

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

Printing date 12.03.2018

Version number 1

Revision: 12.03.2018


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

- **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 Shalfoon Ltd
23 William Pickering Drive, Albany
Auckland 0632, NEW ZEALAND

PO Box 101140, NSMC
Auckland 0745, NEW ZEALAND

Free Phone: 0800 808 855
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:**
International: +01-813-248-0585 (ChemTel Inc.)
0800 764 766 (National Poisons Centre)

2 Hazards identification

- **Classification of the substance or mixture**
Acute Tox. 5 H333 May be harmful if inhaled.
Skin Corr. 3 H316 Causes mild skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Acute 3 H402 Harmful to aquatic life.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **Label elements**
- **GHS label elements**
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 Globally Harmonised System (GHS).
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
2-(2H-benzotriazol-2-yl)-p-cresol
1,3,5-Triazane-2,4,6-triamine, polymer with formaldehyde
Urethane Dimethacrylate (UDMA)
2,2'-ethylenedioxydiethyl dimethacrylate

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· **Hazard statements**

May be harmful if inhaled.
Causes mild skin irritation.
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.
IF INHALED: Call a POISON CENTER/doctor if you feel unwell.
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. Aquatic Chronic 4, H413	10-<25%
CAS: 43048-08-4 EINECS: 256-062-6	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335	5-<10%
CAS: 1985-51-9 EINECS: 217-856-8	2,2-dimethyl-1,3-propanediyl bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319	2.5-<5%
CAS: 128-37-0 EINECS: 204-881-4	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.5-<1%
CAS: 9003-08-1	1,3,5-Triazane-2,4,6-triamine, polymer with formaldehyde Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	0.2-<0.5%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361	0.2-<0.5%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Skin Sens. 1, H317	0.2-<0.5%
CAS: 2440-22-4 EINECS: 219-470-5	2-(2H-benzotriazol-2-yl)-p-cresol Acute Tox. 2, H330; Skin Sens. 1, H317; Aquatic Chronic 4, H413	0.2-<0.5%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	0.2-<0.5%

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

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4 First aid measures

- **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. 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.
- **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 Firefighting measures

- **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
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **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.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
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.

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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:** No special measures required.

- **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.

- **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 item 7.

- **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**

128-37-0 2,6-di-tert-butyl-p-cresol

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.

- **Exposure controls**

- **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.

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.

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· **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

· **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 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.· **Ignition temperature:** Undetermined.· **Decomposition temperature:** Not determined.· **Auto-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:** Not determined.· **Relative density** Not determined.· **Vapour density** Not determined.

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Insoluble.
· 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.
- **Chemical stability**
- **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**

· LD/LC50 values relevant for classification:		
128-37-0 2,6-di-tert-butyl-p-cresol		
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)
72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
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))
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:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **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:**

128-37-0 2,6-di-tert-butyl-p-cresol

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

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.

- **Ecotoxicological effects:**

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Harmful to aquatic organisms

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.

- **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**

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

- **UN proper shipping name**

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

- **Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** not regulated

- **Packing group**

- **ADR, IMDG, IATA** not regulated

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· 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**

· **New Zealand Inventory of Chemicals**

65997-17-3	Glass, oxide, chemicals
72869-86-4	Urethane Dimethacrylate (UDMA)
13760-80-0	Ytterbium trifluoride
112945-52-5	Silicon dioxide
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.
2530-85-0	3-trimethoxysilylpropyl methacrylate
1309-37-1	Iron(III)oxide
21245-01-2	3-methylbutyl 4-(dimethylamino)benzoate
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol
1309-38-2	Iron (II,III) oxide
13463-67-7	titanium dioxide
1879-09-0	6-tert-butyl-2,4-xylenol

· **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:**

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate

2-(2H-benzotriazol-2-yl)-p-cresol

1,3,5-Triazane-2,4,6-triamine, polymer with formaldehyde

Urethane Dimethacrylate (UDMA)

2,2'-ethylenedioxydiethyl dimethacrylate

· **Hazard statements**

May be harmful if inhaled.

Causes mild skin irritation.

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

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· **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.

IF INHALED: Call a POISON CENTER/doctor if you feel unwell.

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**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H400 Very toxic to aquatic life.

H410 Very 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@gceurope.com

· **Abbreviations and acronyms:**

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

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

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 5: Acute toxicity – Category 5

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Corr. 3: Skin corrosion/irritation – Category 3

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3

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

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

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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.

Disclaimer:

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