Safety data sheet
according to 1907/2006/EC, Article 31

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name:**
G-aenial_Universal_Flo

Nanoform
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Auxiliary for dental technology

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental

· **Information department:** Regulatory affairs
· **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)

*
SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labeled according to the CLP regulation.
· **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
Urethane Dimethacrylate (UDMA)
2,2'-ethylenedioxydiethyl dimethacrylate
2-(2H-benzotriazol-2-yl)-p-cresol
1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde
· **Hazard statements**
H317 May cause an allergic skin reaction.

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H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*
SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterization: Mixtures**
· **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· **Dangerous components:**		
72869-86-4	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	10-<25%
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	5-<10%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	5-<10%
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica STOT RE 2, H373, EUH066	1-<2.5%
1879-09-0	6-tert-butyl-2,4-xylenol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.5-<1%
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	0.5-<1%
9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	0.5-<1%
13463-67-7	titanium dioxide Carc. 2, H351	0.5-<1%
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	0.5-<1%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0.5-<1%

· **SVHC**	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:**
Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.
If symptoms persist consult doctor.
· **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Take affected persons into fresh air and keep quiet.
· **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
If skin irritation continues, consult a doctor.
· **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.
· **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

*
SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** CO2, sand, extinguishing powder. Do not use water.
· **For safety reasons unsuitable extinguishing agents:** Water
· **5.2 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.
· **5.3 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.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
· **6.2 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.
· **6.3 Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Dispose of the collected material according to regulations.

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· **6.4 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.

*
SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
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.

· **7.2 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:** None.
· **7.3 Specific end use(s)** No further relevant information available.

*
SECTION 8: Exposure controls/personal protection

· **8.1 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.

· **DNELs**		
1879-09-0 6-tert-butyl-2,4-xylenol		
Inhalative	DNEL inhalation	0.14 mg/m3 (man)
13463-67-7 titanium dioxide		
Inhalative	DNEL inhalation	10 mg/m3 (man)

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

· **8.2 Exposure controls**
· **Additional information about design of technical systems:** No further data; see section 7.
· **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.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Store protective clothing separately.
· **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:***

Tightly sealed goggles

*
SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Physical state***	*Fluid*
· ***Color:***	*According to product specification*
· ***Odor:***	*Odorless*
· ***Odor threshold:***	*Not determined.*
· ***Melting point/Melting range:***	*Undetermined.*
· ***Boiling point/Boiling range:***	*Undetermined.*
· ***Flammability (solid, gaseous):***	*Not applicable.*
· ***Explosion limits:***	
· ***Lower:***	*Not determined.*
· ***Upper:***	*Not determined.*
· ***Flash point:***	*Not applicable.*
· ***Auto igniting:***	*Undetermined.*
· ***Decomposition temperature:***	*Not determined.*
· ***pH-value:***	*Not determined.*
· ***Viscosity:***	
· ***Kinematic:***	*Not determined.*
· ***Dynamic:***	*Not determined.*
· ***Solubility in / Miscibility with***	
· ***Water:***	*Fully miscible.*
· ***Partition coefficient (n-octanol/water):***	*Not determined.*
· ***Vapor pressure:***	*Not determined.*
· ***Density and/or relative density***	
· ***Density:***	*Not determined.*
· ***Relative density***	*Not determined.*

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· **Vapor density**	Not determined.
· **Particle characteristics**	SiO2: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based) Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d50, volume based) 68909-20-6 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica: set including amorphous nanoforms surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform 68611-44-9 Silane, dichlorodimethyl-, reaction products with silica: set including amorphous nanoforms surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform
· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Pasty
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Solvent content:**	
· **VOC (EC)**	0.0 g/l
· **Change in condition**	
· **Evaporation rate**	Not determined.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void

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· **Desensitised explosives**	Void

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

*
SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**		
72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
1879-09-0 6-tert-butyl-2,4-xylenol		
Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)
2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol		
Oral	LD50	10,000 mg/kg (rat (f+m))
Inhalative	LC50/4 h	0.59 mg/l (rat (f+m))
13463-67-7 titanium dioxide		
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)

· **on the skin:** Based on available data, the classification criteria are not met.
· **on the eye:** Based on available data, the classification criteria are not met.
· **Sensitization:** May cause an allergic skin reaction.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
· **Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.
· **Additional toxicological information:**

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Repeated dose toxicity** No further relevant information available.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
72869-86-4 Urethane Dimethacrylate (UDMA)	
EC50/48h (static)	>1.2 mg/l (daphnia magna) (OECD 202)

· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
· **12.7 Other adverse effects**
· **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.
Danger to drinking water if even extremely small quantities leak into the ground.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, ADN, IMDG, IATA** not regulated

· **14.2 UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** not regulated

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· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	not regulated
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	not regulated
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	not regulated

*
SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Sara**

· **Section 355 (extremely hazardous substances):**
None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

13463-67-7	titanium dioxide

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

1309-37-1	Iron(III)oxide	A4
13463-67-7	titanium dioxide	A4

· **MAK (German Maximum Workplace Concentration)**

13463-67-7	titanium dioxide	3A

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

13463-67-7	titanium dioxide

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone- depleting potential)**

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· **Relevant phrases**

H302 Harmful if swallowed.
H310 Fatal in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.
EUH066 Repeated exposure may cause skin dryness or cracking.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method

· **Department issuing SDS:** Regulatory affairs
· **Contact:** msds@gc.dental
· **Date of previous version** 08.03.2022
· **Version number of previous version:** 4
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Carc. 2: Carcinogenicity – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· ***Sources***
• ECHA (http://echa.europa.eu/)
• EnviChem (www.echemportal.org)

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