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

1.1. Product identifier

ZENCHROMA- Universal Composite

1.2. Details of the supplier of the safety data sheet

Company Name: President Dental GmbH

Street: Kesselbodenstrasse 5,

Zip-Code / Town: 85391, Allershausen

Contact for technical information: +49 8166 389 9 820

Phone / Fax / E-Mail: +49 8166 389 9 820 / +49 8166 389 9 821 / info@presidentdental.com

1.3. Emergency Telephone Number

+49 8166 389 9 820 (8.00 am - 4.30 pm Mon-Fri)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to	Skin Sens. 1 H317 May cause an allergic skin reaction.
(EC) No 1272/2008	

2.2 Label Elements

Labelling according to Regulation (EC) No 1272/2008			
The product is classified an	The product is classified and labelled according to the CLP regulation.		
Hazard Pictograms	<u>•</u>		
Signal Word	GHS07 Warning		
Hazard Determining components of labeling	tetramethylene dimethacrylate		
	Skin Irrit. 2: H315 – Causes skin irritation		
	Eye Irrit. 2: H319 – Causes serious eye irritation		
Hazard Statement	H317 May cause an allergic skin reaction.		
Precautionary Statement	P261 Avoid breathing dust/fume/gas/mist/vapours/spray.		

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Prevention	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.	
Labeling of packages when	e the contents do not exceed 125ml	
Hazard Pictograms	•	
	GHS07	
Signal Word	Warning	
Hazard-determining components of labelling:	tetramethylene dimethacrylate	
Hazard statements	H317 May cause an allergic skin reaction.	
Precautionary	P261 Avoid breathing dust/fume/gas/mist/vapours/spray.	
statements	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	
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-Butandioldimethacrylate Urethandimethacrylate Bis-GMA

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Dangerous Compone	nts		
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate Bis-GMA	(!)	2,5-10%
		skin Sens. 1B, H317	
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.

SECTION 5: Fire Fighting 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.

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5.3. Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device.

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. Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in correctly labelled containers.

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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	

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.	

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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

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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.

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 (carcinogenity, 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.

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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 Substance / Preparation:

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

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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

SECTION 14: Transport information

14.1. UN Number		
ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping nai	me	
ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class	s(es)	
ADR, ADN, IMDG, IATA	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		
UN "Model Regulation":		
Void		

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific fort he substance or mixture

Directive 2012/18/EU

· Named dangerous substances - ANNEX I

None of the ingredients is listed.

- · National regulations
- · Technical instructions (air):

Class S	hare in %
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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:	F&E President Dental GMBh
· 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 Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B
	* Data compared to the previous version altered.