

SAFETY DATA SHEETS

This SDS packet was issued with item:

071262153

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

071051572 071051580 071262104 071262112 071262120 071262138 071262195 071262203 071262211 071262229

071262237 071262245 071262252

Safety Data Sheet according to HPR, Schedule 1

Printing date 05/17/2019

Version CA-EN-Rev 1

Reviewed on 05/17/2019

1 Identification

- **Product identifier**

- **Trade name:** G-ænial Universal Injectable (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, BW, CV, CVD, JE, and XBW)

- **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

USA

SDS.gcamerica@gc.dental

- **Information department:** Regulatory Affairs

- **Emergency telephone number:**

During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900

Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard identification

- **Classification of the substance or mixture**

Exempt from classification and labeling – devices and drugs are not regulated according to WHMIS 2015.

Respiratory Sensitizer - Category 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 2 H361 Suspected of damaging fertility or the unborn child.

- **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**

Exempt from classification and labeling – devices and drugs are not regulated according to WHMIS 2015.

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

- **Hazard pictograms**



- **Signal word** Danger

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

bismethacrylate**
 colorant**
 resin**
 dimethacrylate component**
 urethane dimethacrylate (UDMA)
 UV-light absorber**
 stabilizer**

· **Hazard statements**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause an allergic skin reaction.
 Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.
 IF exposed or concerned: Get medical advice/attention.
 Specific treatment (see on this label).
 Take off contaminated clothing and wash it before reuse.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

9.9 % of the mixture consists of an ingredient or ingredients of unknown acute toxicity.

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

	bismethacrylate**	3 – 7% w/w
	dimethacrylate**	1 – 5% w/w
	colorant**	0.1 – 1% w/w
	resin**	0.1 – 1% w/w
	photoinitiator**	0.1 – 1% w/w
	dimethacrylate component**	0.1 – 1% w/w
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	0.1 – 1% w/w
	UV-light absorber**	0.1 – 1% w/w
CAS: 128-37-0	butylated hydroxytoluene	0.1 – 1% w/w
	stabilizer**	0.1 – 1% w/w

· **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 Firefighting 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.
No further relevant information available.
- **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:**
Ensure adequate ventilation.
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.

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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.
Do not inhale dust / smoke / mist.
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.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
- **Breathing equipment:**



Suitable respiratory protective device recommended.

- **Protection of hands:**



Protective gloves

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- **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:

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.

- Upper:

Not determined.

- **Vapor pressure:**

Not determined.

- **Density at 20 °C:**

1.8 g/cm³

- **Relative density**

Not determined.

- **Vapor density**

Not determined.

- **Evaporation rate**

Not determined.

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· Solubility in / Miscibility with Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0 %
· 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:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

CAS: 128-37-0 butylated hydroxytoluene

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))

stabilizer**

Oral	LD50	530 mg/kg (mouse)
		910 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:**
Sensitization possible through inhalation.
Sensitization possible through skin contact.

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· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

titanium dioxide	2B
colorant**	3
butylated hydroxytoluene	3

· **NTP (National Toxicology Program)**

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 (carcinogenicity, mutagenicity and toxicity for reproduction)**

No further relevant information available.

Reproductive Toxicity - Category 2

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

CAS: 128-37-0 butylated hydroxytoluene	
NOEC-value Ecol. other effects	0.07 mg/l (daphnia magna) 21 day, reproductive effects

· **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.

· **Ecotoxicological effects:**

· **Remark:** Harmful to fish

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (German regulation, AwSV) (Self-assessment): slightly hazardous to water

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

Harmful to aquatic organisms

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

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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/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT/TDG, 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**
- **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

glass, oxide, chemicals
ethoxylated bisphenol-A dimethacrylate (Bis-EMA)
bismethacrylate**
surface-treated silica**
surface-treated silica**
titanium dioxide
colorant**
iron(II,III) oxide
resin**
organic fluorophore**

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photoinitiator**

synergist**

dimethacrylate component**

UV-light absorber**

butylated hydroxytoluene

stabilizer**

photoinitiator**

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

None of the ingredients is listed.

· **GHS label elements**

Exempt from classification and labeling – devices and drugs are not regulated according to WHMIS 2015.

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

· **Hazard pictograms**



· **Signal word** Danger

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

bismethacrylate**

colorant**

resin**

dimethacrylate component**

urethane dimethacrylate (UDMA)

UV-light absorber**

stabilizer**

· **Hazard statements**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

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

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• **Contact:**

Regulatory Affairs
Telephone No. +1 (708) 597-0900
SDS.gcamerica@gc.dental

• **Date of the latest revision of the safety data sheet** 05/17/2019 / -

• **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)
TDG: Transportation of Dangerous Goods (Canada)
LEL: Lower Explosive Limit
UEL: Upper Explosive Limit
AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany)
NOEC: No Observed Effect Concentration
ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
OECD: Organization for Economic Cooperation and Development
IMDG Code: International Maritime Dangerous Goods Code
DOT: Department of Transportation (USA)
IATA: International Air Transport Association
CAS: Chemical Abstracts Service (division of the American Chemical Society)
WHMIS: Workplace Hazardous Materials Information System (Canada)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

• **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:**

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