

Printing date 03.10.2023 Version number 3 Revision: 03.10.2023

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

- · Product identifier
- · Trade name: GC Tooth Mousse
- 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

Aquatic Chronic 3 H412 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 Void
- · Signal word Void
- · Hazard statements

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid release to the environment.

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.

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· Dangerous components:			
CAS: 56-81-5 glyc EINECS: 200-289-5	cerol		10-<25%
CAS: 57-55-6 Proj EINECS: 200-338-0	ppylene glycol		1-<2.5%
CAS: 13463-67-7 titar EINECS: 236-675-5	nium dioxide	Carc. 2, H351	1-<2.5%
CAS: 1314-13-2 zinc EINECS: 215-222-5	c oxide	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.25-<0.5%
· Additional information: For the wording of the listed hazard phrases refer to section 16.			

#### 4 First aid measures

- · General information: 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: 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 No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

#### 5 Fire fighting measures

· 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.

- **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.

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.

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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 No special precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · 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 lim	it values that require monitoring at the workplace:
56-81-5 glycerol	
TWA (New Zealand)	Long-term value: 10* mg/m³ *inhalable dust: no asbestos, < 1%free silica
WES (New Zealand)	Long-term value: 10 mg/m³ mist
57-55-6 Propylene g	lycol
WES (New Zealand)	Long-term value: 474* 10** mg/m³, 150* ppm *vapour, particulates; **particulates only
13463-67-7 titanium	dioxide
WES (New Zealand)	Long-term value: 10 mg/m³
DNELs	
13463-67-7 titanium	dioxide
Inhalative DNEL inh	nalation 10 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.

Wash hands before breaks and at the end of work.

- 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.

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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: Safety glasses

#### 9 Physical and chemical properties

· General Information

· Appearance:

· Form: Pasty · Colour: White

Odour: CharacteristicOdour threshold: Not determined.

• **pH-value at 20 °C:** 7

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Flash point:
 Flammability (solid, gas):
 Auto-ignition temperature:
 Decomposition temperature:
 Undetermined.
 Not applicable.
 Undetermined.
 Not determined.

• **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: 0.9 Vol %
Upper: 0.0 Vol %
Vapour pressure: Not determined.
Density at 20 °C: 1.2 g/cm³
Relative density Not determined.
Vapour density Not determined.
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:

• Organic solvents: 22.0 %
 • Water: <57.1 %</li>
 • VOC (EC) <76.3 g/l</li>

• 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.

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· 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:

#### 13463-67-7 titanium dioxide

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)

- · 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 Based on available data, the classification criteria are not met.
- · 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.
- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  No further relevant information available.

#### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 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:

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.

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### 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 NZS, ADN, IMDG, IATA	not regulated	
	noi reguiatea	
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 I	I of Marpol	
and the IBC Code	Not applicable.	

### 15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· New Zealan	· New Zealand Inventory of Chemicals	
7732-18-5	Water	
56-81-5	glycerol	
50-70-4	D-glucitol	
57-55-6	Propylene glycol	
7631-86-9	silicon dioxide	
9004-32-4	sodium carboxyl methyl cellulose (CMC-Na)	
13463-67-7	titanium dioxide	
87-99-0	xylitol	
128-44-9	1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	
1314-13-2	zinc oxide	
7664-38-2	phosphoric acid	

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94-13-3	propyl 4-hydroxybenzoate
	butyl-4-hydroxybenzoat
	ethyl 4-hydroxybenzoate
1309-48-4	magnesium oxide
9000-30-0	guar Gum
· HSNO Approval numbers	
None of the ingredients is listed.	

- GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements

Harmful to aquatic life with long lasting effects.

· Precautionary statements

Avoid release to the environment.

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

H351 Suspected of causing cancer.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- · 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

vPvB: very Persistent and very Bioaccumulative

Carc. 2: Carcinogenicity – Category 2

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

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

- · 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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