according to Regulation (EC) No 1907/2006

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SECTION 1: Identification of t	he substance/mixture and of the cor	npany/undertaking			
1.1. Product identifier					
T-Fill Product group:	Composite				
U 1	he substance or mixture and uses advis	ed against			
Use of the substance/mixture					
	porary one-component closure material for to the light curing immediately durable an				
Uses advised against		-			
Application of eugenol con polymerization.	taining material, specifically base liners, is	not indicated, it will inhibit the			
1.3. Details of the supplier of the	<u>safety data sheet</u>				
Company name: Street: Place:	MEGADENTA Dentalprodukte Gmb Carl-Eschebach-Str. 1A 01454 Radeberg, Germany	θH			
Telephone: e-mail: Internet:	+49-3528 4530 info@megadenta.de www.megadenta.de	Telefax: +49-3528 45321			
1.4. Emergency telephone number:	+49-3528 453-0 (just during usual o	office time: GMT+1)			
SECTION 2: Hazards identific	ation				
2.1. Classification of the substar	nce or mixture				

Regulation (EC) No. 1272/2008

Hazard categories: Respiratory or skin sensitisation: Skin Sens. 1 Hazardous to the aquatic environment: Aquatic Chronic 3 Hazard Statements: May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

poly-(methyl methacrylate)-co-(butylmethacrylate)-co-(4-acryloxybutyl-isopropenyl-.alpha.,.alpha.-dimethylbenzyl carbamate)-co-(maleicanhydride) Neopentyl glycol propoxylate (1 PO/OH) diacrylate Warning

Signal word:

Pictograms:



Hazard statements

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

rooudlionaly oluton	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing

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	protection.	
P302+P352	IF ON SKIN: Wash with plenty of water.	
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.	
P362+P364	Take off contaminated clothing and wash it before reuse.	

Special labelling of certain mixtures

Contains 15 - < 20 % of components with unknown hazards to the aquatic environment.

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name					
	EC No Index No REACH No					
	GHS Classification					
	poly-(methyl methacrylate)-co-(butylmethacrylate)-co- (4-acryloxybutyl-isopropenylalpha.,.alphadimethylbenzyl carbamate)-co-(maleicanhydride)			20 - < 25 %		
	419-590-1	607-415-00-1				
	Flam. Sol. 1, Skin Sens. 1; H228 H317					
84170-74-1	74-1 Neopentyl glycol propoxylate (1 PO/OH) diacrylate			5 - < 10 %		
	Skin Sens. 1, Aquatic Chronic 2; H317 H411					

Full text of H and EUH statements: see section 16.

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
84170-74-1	Neopentyl glycol propoxylate (1 PO/OH) diacrylate		5 - < 10 %
	inhalation: LC50 = >2 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Polymerized material is non-hazardous.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

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5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

The unprotected substance must not be exposed to the light before processing, because it polymerizes. Only adequately trained personnel should handle this product. For use in dentistry only.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Light-sensitive substance. Protect from exposure to the light. Store not above 25°C.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

T-Fill is a light-curing, temporary one-component closure material for all types of Temporary fillings. T-Fill is easy and fast to apply, due to the light curing immediately durable and easy to remove.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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DNEL/DMEL values

CAS No	Substance					
DNEL type		Exposure route	Effect	Value		
84170-74-1 Neopentyl glycol propoxylate (1 PO/OH) diacrylate						
3						

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Colour:	solid paste	
Odour:	between tooth colour and gray practically odorless	
pH-Value:		not determined
Changes in the physical state		
Melting point:		not determined
Boiling point or initial boiling point and boiling range:		100 °C
Flash point:		> 113 °C
Flammability Solid/liquid:		not determined
Gas:		not applicable
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Auto-ignition temperature:		113 °C
Self-ignition temperature		
Solid: Gas:		not determined not applicable
Decomposition temperature:		not determined

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Oxidizing properties Not oxidising.		
Vapour pressure: (at 20 °C)	<1,33 hPa	
Density (at 20 °C):	1,48 g/cm³	
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.	
Solubility in other solvents not determined		
Partition coefficient n-octanol/water:	not determined	
Relative vapour density:	not determined	
Evaporation rate:	not determined	
0.2. Other information		
Solid content:	68,55 %	

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

Protect from exposure to the light. Keep away from heat and direct sunlight.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

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.

CAS No	Chemical name						
	Exposure route	Dose	Species	Source	Method		
84170-74-1	Neopentyl glycol propoxylate (1 PO/OH) diacrylate						
		LD50 >5000 mg/kg	Ratte				
		LD50 >2000 mg/kg	Ratte				
	inhalation (4 h) vapour	LC50 >2 mg/	I Ratte				

Irritation and corrosivity

Based on available data, the classification criteria are not met.

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Sensitising effects

May cause an allergic skin reaction. (poly-(methyl methacrylate)-co-(butylmethacrylate)-co-(4-acryloxybutyl-isopropenyl-.alpha.,.alpha.-dimethylbenzyl carbamate)-co-(maleicanhydride); Neopentyl glycol propoxylate (1 PO/OH) diacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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.

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method
84170-74-1	Neopentyl glycol propoxylate (1 PO/OH) diacrylate						
	Acute fish toxicity	LC50	2.7 mg/l		Brachydanio rerio (Zebrafisch)		
	Acute algae toxicity	ErC50	11 mg/l		Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50	37 mg/l	48 h	Daphnia magna		

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
84170-74-1	Neopentyl glycol propoxylate (1 PO/OH) diacrylate				
	No data available.	51%	28		

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
84170-74-1	Neopentyl glycol propoxylate (1 PO/OH) diacrylate	1-4,86

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information	
2010/75/EU (VOC):	17,38 % (257,224 g/l)
2004/42/EC (VOC):	31,385 % (464,501 g/l)
National regulatory information	
Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	2 - obviously hazardous to water
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 4,5,6,7,8,9,10,11,12,13,14,15,16.

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 Harmonized 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 LC50: Lethal concentration, 50% LD50: Lethal dose, 50%

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Relevant H and EUH sta	atements (number and full text)					
H228	Flammable solid.					
H317	May cause an allergic skin reaction.					
H411	Toxic to aquatic life with long lasting effects.					
H412	Harmful to aquatic life with long lasting effects.					
Further Information						
The above information	on describes exclusively the safety requirements of the product and is based on our					
present-day knowled	ge. The information is intended to give you advice about the safe handling of the product					
named in this safety	data sheet, for storage, processing, transport and disposal. The information cannot be					
transferred to other p	roducts. In the case of mixing the product with other products or in the case of					

processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)