

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: TEMPSMART DC Paste B
- · 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 sensitisation Category 1 H317 May cause an allergic skin reaction. Reproductive toxicity Category 1

H360 May damage fertility or the unborn child. Specific target organ toxicity - repeated exposure H373 May cause damage to the lung through

Category 2 prolonged or repeated exposure. Route of exposure: Inhalation.

Hazardous to the aquatic environment chronic Category 2H411 Toxic 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 Danger
- · Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica 2,2'-ethylenedioxydiethyl dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

May damage fertility or the unborn child.

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May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation. Toxic to aquatic life with long lasting effects.

Duagantion and statements

· Precautionary statements

Do not breathe dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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: 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	50-<75%	
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	25-<50%	
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate	10-<25%	
CAS: 67-43-6 EINECS: 200-652-8	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) Reproductive toxicity Category 1, H360; Specific target organ toxicity - repeated exposure Category 2, H373; Acute inhalation toxicity Category 4, H332; Eye irritation Category 2, H319	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%	

[·] 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.

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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 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.

Avoid formation of dust.

Avoid contact with the eyes and skin.

Wear protective clothing.

· Environmental precautions:

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

· Methods and material for containment and cleaning up:

Pick up mechanically.

Prevent formation of dust.

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

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

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Avoid contact with the eyes and skin.

- · Information about fire and explosion protection: Dust can combine with air to form an explosive mixture.
- · 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:		
128-37-0 Butylated hydroxytoluene		
TWA (New Zealand)	Long-term value: 10 mg/m³	
WES (New Zealand)	Long-term value: 10 mg/m³ dsen	

· DNELs

128-37-0 Butylated hydroxytoluene

	•	•	-	
Dermal	DNEL	dermal		0.5 mg/kg bw/day (man)
Inhalative	DNEL	inhalatio	on	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.

Do not inhale dust / smoke / mist.

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.

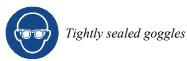
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· Eye protection:



9 Physical and chemical properties

· General Information

· Appearance:

· Form: Pasty · Colour: White

Odour: Characteristic
Odour threshold: Not determined.
pH-value: Not applicable.

· Change in condition

• Melting point/freezing point: Undetermined. • Initial boiling point and boiling range: 283 °C • Flash point: 101 °C

Flammability (solid, gas): Not determined.
 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 applicable.
Density at 20 °C: 1.3 g/cm³
Relative density Not determined.
Vapour density Not applicable.
Evaporation rate Not applicable.

· Solubility in / Miscibility with

water: Insoluble.
Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable.Kinematic: Not applicable.

• 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:					
72869-86	72869-86-4 Urethane Dimethacrylate (UDMA)				
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)			
67-43-6 N	67-43-6 N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)				
Inhalative LC50/4 h 1.5 mg/l (ATE)					
128-37-0	128-37-0 Butylated hydroxytoluene				
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)			

- · 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 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 May damage fertility or the unborn child.
- · 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.
- · Additional toxicological information:
- 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.
- · 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:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Harmful to aquatic organisms

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.

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- · 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 NZS, IMDG, IATA	UN3077
	0113077
UN proper shipping name	2077 FAMIDANAFATALLY HAZADDAHG GUDGTAN
NZS	3077 ENVIRONMENTALLY HAZARDOUS SUBSTAN SOLID, N.O.S. (Urethane Dimethacrylate (UDMA))
IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTAN
IMD G	SOLID, N.O.S. (Urethane Dimethacrylate (UDM
	Butylated hydroxytoluene), MARINE POLLUTANT
IATA	ENVIRONMENTALLY HAZARDOUS SUBSTAN
	SOLID, N.O.S. (Urethane Dimethacrylate (UDMA))
Transport hazard class(es)	
NZS	
Class	9 (M7) Miscellaneous dangerous substances and articles
Label	y
IMDG, IATA	
Class	9 Miscellaneous dangerous substances and articles.
Label	9
Packing group	
NZS, IMDG, IATA	III
Environmental hazards:	
Marine pollutant:	No
	Symbol (fish and tree)
Special marking (NZS):	Symbol (fish and tree)

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Special precautions for user Hazard identification number (Kemler code): EMS Number: Stowage Category Stowage Code	Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A SW23 When transported in BK3 bulk container, see 7.6.2.1.
	and 7.7.3.9.
Transport in bulk according to Annex II of Mar and the IBC Code	Not applicable.
Transport/Additional information:	
NZS Limited quantities (LQ) Excepted quantities (EQ) Transport category Tunnel restriction code	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 3 (-)
IMDG Limited quantities (LQ) Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
UN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOU SUBSTANCE, SOLID, N.O.S. (URETHAN DIMETHACRYLATE (UDMA)), 9, III

15 Regulatory information

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

· New Zealand Inventory of Chemicals		
72869-86-4	Urethane Dimethacrylate (UDMA)	
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	
112945-52-5	Silicon dioxide	
13122-18-4	tert-butylperoxy-3,5,5-trimethylhexanoate (not more than 42%, and inert solid not less than 58%)	
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	
128-37-0	Butylated hydroxytoluene	
· 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). (Contd. on page 9)

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· Hazard pictograms







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GHS0

· Signal word Danger

· Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica

2,2'-ethylenedioxydiethyl dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

May damage fertility or the unborn child.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Toxic to aquatic life with long lasting effects.

· Precautionary statements

Do not breathe dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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.
- · Seveso category E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

· Relevant phrases

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360 May damage 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.

- · 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

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

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 inhalation toxicity Category 4: Acute toxicity – Category 4

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

Reproductive toxicity Category 1: Reproductive toxicity – Category 1

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

· 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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