Safety Data Sheet
in accordance with HSNO

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1 Identification of the substance or mixture and of the supplier

· **Other means of identification**

· **Trade name: GC_FujiCEM_2_Paste_A**
· **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 irritation Category 2	H315 Causes skin irritation.
Eye irritation Category 2	H319 Causes serious eye irritation.
Skin sensitisation Category 1	H317 May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure Category 2	H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Hazardous to the aquatic environment chronic Category 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**

GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labelling:**
2-hydroxyethyl metacrylate
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
2,2'-ethylenedioxydiethyl dimethacrylate
Urethane Dimethacrylate (UDMA)

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· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
Harmful to aquatic life with long lasting effects.
· **Precautionary statements**
Do not breathe 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 / eye protection / face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl metacrylate Skin irritation Category 2, H315; Eye irritation Category 2, H319; Skin sensitisation Category 1, H317	10-<25%
CAS: 68909-20-6 EINECS: 272-697-1	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica Specific target organ toxicity - repeated exposure Category 2, H373	5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin sensitisation Sub-category 1B, H317	5-<10%
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	2.5-<5%
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	2.5-<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	0.1-<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.

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· ***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.
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.

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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

· ***Appropriate engineering controls*** *No further data; see section 7.*
· ***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 Butylated hydroxytoluene		
Dermal	*DNEL dermal*	*0.5 mg/kg bw/day (man)*
Inhalative	*DNEL inhalation*	*3.5 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.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
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.

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· **Eye protection:**

Tightly sealed goggles

*
9 Physical and chemical properties

· **General Information**	
· **Appearance:**	
· **Form:**	Pasty
· **Colour:**	Orange
· **Odour:**	Characteristic
· **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:**	Not applicable.
· **Flammability**	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:**	Not determined.
· **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:**	
· **VOC (EC)**	0.0 g/l

· **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) 68909-20-6 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica: set including amorphous nanoforms; surface-treated nanoforms; Spheroidal; amorphous forms; amorphous nanoform

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· **Physical state**	Liquid

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)
128-37-0 Butylated hydroxytoluene		
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Causes skin irritation.
· **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** 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**
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
· **Aspiration hazard** Based on available data, the classification criteria are not met.
· **Interactive effects**
· **Repeated dose toxicity** May cause damage to organs through prolonged or repeated exposure.
· **CMR effects (carcinogenity, 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.

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· ***Behaviour in environmental systems:***
· ***Bioaccumulative potential*** *No further relevant information available.*
· ***Mobility in soil*** *No further relevant information available.*
· ***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.
· ***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.*
· ***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***
All ingredients are listed.

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· **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**

GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labelling:**
2-hydroxyethyl metacrylate
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
2,2'-ethylenedioxydiethyl dimethacrylate
Urethane Dimethacrylate (UDMA)
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
Harmful to aquatic life with long lasting effects.
· **Precautionary statements**
Do not breathe 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 / eye protection / face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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.
H319 Causes serious eye irritation.
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.
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

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