

Printing date 07/13/2018

Version US-EN-Rev 1

Reviewed on 07/13/2018

1 Identification

- · Product identifier
- · Trade name: G-ænial Flo X
- · Relevant identified uses of the substance or mixture and uses advised against

Dental material

No further relevant information available.

The product is intended for professional use.

To avoid risks for humans and environment obtain instructions.

- · Application of the substance / the mixture Auxiliary for dental technology
- · Details of the supplier of the safety data sheet
- · 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

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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



GHS08

- · Signal word Danger
- · Hazard-determining components of labeling:

urethane dimethacrylate (UDMA) dimethacrylate component**

stabilizer**

UV-light absorber**

· Hazard statements

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

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.

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[In case of inadequate ventilation] wear respiratory protection.

If experiencing respiratory symptoms: Call a poison center/doctor.

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

- · Hazard not otherwise classified (HNOC): None known.
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 0 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 0
 Fire = 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: consisting of the following components.

· Dangerous components:			
CAS: 41637-38-1	ethoxylated bisphenol-A dimethacrylate (Bis-EMA)	10 - < 25%	
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	5 - < 10%	
	dimethacrylate component**	2.5 - < 5%	
	stabilizer**	0.1 - < 0.2%	
	UV-light absorber**	0.1 - < 0.2%	

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.

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately rinse with water.

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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 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.

Do not allow to penetrate the ground/soil.

Do not allow to enter sewers/ surface or ground water.

· Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Allow to evaporate.

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.

· 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).

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excerpt from Introd	uction to PAC Table 2 – PAC Rev. 29 – May 2016	(Contd. of page
PAC-1:	,	
CAS: 65997-17-3	glass, oxide, chemicals	15 mg/m ³
	silane**	71 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	120 mg/m ³
	dimethacrylate component**	33 mg/m ³
CAS: 112945-52-5	silicon dioxide, amorphous	18 mg/m ³
PAC-2:		
CAS: 65997-17-3	glass, oxide, chemicals	170 mg/m ³
	silane**	780 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	1,300 mg/m ³
	dimethacrylate component**	360 mg/m ³
CAS: 112945-52-5	silicon dioxide, amorphous	100 mg/m ³
PAC-3:		
CAS: 65997-17-3	glass, oxide, chemicals	990 mg/m ³
	silane**	4,700 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	7,900 mg/m ³
	dimethacrylate component**	2,100 mg/m ³
CAS: 112945-52-5	silicon dioxide, amorphous	630 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 dust.

Do not inhale dust / smoke / mist.

Any deposit of dust which cannot be avoided must be regularly removed.

Avoid contact with the eyes and skin.

Open and handle receptacle with care.

Information about protection against explosions and fires:

Keep respiratory protective device available.

Dust can combine with air to form an explosive mixture.

- · 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.

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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.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Store protective clothing separately.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.



Suitable respiratory protective device recommended.

· Protection of hands:

See below

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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: According to product specification

· Odor: Odorless

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· Odor threshold:	Not determined.
· pH-value:	Not applicable.
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	Undetermined. Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· 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: Upper: 	Not determined. Not determined.
· Vapor pressure:	Not applicable.
 Density: Relative density Vapor density Evaporation rate 	Not determined. Not determined. Not applicable. Not applicable.
· Solubility in / Miscibility with Water:	Insoluble.
· Partition coefficient (n-octanol/wa	ter): Not determined.
· Viscosity: Dynamic: Kinematic:	Not applicable. Not applicable.
· Solvent content: VOC content:	0.00 %
Solids content: Other information	100.0 % 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.

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11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values that are relevant for classification:	
stabi	lizer**
Oral	LD50 530 mg/kg (mouse)

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.

· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Carcinogenic if inhaled.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)		
glass, oxide, chemicals	65997-17-3	
silicon dioxide, amorphous	3	

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

910 mg/kg (rat (f+m)) (OECD 401)

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.

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- · 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
· 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 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.

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· 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)

silane*

urethane dimethacrylate (UDMA)

dimethacrylate component**

synergist**

stabilizer**

UV-light absorber**

· TSCA new (21st Century Act) (Substances not listed)

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

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· 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



GHS08

· Signal word Danger

· Hazard-determining components of labeling:

urethane dimethacrylate (UDMA) dimethacrylate component** stabilizer**

UV-light absorber**

· Hazard statements

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

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.

[In case of inadequate ventilation] wear respiratory protection.

If experiencing respiratory symptoms: Call a poison center/doctor.

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

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· 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 07/13/2018 / -
- Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO) 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

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

Resp. Sens. 1: Respiratory sensitisation - Category 1

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.

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· * Data compared to the previous version altered.

This version replaces all previous versions.

· Disclaimer:

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