

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:****TEMPSMART DC Paste B**

Nanoform

1.2 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

1.3 Details of the supplier of the safety data sheet**Manufacturer/Supplier:**

GC EUROPE N.V.

Interleuvenlaan 33

B-3001 Leuven

Tel. +32/(0)16/74.10.00

Fax +32/(0)16/40.26.84

msds@gc.dental

Further information obtainable from: Regulatory affairs

1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT RE 2 H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

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

GHS09

Signal word Warning

Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA)

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

2,2'-ethylenedioxydiethyl dimethacrylate

(Contd. on page 2)

EU

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **TEMPSMART_DC_Paste_B**

(Contd. of page 1)

- **Hazard statements**

H317 May cause an allergic skin reaction.

H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

H411 Toxic to aquatic life with long lasting effects.

- **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Determination of endocrine-disrupting properties**

128-37-0	Butylated hydroxytoluene	List II
----------	--------------------------	---------

SECTION 3: Composition/information on ingredients

- **3.2 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:**

72869-86-4	Urethane Dimethacrylate (UDMA) <i>Aquatic Chronic 2, H411; Skin Sens. 1B, H317</i>	50-<75%
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica <i>STOT RE 2, H373, EUH066</i> Nanoform: set including amorphous nanoforms; surface-treated nanoforms; Spheroidal; amorphous forms; amorphous nanoform	25-<50%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate <i>Skin Sens. 1B, H317</i>	10-<25%
67-43-6	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) <i>Repr. 1B, H360D; STOT RE 2, H373; Acute Tox. 4, H332; Eye Irrit. 2, H319</i> ATE: LC50/4 h inhalative: 1.5 mg/l	0.2-<0.5%
128-37-0	Butylated hydroxytoluene <i>Aquatic Acute 1, H400; Aquatic Chronic 1, H410</i> Substance identified as having endocrine disrupting properties (II)	≥0.25-<0.5%

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

(Contd. on page 3)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **TEMPSMART_DC_Paste_B**

(Contd. of page 2)

- **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.
- **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 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
- **5.2 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.
- **5.3 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.

SECTION 6: Accidental release measures

- **6.1 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.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
Prevent formation of dust.
Dispose of the material collected according to regulations.
- **6.4 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.

EU

(Contd. on page 4)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **TEMPSMART_DC_Paste_B**

(Contd. of page 3)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Prevent formation of dust.
Any unavoidable deposit of dust must be regularly removed.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 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 Butylated hydroxytoluene

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m ³ (man)

- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Hand protection**



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.

(Contd. on page 5)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: *TEMPSMART_DC_Paste_B*

(Contd. of page 4)

· Eye/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Solid
· Colour:	White
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	283 °C
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	101 °C
· Auto-ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	1.3 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	SiO ₂ : Diameter particle structure = 2.5 - 50 nm (TEM, d ₅₀ , number-based) Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d ₅₀ , 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

· 9.2 Other information

· Appearance:

· Form:

Pasty

· Important information on protection of health and environment, and on safety.

· Ignition temperature:

Product is not selfigniting.

(Contd. on page 6)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **TEMPSMART_DC_Paste_B**

(Contd. of page 5)

· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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)
------	------	--------------------------------------

67-43-6 N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)

Inhalative	LC50/4 h	1.5 mg/l (ATE)
------------	----------	----------------

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.

(Contd. on page 7)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **TEMPSMART_DC_Paste_B**

(Contd. of page 6)

- **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.
- **Additional toxicological information:**
- **Repeated dose toxicity** May cause damage to organs through prolonged or repeated exposure.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **11.2 Information on other hazards**

· Endocrine disrupting properties		
128-37-0	Butylated hydroxytoluene	List II

SECTION 12: Ecological information

- **12.1 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)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Harmful to aquatic organisms

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue	
18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 07	chemicals other than those mentioned in 18 01 06

(Contd. on page 8)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: *TEMPSMART_DC_Paste_B*

(Contd. of page 7)

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA** UN3077

· **14.2 UN proper shipping name**

· **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA))

· **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA), Butylated hydroxytoluene), MARINE POLLUTANT

· **IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Urethane Dimethacrylate (UDMA))

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class** 9 (M7) Miscellaneous dangerous substances and articles.

· **Label** 9

· **IMDG, IATA**



· **Class** 9 Miscellaneous dangerous substances and articles.

· **Label** 9

· **14.4 Packing group**

· **ADR, IMDG, IATA** III

· **14.5 Environmental hazards:**

· **Marine pollutant:** No
Symbol (fish and tree)

· **Special marking (ADR):** Symbol (fish and tree)

· **Special marking (IATA):** Symbol (fish and tree)

· **14.6 Special precautions for user**

· **Hazard identification number (Kemler code):** 90

· **EMS Number:** F-A,S-F

· **Stowage Category** A

· **Stowage Code** SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

(Contd. on page 9)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **TEMPSMART_DC_Paste_B**

(Contd. of page 8)

· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **Transport category**

3

· **Tunnel restriction code**

(-)

· **IMDG**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **UN "Model Regulation":**

UN 3077 ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (URETHANE
DIMETHACRYLATE (UDMA)), 9, III

SECTION 15: Regulatory information

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

· **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

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· **Relevant phrases**

H317 May cause an allergic skin reaction.

(Contd. on page 10)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: TEMPSMART_DC_Paste_B

(Contd. of page 9)

- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H360D May damage 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.
- EUH066 Repeated exposure may cause skin dryness or cracking.

· **Classification according to Regulation (EC) No 1272/2008 Calculation method**

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **Date of previous version:** 16.11.2021

· **Version number of previous version:** 2

· **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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

ATE: Acute toxicity estimate values

Acute Tox. 4: Acute toxicity – Category 4

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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 1B: Reproductive toxicity – Category 1B

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 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

· **Sources**

• ECHA (<http://echa.europa.eu/>)

• EnviChem (www.echemportal.org)

· *** Data compared to the previous version altered.**

This version replaces all previous versions.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.