

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: G-aenial Universal Injectable

Manufacturer: GC Corporation

SDS Expiry: 28 January 2026

Supplier Details: Henry Schein New Zealand

23 William Pickering Drive, Albany

PO Box 101 140, North Shore, Auckland 0745

Ph. 0800 808 855

www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –

0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6 / 9

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020

HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared on May 2021

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.





Printing date 28.01.2021 Version number 1 Revision: 28.01.2021

# 1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: GC 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 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: 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).

· 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



- · Signal word Warning
- · Hazard-determining components of labelling:

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate 6-tert-butyl-2,4-xylenol

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

2,2'-ethylenedioxydiethyl dimethacrylate

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

Urethane Dimethacrylate (UDMA)

· 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.

CAS: 41637-38-1  CAS: 43048-08-4  EINECS: 256-062-6  CAS: 1985-51-9  EINECS: 217-856-8	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.  Aquatic Chronic 4, H413 (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 2,2-dimethyl-1,3-propanediyl bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319	10-<25% 5-<10% 2.5-<5%
EINECS: 256-062-6 CAS: 1985-51-9	(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 2,2-dimethyl-1,3-propanediyl bismethacrylate	
EINECS: 256-062-6 CAS: 1985-51-9	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335 2,2-dimethyl-1,3-propanediyl bismethacrylate	
CAS: 1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	2.5-<5%
	L	2.5-<5%
EINECS: 217-856-8	Skin Irrit 2 H315: Eve Irrit 24 H319	l .
	Sivil 11100. 2, 11010, 1100. 211, 11017	
CAS: 128-37-0	Butylated hydroxytoluene	0.5-<1%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
CAS: 9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde	0.2-<0.5%
	Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0.2-<0.5%
EINECS: 278-355-8	Repr. 2, H361	
CAS: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	0.2-<0.5%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.2-<0.5%
EINECS: 219-470-5	Acute Tox. 3, H311; Skin Sens. 1, H317; Aquatic Chronic 4, H413	
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	0.2-<0.5%
EINECS: 276-957-5	Skin Sens. 1, H317	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	0.1-<0.2%
EINECS: 217-533-1	Acute Tox. 2, H310; Acute Tox. 3, H331; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Aquatic Acute 2, H401	

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

### 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 eve 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

- · 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.

No further relevant information available.

- · 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.

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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: 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.

	T		
· DNELs			
128-37-	128-37-0 Butylated hydroxytoluene		
Dermal	DNEL dermal	0.5 mg/kg bw/day (man)	
Inhalati	ve DNEL inhalation	3.5 mg/m3 (man)	
1879-09	1879-09-0 6-tert-butyl-2,4-xylenol		
Inhalati	ve DNEL inhalation	0.14 mg/m3 (man)	

- · 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:



#### · 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 chem	ical properties
General Information	
· Appearance: Form:	Pasty
rorm: Colour:	•
· Odour:	According to product specification  Odourless
· Odour: · Odour threshold:	Not determined.
· Ouour inresnoui.	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 at 20 °C:	$1.8 \text{ g/cm}^3$
· 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	LD/LC50 values relevant for classification:		
128-37-0 I	128-37-0 Butylated hydroxytoluene		
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)	
2440-22-4	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))	
72869-86-	72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)	
1879-09-0	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)	
B. I			

- · 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 (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

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### 12 Ecological information

· Toxicity

#### · Aquatic toxicity:

### 128-37-0 Butylated hydroxytoluene

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.
- · Ecotoxical 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.

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	

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		(Contd. of page 7)
· 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	· 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:

 $(octahydro-4, 7-methano-1 H-indenediyl) bis (methylene)\ bis methacry late$ 

6-tert-butyl-2,4-xylenol

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

2,2'-ethylenedioxydiethyl dimethacrylate

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

Urethane Dimethacrylate (UDMA)

· Hazard statements

May be harmful if inhaled.

Causes mild skin irritation.

May cause an allergic skin reaction.

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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.

- · 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.

H311 Toxic 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.

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.

H401 Toxic to aquatic life.

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.

#### · Department issuing SDS: Regulatory affairs

· Contact: msds@gc.dental

#### · 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. 4: Acute toxicity - oral - Category 4

Acute Tox. 2: Acute toxicity - dermal - Category 2

Acute Tox. 3: Acute toxicity - dermal - Category 3

Acute Tox. 5: Acute toxicity - inhalation - 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

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# Safety Data Sheet in accordance with HSNO

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Skin Sens. 1: Skin sensitisation – Category 1 Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard - Category 2 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 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2 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 · 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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