

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.04.2016

Version: 5

Revision: 22.04.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Hybrid- / Flow- Composite - 20/20 Syringe 3 gram Refill (A2 - 3 - 3.5 - B1 - B3 - C3)
- **Article number:** 9006380 to 9006385
- **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** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**

· Manufacturer/Supplier:	Authorized EU Representative:	Contact:
· Henry Schein Inc.	Henry Schein Services GmbH	cbdeurope@henryschein.com
· 135 Duryea Road	Monzastrasse 2a	www.henryscheinbrand.com
· Melville, NY 11747 / USA	63225 Langen / Germany	Tel: +49 6103 757 5000

- - **Responsible for the Safety Data Sheet: Regulatory Affairs Europe - cbdeurope@henryschein.com**
- **1.4 Emergency telephone number INTERNATIONAL:** +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)

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.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
tetramethylene dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P321	Specific treatment (see on this label).
P363	Wash contaminated clothing before reuse.
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.

- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
tetramethylene dimethacrylate

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31


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Version: 5

Revision: 22.04.2016

Trade name: Hybrid- / Flow- Composite

(Contd. of page 1)

· Hazard statements*H317 May cause an allergic skin reaction.***· Precautionary statements***P261 Avoid breathing dust/fume/gas/mist/vapours/spray.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P321 Specific treatment (see on this label).**P363 Wash contaminated clothing before reuse.**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.**SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: Mixtures****· Description:***1,4-Butandiol dimethacrylate**Urethane dimethacrylate**Bis-GMA***· Dangerous components:***CAS: 2082-81-7**tetramethylene dimethacrylate* *Skin Sens. 1B, H317**2,5-10%**EINECS: 218-218-1***· Additional information** For the wording of the listed risk phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information** No special measures required.**· After inhalation** Supply fresh air; consult doctor in case of complaints.**· After skin contact***Immediately wash with water and soap and rinse thoroughly.**If skin irritation continues, consult a doctor.***· After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.**· After swallowing** Do not induce vomiting; call for medical help immediately.**· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**· 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***Foam**Fire-extinguishing powder**Water haze**Carbon dioxide***· For safety reasons unsuitable extinguishing agents** Water with full jet.**· 5.2 Special hazards arising from the substance or mixture** No further relevant information available.**· 5.3 Advice for firefighters****· Protective equipment:** Wear self-contained respiratory protective device.

GB

(Contd. on page 3)

Safety data sheet
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Version: 5

Revision: 22.04.2016

Trade name: Hybrid- / Flow- Composite

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep receptacles tightly sealed.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Close container immediately after use and protect product from light incidence.
Storage between 10 °C and 25 °C.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:** Protective gloves.
- **Material of gloves** Butyl rubber, BR
- **Penetration time of glove material**
0,1 - 0,2 mm
Penetration time: 5 min.
- **Eye protection:** Safety glasses

GB

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.04.2016

Version: 5

Revision: 22.04.2016

Trade name: Hybrid- / Flow- Composite

(Contd. of page 3)

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Viscous
· Colour:	Different according to colouring
· Odour:	Weak, characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	251 °C

· **Flash point:** 101 °C

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 370 °C

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** 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:** Not miscible or difficult to mix

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· dynamic:	Not determined.
· kinematic:	Not determined.

· **Solvent content:**

· **Organic solvents:** 0,0 %

· **9.2 Other information** No further relevant information available.

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**

Photoreactive

Danger of polymerization

· **10.4 Conditions to avoid** No further relevant information available.

· **10.5 Incompatible materials:**

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

(Contd. on page 5)

Safety data sheet
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Version: 5

Revision: 22.04.2016

Trade name: Hybrid- / Flow- Composite

(Contd. of page 4)

· **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)
- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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.
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must be specially treated adhering to official regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

08 04 10	waste adhesives and sealants other than those mentioned in 08 04 09
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- **Uncleaned packaging:**
- **Recommendation:**
Packagings that may not be cleansed are to be disposed of in the same manner as the product.
- **Recommended cleansing agents:** Alcohol

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(Contd. on page 6)

Safety data sheet
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(Contd. of page 5)

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

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.
 - National regulations
 - Technical instructions (air):
- | Class | Share in % |
|-------|------------|
| III | 2,5-10 |
- Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.
 - 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H317 May cause an allergic skin reaction.
- **Department issuing MSDS:** : Regulatory Affairs Europe
- **Contact:** cbdeurope@henryschein.com
- **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
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

(Contd. on page 7)

Safety data sheet
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Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B

(Contd. of page 6)

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

GB