

Safety Data Sheet according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Other means of identification**
- **Trade name:** G-aenial FLO X
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**

GC Australasia Dental Pty Ltd
1753 Botany Road
Banksmeadow, NSW 2019
Tel: +61 2 9301 8200

- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **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 labelling:**
Urethane Dimethacrylate (UDMA) (5-<10 %)
2,2'-ethylenedioxydiethyl dimethacrylate (2.5-<5 %)
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves.
If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 2)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 1)

Specific treatment (see on this label).

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

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

3 Composition and Information on Ingredients

- **Chemical characterisation: 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)	5-<10%
	Skin sensitisation – Category 1B, H317	
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	2.5-<5%
	Skin sensitisation – Category 1B, H317	
1309-37-1	Iron(III)oxide	0.5-<1%
9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde	0.5-<1%
	Eye damage/irritation – Category 1, H318; Skin sensitisation – Category 1, H317; Specific target organ toxicity (single exposure) – Category 3, H335	
13463-67-7	titanium dioxide	0.5-<1%
	Carcinogenicity – Category 2, H351	
1879-09-0	6-tert-butyl-2,4-xlenol	0.1-<0.2%
	Acute toxicity - dermal – Category 2, H310; Specific target organ toxicity (repeated exposure) – Category 2, H373; Acute toxicity - oral – Category 4, H302; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.1-<0.2%
	Acute toxicity - inhalation – Category 3, H331; Skin sensitisation – Category 1, H317	

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

4 First Aid Measures

- **General information:**

Immediately remove any clothing soiled by the product.

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.

(Contd. on page 3)

Safety Data Sheet according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 2)

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

- **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.
- **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:**
Allow to evaporate.
Pick up mechanically.
Prevent formation of dust.
Dispose of the material collected 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.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
Any unavoidable deposit of dust must be regularly removed.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:**
Protect against electrostatic charges.
Dust can combine with air to form an explosive mixture.

(Contd. on page 4)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 3)

- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Appropriate engineering controls** No further data; see section 7.

- **Ingredients with limit values that require monitoring at the workplace:**

1309-37-1 Iron(III)oxide

WES Long-term value: 5 mg/m³

13463-67-7 titanium dioxide

WES Long-term value: 10 mg/m³
inhalable dust

- **DNELs**

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m³ (man)

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.

- **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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 4)

· **Eye protection:**

Tightly sealed goggles

9 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/freezing point:**

Undetermined.

· **Initial boiling point and boiling range:**

180 °C (356 °F)

· **Flash point:**

Not applicable.

· **Flammability**

Not determined.

· **Auto-ignition temperature:**

Undetermined.

· **Decomposition temperature:**

Not determined.

· **Ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

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.

· **Other information**· **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)

· **Physical state**

Solid

10 Stability and Reactivity

· **Reactivity** No further relevant information available.· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

(Contd. on page 6)

Safety Data Sheet

according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 5)

- **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** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:		
72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
1309-37-1 Iron(III)oxide		
Oral	LD50	>5,000 mg/kg (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)
1879-09-0 6-tert-butyl-2,4-xyleneol		
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))

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** 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.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Interactive effects**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

12 Ecological Information

- **Toxicity**

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

- **Persistence and degradability** No further relevant information available.

(Contd. on page 7)

Safety Data Sheet according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 6)

- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
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**
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.

14 Transport information

· UN-Number	
· ADG, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, ADN, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Industrial Chemicals**
All ingredients are listed.

(Contd. on page 8)

AU

Safety Data Sheet according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 7)

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

Urethane Dimethacrylate (UDMA) (5-<10 %)

2,2'-ethylenedioxydiethyl dimethacrylate (2.5-<5 %)

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

Wear protective gloves.

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

Specific treatment (see on this label).

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

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.

H373 May cause damage to organs through prolonged or repeated exposure.

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **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)

(Contd. on page 9)

Safety Data Sheet according to WHS Regulations

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

Trade name: G-aenial_FLO_X

(Contd. of page 8)

ADR: Accord relatif au transport international 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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute toxicity - oral - Category 4: Acute toxicity - Category 4

Acute toxicity - dermal - Category 2: Acute toxicity - Category 2

Acute toxicity - inhalation - Category 3: Acute toxicity - Category 3

Skin corrosion/irritation - Category 2: Skin corrosion/irritation - Category 2

Eye damage/irritation - Category 1: Serious eye damage/eye irritation - Category 1

Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A

Skin sensitisation - Category 1: Skin sensitisation - Category 1

Skin sensitisation - Category 1B: Skin sensitisation - Category 1B

Carcinogenicity - Category 2: Carcinogenicity - Category 2

Specific target organ toxicity (single exposure) - Category 3: Specific target organ toxicity (single exposure) - Category 3

Specific target organ toxicity (repeated exposure) - Category 2: Specific target organ toxicity (repeated exposure) - Category 2

• 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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