. on page 9)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 8)

- **Hazard pictograms**



GHS07

- **Signal word** Warning

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

bismethacrylate**

UV-light absorber**

urethane dimethacrylate (UDMA)

dimethacrylate component**

- **Hazard statements**

May cause an allergic skin reaction.

- **Precautionary statements**

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

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

Wear protective gloves.

If skin irritation or rash occurs: Get medical advice/attention.

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** 06/28/2018 / -

- **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)

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

(Contd. on page 10)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 06/28/2018

Version US-EN-Rev 1

Reviewed on 06/28/2018

Trade name: G-æniel Bulk Injectable

(Contd. of page 9)

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

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.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

US