

Fibrafill® DENTIN

Date of issue: 05/06/2020


Version: 1.00

Revision date: 05/06/2020

1 Identification

1.1	Product identifier	Fibrafill® DENTIN
1.2	Recommended use and restrictions	Dental products, restorative, for use only by dental professionals
1.3	Manufacturer/Supplier details	ADM, a.s., U Vodárny 2965/2, 616 00, Brno, Czech Republic
1.4	TOX emergency number	+420 511 205 360

2 Hazards identification

2.1	Compound/mixture identification (ES) Nr.1272/2008	exempted from the requirements – product regulated as medical due to agent or in vitro medical agent		
2.2	Hazard statement	Skin Sens.	1	H317 May cause an allergic skin reaction.
		Eye Dam.	1	H319 Causes serious eye irritation.
2.3	Label elements	Signal word:	Warning	
		Symbols:	Exclamation mark 	
		Pictograms:	GHS07	
2.4	Prevention	P261	Avoid breathing dust/fume/gas/mist/vapors/spray.	
		P272	Contaminated work clothing should not be allowed out of the workplace.	
		P280	Wear protective gloves/protective clothing/eye protection/face protection.	
2.5	Response	P302+352	IF ON SKIN: Wash with plenty of soap and water.	
		P305+351+338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.	
2.6	Storage	P410	Protect from sunlight.	
		P411	Store at temperatures not exceeding 25°C / 77°F	
2.7	Disposal	P501	Dispose of contents/container in accordance with applicable local/regional/national/international regulations.	
2.8	Hazards or otherwise classified	None		

3 Composition / Information on ingredients

Ingredient	CAS No.	Content (%wt.)
Isopropylidenediphenol PEG-2 Dimethacrylate (Bis-EMA)	41637-38-1	<10
Bisphenol A Glycidyl Methacrylate (Bis-GMA)	1565-94-2	<5
Urethane Dimethacrylate (UDMA)	72869-86-4	<10
Triethylene glycol dimethacrylate (TEGDMA)	109-16-0	<5
2-hydroxyethyl methacrylate (HEMA)	868-77-9	<1
Camphorquinone (CQ)	10373-78-1	<1
2-(dimethylamino)ethyl methacrylate (DMAEMA)	2867-47-2	<1
3,5-di-tert-4-butylhydroxytoluene (BHT)	128-37-0	<1
Silane treated silica	248596-91-0	<5

Fibrafill® DENTIN

Date of issue: 05/06/2020

Version: 1.00

Revision date: 05/06/2020

Silane treated glass
Silane treated silica fibers

65997-17-3
Not Assigned

<80
<10

4 First aid measures

- | | | |
|-----|--------------|--|
| 4.1 | IF INHALED | Remove person to fresh air and keep comfortable for breathing. * |
| 4.2 | IF IN EYES | Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. * |
| 4.3 | IF ON SKIN | Wash with plenty of soap and water. * |
| 4.4 | IF SWALLOWED | Rinse mouth. Drink plenty of water. * |

*** IF SIGNS / SYMPTOMS / PERSON FEELING UNWELL, GET MEDICAL ATTENTION!**

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| 4.5 | Most important symptoms (both acute and delayed) | See Section 11.1 Information on toxicological effects. |
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5 Fire-fighting measures

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|-----|---|---|
| 5.1 | Suitable extinguishing media | Chemical foam, CO ₂ , water or dry chemical |
| 5.2 | Special hazards arising from the substance or mixture | None inherent in this product |
| 5.3 | Hazardous decomposition or by-products | Carbon dioxide and carb. monoxide are produced during combustion. |
| 5.4 | Special protective actions or fire-fighters | No special protective actions for fire-fighters are anticipated. |

6 Accidental release measures

- | | | |
|------|---|--|
| 6.1 | Personal precautions, protective equipment and emergency procedures | Remove people to safety.
Prevent formation of dust.
Avoid contact with skin and eyes.
Wear personal protective clothing. |
| 6.2 | Environmental precautions | Avoid release to the environment, otherwise contact competent authorities. |
| 6.3 | Methods and materials for containment and cleaning up | Gather mechanically. Avoid formation of dust. Dispose in accordance with applicable local/regional/national/international regulations. |
| 6.4. | Additional information: | Information on safe handling – see Section 7.
Information on personal protective clothing – see Section 8.
Information on disposal – see Section 13. |

7 Handling and storage

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|-----|-------------------------------|---|
| 7.1 | Precautions for safe handling | Avoid breathing of dust created by cutting, sanding, grinding or machining. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Avoid breathing dust/fume/gas/mist/ |
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Fibrafill® DENTIN

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vapors/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Avoid release to the environment. Avoid contact with oxidizing and/or reducing agents.

7.2 Conditions for safe storage including any incompatibilities Store at 4-25 °C / 39-77 °F, away from direct sunlight, initiators, oxidizing, and/or reducing agents. Store in unopened original packaging. Over time, spontaneous polymerization may occur.

7.3 Fire- and explosion protection Not required

8 Exposure controls / personal protection

8.1 Exposure controls Use general dilution ventilation and/or local exhaust ventilation to control airborne exposure and dust/fume/gas/mist/vapor/spray. If ventilation is not adequate use respiratory protection equipment.

