

Safety Data Sheet in accordance with HSNO

Date of issue: 07.07.2025

Version number 6

Revision: 07.07.2025

1 Identification of the substance or mixture and of the supplier

- **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**
Henry Schein Dental

243-249 Bush Road, Rosedale
Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 0800 764 766 (National Poisons Centre)

2 Hazards identification

- **Classification of the substance or mixture**
Skin sensitisation Category 1 H317 May cause an allergic skin reaction.
Hazardous to the aquatic environment chronic Category 3H412 Harmful to aquatic life with long lasting effects.

- **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)
2,2'-ethylenedioxydiethyl dimethacrylate
- **Hazard statements**
May cause an allergic skin reaction.
Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Avoid release to the environment.
Wear protective gloves.

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

CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Hazardous to the aquatic environment chronic Category 4, H413	10-<25%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Hazardous to the aquatic environment chronic Category 2, H411; Skin sensitisation Sub-category 1B, H317	5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin sensitisation Sub-category 1B, H317	2.5-<5%
CAS: 1309-37-1 EINECS: 215-168-2	Iron(III)oxide	0.5-<1%
CAS: 9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde Serious eye damage Category 1, H318; Skin sensitisation Category 1, H317; Specific target organ toxicity - single exposure Category 3, H335	0.5-<1%
CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide Carcinogenicity – Category 2, H351	0.5-<1%
CAS: 1879-09-0 EINECS: 217-533-1	6-tert-butyl-2,4-xilenol Acute dermal toxicity Category 2, H310; Specific target organ toxicity - repeated exposure Category 2, H373; Acute oral toxicity Category 4, H302; Skin irritation Category 2, H315; Eye irritation Category 2, H319	0.1-<0.2%
CAS: 2440-22-4 EINECS: 219-470-5	2-(2H-benzotriazol-2-yl)-p-cresol Acute inhalation toxicity Category 3, H331; Skin sensitisation Category 1, H317	0.1-<0.2%

- **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.

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*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.***· 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.*

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*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.***· 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/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 (New Zealand)	Long-term value: 5 mg/m ³ as Fe, w
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13463-67-7 titanium dioxide

WES (New Zealand)	Long-term value: 10 mg/m ³ interim WES
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· DNELs**13463-67-7 titanium dioxide**

Inhalative	DNEL inhalation	10 mg/m ³ (man)
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1879-09-0 6-tert-butyl-2,4-xyleneol

Inhalative	DNEL inhalation	0.14 mg/m ³ (man)
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· 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.*

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· **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

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

· **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

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10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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.

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)
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1309-37-1 Iron(III)oxide

Oral	LD50	>5,000 mg/kg (rat (f+m))
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13463-67-7 titanium dioxide

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
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Inhalative	LC50/4 h	>6.82 mg/l (rat male)
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1879-09-0 6-tert-butyl-2,4-xyleneol

Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
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Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)
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2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol

Oral	LD50	10,000 mg/kg (rat (f+m))
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Inhalative	LC50/4 h	0.59 mg/l (rat (f+m))
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- **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.

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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.

- **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**

- **NZS, ADN, IMDG, IATA** not regulated

- **UN proper shipping name**

- **NZS, ADN, IMDG, IATA** not regulated

- **Transport hazard class(es)**

- **NZS, ADN, IMDG, IATA**

- **Class** not regulated

- **Packing group**

- **NZS, 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.

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· UN "Model Regulation": not regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **New Zealand Inventory of Chemicals**

65997-17-3	Glass, oxide, chemicals
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.
2530-85-0	3-trimethoxysilylpropyl methacrylate
72869-86-4	Urethane Dimethacrylate (UDMA)
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica
1309-37-1	Iron(III)oxide
1309-38-2	Iron (II,III) oxide
7128-64-5	2,5-Thiophendiylbis(5-tert-butyl-1,3-benzoxazol)
9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde
13463-67-7	titanium dioxide
20344-49-4	Iron hydroxide oxide
10287-53-3	ethyl 4-dimethylaminobenzoate
1879-09-0	6-tert-butyl-2,4-xylenol
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol
10373-78-1	Camphorquinone
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **HSNO Approval numbers**

1879-09-0	6-tert-butyl-2,4-xylenol	HSR003625
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· **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)

2,2'-ethylenedioxydiethyl dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

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

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

Avoid release to the environment.

Wear protective gloves.

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*If skin irritation or rash occurs: Get medical advice/attention.**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.**H411 Toxic to aquatic life with long lasting effects.**H413 May cause long lasting harmful effects to aquatic life.*

- **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)**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 oral toxicity Category 4: Acute toxicity – Category 4**Acute dermal toxicity Category 2: Acute toxicity – Category 2**Acute inhalation toxicity Category 3: Acute toxicity – Category 3**Skin irritation Category 2: Skin corrosion/irritation – Category 2**Serious eye damage Category 1: Serious eye damage/eye irritation – Category 1**Eye irritation Category 2: Serious eye damage/eye irritation – Category 2**Skin sensitisation Category 1: Skin sensitisation – Category 1**Skin sensitisation Sub-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**Hazardous to the aquatic environment chronic Category 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Hazardous to the aquatic environment chronic Category 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3**Hazardous to the aquatic environment chronic Category 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4*

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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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