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: GC G-aenial Flo X**

· **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** Auxillary 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@gceurope.com

· **Further information obtainable from:** Regulatory affairs

· **1.4 Emergency telephone number:**
National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Skin Sens. 1 H317 May cause an allergic skin reaction.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
2,2'-ethylenedioxydiethyl dimethacrylate
2-(2H-benzotriazol-2-yl)-p-cresol

· **Hazard statements**
H317 May cause an allergic skin reaction.

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· **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P272 Contaminated work clothing should not be allowed out of the workplace.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P302+P352 IF ON SKIN: Wash with plenty of water.
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.

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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:**		
CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	20-25%
CAS: 72869-86-4 EINECS: 276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	5-10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	1-5%
CAS: 2440-22-4 EINECS: 219-470-5	2-(2H-benzotriazol-2-yl)-p-cresol Aquatic Chronic 1, H410; Skin Sens. 1, H317	< 0.5%
CAS: 1879-09-0 EINECS: 217-533-1	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%

SECTION 4: First aid measures

· **4.1 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.
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.

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· ***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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
· ***For safety reasons unsuitable extinguishing agents:*** *Water with full jet*
· ***5.2 Special hazards arising from the substance or mixture***
Formation of toxic gases is possible during heating or in case of fire.
· ***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.

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SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Remove persons from danger area.
Avoid formation of dust. Personal respirator must be worn in dusty atmospheres.
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.
Do not allow to penetrate the ground/soil.
Do not allow to enter sewers/ surface or ground water.
· ***6.3 Methods and material for containment and cleaning up:***
Allow to evaporate.
Pick up mechanically.
Prevent formation of dust.
Dispose of the material collected according to regulations.
· ***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***
Prevent formation of dust.
Any unavoidabledeposit of dust must be regularly removed.
Avoid contact with the eyes and skin.
· ***Information about fire - and explosion protection:*** *Dust can combine with air to form an explosive mixture.*

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· **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

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**
· **Ingredients 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)

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

· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
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
· **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Suitable respiratory protective device recommended.
· **Protection of hands:**
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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eye protection:**

Tightly sealed goggles

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Pasty
Colour:	According to product specification
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not determined.
· **Ignition temperature:**	Undetermined.
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with water:**	Insoluble.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	100.0 %

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· **9.2 Other information** No further relevant information available.

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:**

· **LD/LC50 values relevant for classification:**		
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)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Repeated dose toxicity** No further relevant information available.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **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.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (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.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

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SECTION 13: Disposal considerations

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

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **14.2 UN proper shipping name** · **ADR, ADN, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **14.4 Packing group** · **ADR, IMDG, IATA**	Void
· **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":**	-

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **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.
H319 Causes serious eye irritation.
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.

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

· **Department issuing MSDS:** Regulatory affairs
· **Contact:** msds@gceurope.com
· **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 Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
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
IATA: International Air Transport Association
GHS: Globally Harmonized 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)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Acute Tox. 4: Acute toxicity, Hazard Category 4
Acute Tox. 2: Acute toxicity, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2
Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic 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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