

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** G-aenial Universal Injectable
- **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**

Eye irritation Category 2	H319 Causes serious eye irritation.
Skin sensitisation Category 1	H317 May cause an allergic skin reaction.
Reproductive toxicity Category 2	H361 Suspected of damaging fertility or the unborn child.
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 GHS08

· Signal word Warning

· Hazard-determining components of labelling:

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde

· Hazard statements

Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.

(Contd. on page 2)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: G-aenial_ Universal_Injectable

(Contd. of page 1)

*Harmful to aquatic life with long lasting effects.***· Precautionary statements***Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.**IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**IF exposed or concerned: Get medical advice/attention.**Specific treatment (see on this label).**Take off contaminated clothing and wash it before reuse.**Store locked up.**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: 43048-08-4 EINECS: 256-062-6	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate Skin irritation Category 2, H315; Eye irritation Category 2, H319; Skin sensitisation Category 1, H317; Specific target organ toxicity - single exposure Category 3, H335	5-<10%
CAS: 1985-51-9 EINECS: 217-856-8	2,2-dimethyl-1,3-propanediyl bismethacrylate Skin irritation Category 2, H315; Eye irritation Category 2, H319	2.5-<5%
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	1-<2.5%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Hazardous to the aquatic environment chronic Category 2, H411; Skin sensitisation Category 1, H317	0.5-<1%
CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide Carcinogenicity – Category 2, H351	0.2-<0.5%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin sensitisation Category 1, H317	0.2-<0.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Hazardous to the aquatic environment acute Category 1, H400; Hazardous to the aquatic environment chronic Category 1, H410	≥0.25-<0.5%
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	0.2-<0.5%

(Contd. on page 3)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: **G-aenial_ Universal_Injectable**

		(Contd. of page 2)
CAS: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0.2-<0.5%
EINECS: 278-355-8	Reproductive toxicity Category 2, H361	
CAS: 1879-09-0	6-tert-butyl-2,4-xlenol	0.1-<0.2%
EINECS: 217-533-1	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	

· **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.

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:**

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then 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 contact with the eyes and skin.

(Contd. on page 4)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: **G-aenial_ Universal_Injectable**

(Contd. of page 3)

*Wear protective clothing.***· 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.***· Methods and material for containment and cleaning up:***Absorb liquid components with liquid-binding material.**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 aerosols.**Avoid contact with the eyes and skin.***· Information about fire - and explosion protection:** *Protect against electrostatic charges.***· 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

· Additional information about design of technical facilities: *No further data; see section 7.***· Ingredients with limit values that require monitoring at the workplace:****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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128-37-0 Butylated hydroxytoluene

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m ³ (man)

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.**Avoid contact with the eyes and skin.*

(Contd. on page 5)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: G-aenial_Universal_Injectable

(Contd. of page 4)

*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:** Suitable respiratory protective device recommended.· **Protection of hands:**

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:**

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 determined.

· Change in condition

· Melting point/freezing point:

Undetermined.

· Initial boiling point and boiling range:

Undetermined.

· Flash point:

>150 °C

· Flammability (solid, gas):

Not applicable.

· 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 determined.

· Density at 20 °C:

1.8 g/cm³

· Relative density

Not determined.

· Vapour density

Not determined.

· Evaporation rate

Not determined.

· Solubility in / Miscibility with

· water:

Insoluble.

(Contd. on page 6)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: G-aenial_Universal_Injectable

(Contd. of page 5)

- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not determined.
- **Kinematic:** Not determined.
- **Solvent content:**
- **VOC (EC)** 0.0 g/l
- **Other information** No further relevant information available.

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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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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128-37-0 Butylated hydroxytoluene

Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)
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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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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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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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** Suspected of damaging fertility or the unborn child.
- **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.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.

(Contd. on page 7)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: G-aenial_ Universal_Injectable

(Contd. of page 6)

- **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)
128-37-0 Butylated hydroxytoluene	
EC50/48h (static)	0.48 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.

- **Ecotoxicological effects:**

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Water hazard class 3 (German Regulation) (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.

Harmful to aquatic organisms

- **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

(Contd. on page 8)

-NZ-

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: **G-aenial_Universal_Injectable**

(Contd. of page 7)

· Packing group · NZS, IMDG, IATA	<i>not regulated</i>
· Environmental hazards: · Marine pollutant:	<i>No</i>
· Special precautions for user	<i>Not applicable.</i>
· Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>not regulated</i>

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.
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate
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
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
72869-86-4	Urethane Dimethacrylate (UDMA)
1309-37-1	Iron(III)oxide
1317-61-9	triiron tetraoxide
13463-67-7	titanium dioxide
20344-49-4	Iron hydroxide oxide
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
128-37-0	Butylated hydroxytoluene
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol
10287-53-3	ethyl 4-dimethylaminobenzoate
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
1879-09-0	6-tert-butyl-2,4-xilenol
10373-78-1	Camphorquinone

· **HSNO Approval numbers**

1879-09-0	6-tert-butyl-2,4-xilenol	HSR003625
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· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).

(Contd. on page 9)

NZ

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: G-aenial_ Universal_Injectable

(Contd. of page 8)

· Hazard pictograms



GHS07 GHS08

· Signal word Warning

· Hazard-determining components of labelling:

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde

· Hazard statements

Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
Harmful to aquatic life with long lasting effects.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see on this label).
Take off contaminated clothing and wash it before reuse.
Store locked up.
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.

· 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
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· 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.
H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.

(Contd. on page 10)

Safety Data Sheet in accordance with HSNO

Printing date 08.07.2024

Version number 3

Revision: 08.07.2024

Trade name: G-aenial_ Universal_Injectable

(Contd. of page 9)

H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **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)

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)

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

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

Carcinogenicity – Category 2: Carcinogenicity – Category 2

Reproductive toxicity Category 2: Reproductive toxicity – 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 acute Category 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Hazardous to the aquatic environment chronic Category 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

· **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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