Telefax: +49 6031 7283-29



Safety Data Sheet

according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 1 of 7

1. Identification

Product identifier

Renamel Bulkfill

Recommended use of the chemical and restrictions on use

Use of the substance/mixture

dental use

Details of the supplier of the safety data sheet

Manufacturer

Company name: Deltamed GmbH .

Street: Raiffeisenstr. 8a

Place: D-61169 Friedberg

Telephone: +49 6031 7283-0

e-mail: info@deltamed.de Internet: www.deltamed.de

Responsible Department: F&E

Telefax +49 6031 7283-29

Supplier

Company name: COSMEDENT, Inc.

Street: 401 North Michigan Avenue Ste . 2500

Place: USA-IL 60611 Chicago

Telephone: 1-800-621-6729

Contact person: Mary O` Malley Telephone: 312-644-9586

e-mail: mary@cosmedent.com Internet: cosmedent.com

Emergency phone number: 312-644-9586

2. Hazard(s) identification

Label elements

Hazards not otherwise classified

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Mixture of acrylic resins, fillers and initiators.

Hazardous components

CAS No	Components	Quantity
1565-94-2	Bisphenol A Diglycidyl Methacrylate (BIS-GMA)	* < 25 %
72869-86-4	urethane dimethacrylate (UDMA)	* < 25 %

Further Information

* The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures



Deltamed GmbH.

according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 2 of 7

General information

Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product or by inhalation of its vapours. Take off all contaminated clothing immediately.

After inhalation

Provide fresh air. Medical treatment necessary.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

After ingestion

Do NOT induce vomiting. Medical treatment necessary.

Most important symptoms and effects, both acute and delayed

No information available.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Foam. Extinguishing powder, Carbon dioxide,

Specific hazards arising from the chemical

In case of fire may be liberated: Carbon monoxide Carbon dioxide Hazardous decomposition products

Special protective equipment and precautions for fire-fighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

General measures

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

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

Other information

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

Reference to other sections

Safe handling: see section 7

Personal protection equipment (PPE): see section 8

Disposal: see section 13

7. Handling and storage

Precautions for safe handling





according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 3 of 7

Advice on safe handling

Provide adequate ventilation.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes. 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.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Protect from the action of light. Keep only in the original container at a temperature between 4 - 24 °C (39 -77°F). Can polymerize with intense heat release.

Hints on joint storage

Do not store together with:

strong

food

8. Exposure controls/personal protection

Control parameters

Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

tightly fitting goggles

Hand protection

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

Skin protection

Wear suitable protective clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: pasty

Color: various, depending on coloration

Odor: hardly noticeable

Changes in the physical state

Melting point/freezing point:

Boiling point or initial boiling point and

not determined

boiling range:

Flash point: > 100 °C

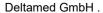
Flammability

Solid/liquid: not applicable
Gas: not applicable
Lower explosion limits: not determined
Upper explosion limits: not determined

Self-ignition temperature

Solid: not applicable
Gas: not applicable

Decomposition temperature: not determined





according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 4 of 7

pH-Value: not determined Viscosity / dynamic: 150 * 1000 mPa·s

Water solubility: The study does not need to be conducted

because the substance is known to be

insoluble in water.

Partition coefficient n-octanol/water:

Vapor pressure:

Density:

not determined

not determined

not determined

not determined

not determined

Other information

Other safety characteristics

Solid content: not determined Evaporation rate: not determined

Further Information

10. Stability and reactivity

Reactivity

No hazardous reaction when handled and stored according to provisions.

Chemical stability

Stability: Stable

The product is stable under storage at normal ambient temperatures.

Possibility of hazardous reactions

Hazardous reactions: Will not occur

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

Conditions to avoid

Protect from the action of light. Keep only in the original container at a temperature between 4 - 24 °C (39 -77°F). Can polymerize with intense heat release.

Incompatible materials

Oxidising agent, Reducing agent, Heavy metals, acids, Alkali (lye)

Hazardous decomposition products

No known hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity

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

CAS No	Components							
	Exposure route	Dose		Species	Source	Method		
72869-86-4	urethane dimethacrylate (UDMA)							
		LD50 mg/kg	>2000	Rat	OECD 401			
	inhalation (4 h) aerosol	LC50	>5 mg/l					

Irritation and corrosivity

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





according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 5 of 7

Sensitizing effects

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

Possible sensitization in case of persons suffering from hypersensitivity.

Carcinogenic/mutagenic/toxic effects for reproduction

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

Specific target organ toxicity (STOT) - single exposure

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

Specific target organ toxicity (STOT) - repeated exposure

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

Carcinogenicity (OSHA): No ingredient of this mixture is listed.

Carcinogenicity (IARC): No ingredient of this mixture is listed.

Carcinogenicity (NTP): No ingredient of this mixture is listed.

Aspiration hazard

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

Further information

Product has not been tested. The statement is derived from the properties of the components.

12. Ecological information

Persistence and degradability

The product has not been tested.

Bioaccumulative potential

The product has not been tested.

Mobility in soil

The product has not been tested.

Other adverse effects

No information available.

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

Waste treatment methods

Disposal recommendations

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities. Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

14. Transport information

US DOT 49 CFR 172.101

<u>Proper shipping name:</u> Not a hazardous material with respect to these transport regulations.

Marine transport (IMDG)

Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)



according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 6 of 7

Other applicable information (air transport)

No dangerous good in sense of these transport regulations.

Special precautions for user

No information available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not applicable

15. Regulatory information

U.S. Regulations

National Inventory TSCA

All components of this product are included on the TSCA Chemical Inventory ore are not required to be listed on the TSCA Chemical Inventory.

National regulatory information

SARA Section 311/312 Hazards:

Bisphenol A Diglycidyl Methacrylate (BIS-GMA) (1565-94-2): Immediate (acute) health hazard urethane dimethacrylate (UDMA) (72869-86-4): Immediate (acute) health hazard

State Regulations

Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product can not expose you to chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Other information

Hazardous Materials Information Label (HMIS)

Health: 1
Flammability: 0
Physical Hazard: 0

NFPA Hazard Ratings

Health: 1
Flammability: 0
Reactivity: 0
Unique Hazard:

Changes

Revision date: 11/10/2020 Revision No: 1,00

reason of revision: classification according CLP / GHS.

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

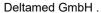
CAS: Chemical Abstracts Service LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Other data

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product







according to 29 CFR 1910.1200(g)

Renamel Bulkfill

Revision date: 11/10/2020 Product code: 1125XXXUSA Page 7 of 7

named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. 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.)