8.2 Personal protective equipment

8.2.1 Protective and hygiene measures General rules of hygiene apply as when working with chemicals. Avoid contact with skin, eyes and clothes. Draw up and observe skin protection program. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

8.2.2 Eye/face protection Use tightly fitting safety goggles.



8.2.3 Hand protection Use suitable safety gloves. Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

Note: The right safety gloves selection does not depend on the material only as some other parameters may vary depending on the manufacturer. Safety gloves are mostly made out of mixture of materials and it is not possible to calculate the material penetration time - it is therefore recommended to perform a test before use.

8.2.4 Skin protection Wear suitable protective clothes.

9 Physical and chemical properties

9.1 Appearance Generally physical form: Solid
Specific physical form: Paste
Color: Colorless to light yellow

9.2 Odor Hardly noticeable but characteristic (moderate acrylate)

9.3 Change in the physical state: Melting point/melting range: Not determined
Boiling point/boiling range: Not determined
Flash point: No flash point
Auto-ignition temperature: Not determined
Danger of explosion: Not determined
Density: Not determined

Fibrafill® DENTIN

Date of issue: 05/06/2020

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Vapor pressure:	Not determined
Viscosity:	Not determined
pH:	Not determined
Solubility in/miscibility with Water:	Negligible
Content of solvents:	Not determined
Other information	No data available

10 Stability and reactivity

10.1 Reactivity:	No unsafe reaction when handled and stored according to provisions
10.2 Chemical stability	Stable
10.3 Possibility of hazardous reactions	None known
10.4 Conditions to avoid	Protect from light, store in original packaging.
10.5 Incompatible materials	Strong oxidizing agents
10.6 Hazardous decomposition products	None known

11 Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

If the component is listed in the Section 3 but does not appear in the table below, either no data are available or the data are not sufficient for the classification.

11.1 Acute toxicity

Name	Route	Species	Value
Overall Product			No data available; ATE 2000-5000mg/kg
Urethane Dimethacrylate (UDMA)	Ingestion	Rat (f+m)	LD50>5000mg/kg
2-hydroxyethyl methacrylate (HEMA)	Ingestion	Rat	LD50=5050mg/kg
	Dermal	Rabbit	LD50>3000mg/kg
2-(dimethylamino)ethyl methacrylate (DMAEMA)	Ingestion	Rat	LD50>2000mg/kg
	Dermal	Rat	LD50>2000mg/kg
	Dermal	Rabbit	LD50>3000mg/kg
3,5-di-tert-4-butylhydroxytoluene (BHT)	Ingestion	Rat (f+m)	LD50>6000mg/kg
	Dermal	Rat	LD50>2000mg/kg
Silane treated silica	Dermal		LD50 estimated to be >5000mg/kg
	Ingestion		LD50 estimated to be >5000mg/kg

Note: ATE = Acute Toxicity Estimate

11.2 Skin corrosion/Irritation	Based on available data, the classification criteria are not met.
11.3 Sensitization effects	May cause an allergic skin reaction. Possible sensitization in case of persons suffering from hypersensitivity.
11.4 Respiratory sensitization	Based on available data, the classification criteria are not met.

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11.5	Specific organ target toxicity Single exposure Prolonged exposure	Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.
11.6	Germ cell mutagenicity	Based on available data, the classification criteria are not met.
11.7	Carcinogenicity	Based on available data, the classification criteria are not met.

12 Ecological information

12.1	Persistence and degradability	The product has not been tested.
12.2	Bioaccumulative potential	The product has not been tested.
12.3	Mobility in soil	The product has no been tested.
12.4	Additional ecological information	Water hazard class 3 (self-assessment) – extremely hazardous for water. Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.
12.5	Further information	Do not allow uncontrolled discharge of product into the environment. Do not allow to enter into surface water or drains.

13 Disposal considerations

13.1	Disposal methods	Dispose of contents/container in accordance with applicable local/regional/national/international regulations.
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14 Transport information

14.1	UN-number	ADR, ADN, IMDG, IATA	not regulated
14.2	UN proper shipping name	ADR, ADN, IMDG, IATA	not regulated
14.3	Transport hazard class	ADR, ADN, IMDG, IATA	not regulated
14.4	Packaging group	ADR, IMDG, IATA	not regulated
14.5	Environmental hazard	Marine pollutant:	no
14.6	Special precautions for user	Not applicable	
14.7	Transport in bulk (Annex II of Marpol and the IBC Code)	Not applicable	
14.8	UN "Model Regulation"	not regulated	

15 Regulatory information

15	Substance/mixture specific safety, health and environmental regulations/legislation	This MSDS meets the requirements of Regulation (EC) No. 1907/2006. Directive 2012/18/EU Named dangerous substances - ANNEX I: None
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15.2	Chemical safety assessment	A Chemical Safety Assessment has not been carried out.	
15.3	US Federal regulation	Contact ADM,a.s. for more information	
15.4	311/312 Hazard categories	Fire hazard	No
		Pressure hazard	No
		Reactivity hazard	No
		Immediate hazard	No
		Delayed hazard	No

16 Other information

16.1	Other relevant phrases	H302 Harmful if swallowed. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H373 May cause damage to organs through prolonged or repeated exposure. H413 May cause long lasting harmful effects to aquatic life.	
16.2	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 CAS: Chemical Abstracts Service (American Chemical Society division) LD50: Lethal dose, 50 percent	

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