

Safety Data Sheet

according to 29 CFR 1910.1200(g)

ExperTemp™ (All Shades)

Revision date: 11/11/2024

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1. Identification

Product identifier

ExperTemp™ (All Shades) **Further Trade Names:** ExperTemp™ (All Shades)

Article Number: SDS 336-001.09R01, 6340, 6341, 6344, 6347

Recommended use of the chemical and restrictions on use

Use of the substance/mixture

Medical device for use in dentistry, observe instructions for use.

Uses advised against

Observe instructions for use.

Details of the supplier of the safety data sheet

Company name:	Manufactured by Kettenbach GmbH & Co. KG for Ultradent Products, Inc.
Street:	505 W. Ultradent Drive (10200 S)
Place:	South Jordan, UT 84095-3942 USA
Telephone:	(800) 552-5512
E-mail:	onlineordersupport@ultradent.com
Responsible Department:	Regulatory Compliance

Further Information

The product is intended for professional use.

Emergency Telephone: CHEMTREC (NORTH AMERICA): +1 (800) 424-9300
(INTERNATIONAL): +(703) 527-3887

2. Hazard(s) identification

Classification of the chemical

29 CFR Part 1910.1200

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2A

Respiratory or skin sensitization: Skin Sens. 1

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. In particular, they serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required in accordance with FDA regulations. This product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (29 CFR § 1910.1200). They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

Label elements

29 CFR Part 1910.1200

Signal word: Danger

Pictograms:



Hazard statements

Causes skin irritation

May cause an allergic skin reaction

Causes serious eye irritation

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Precautionary statements

Do not breathe dust/fume/gas/mist/vapors/spray.
 Avoid release to the environment.
 Wear protective gloves and eye protection/face protection.
 If skin irritation or rash occurs: Get medical advice/attention.
 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
 Continue rinsing.
 Disposal of the contents/container in accordance with local/regional/national international regulations.

Hazards not otherwise classified

Due to the physical form (paste), classification with H372 and H373 is not indicated. Inhalation is not possible.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Preparation of multifunctional methacrylates, filler materials and additives.

Hazardous components

CAS No	Components	Quantity
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	15 - < 40 (*) %
14464-46-1	Cristobalite	30 - < 60 (*) %
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE	3 - < 7 (*) %
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	1 - < 5 (*) %

Further Information

(*) The actual concentration is withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap.

After contact with eyes

If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

After ingestion

IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

Most important symptoms and effects, both acute and delayed

Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

After skin contact: Not expected to present a significant skin hazard under anticipated conditions of normal use.

In case of ingestion: Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

Indication of any immediate medical attention and special treatment needed

First Aid, decontamination, treatment of symptoms.

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5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Thermal decomposition can lead to the escape of irritating gases and vapors.

Carbon monoxide

Carbon dioxide (CO₂)

Special protective equipment and precautions for fire-fighters

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

Additional information

Suppress gases/vapors/mists with water spray jet.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Do not breathe mist/vapors/spray.

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Other information

Allow stiffening. Take up mechanically.

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

Advice on safe handling

Keep away from heat, flame and direct sunlight.

Wear personal protection equipment (refer to section 8).

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Usual measures for fire prevention.

Advice on general occupational hygiene

Contaminated work clothing should not be allowed out of the workplace.

When using do not eat, drink, smoke, sniff.

Avoid contact with skin, eyes and clothes.

Further information on handling

Wash contaminated clothing before reuse.

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Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool place.

Further information on storage conditions

Please pay attention to the information on the package!

8. Exposure controls/personal protection

Control parameters

Exposure limits

CAS No	Substance	ppm	mg/m ³	f/cc	Category	Origin
14464-46-1	Silica, crystalline cristobalite, respirable dust	(Z-3)	(Z-3)		TWA (8 h)	PEL

Additional advice on limit values

None.

Exposure controls



Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Protective gloves.

Suitable material:

,NR (Natural rubber (Caoutchouc), Natural latex),.

Unsuitable material:

NBR (Nitrile rubber)

Skin protection

Protective clothing.

Respiratory protection

Not required.

Thermal hazards

None.

Environmental exposure controls

Do not allow to enter into surface water or drains.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:

Paste

Color:

tooth-colored

Odor:

almost odourless

Melting point/freezing point:

No data available

Boiling point or initial boiling point and

No data available

boiling range:

Flammability:

No data available

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Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	>100 °C
Auto-ignition temperature:	>300 °C
Decomposition temperature:	No data available
pH-Value:	No data available
Viscosity / kinematic:	No data available
Solubility in other solvents	
No data available	
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Vapor pressure:	No data available
Vapor pressure:	No data available
Density (at 20 °C):	~1.4 g/cm ³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	not applicable
Particle characteristics:	No data available

Other information

Information with regard to physical hazard classes

Explosive properties

not applicable

Oxidizing properties

not applicable

Other safety characteristics

Viscosity / dynamic:

~9000 mPa·s

(at 23 °C)

Further Information

The physical data presented above are typical values and should not be construed as a specification.

10. Stability and reactivity

Reactivity

None by intended use.

Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

Possibility of hazardous reactions

No known hazardous reactions.

Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

Incompatible materials

No data available

Hazardous decomposition products

Carbon monoxide

Carbon dioxide (CO₂)

11. Toxicological information

Information on toxicological effects

Acute toxicity

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

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ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) 2691 mg/kg; ATE (inhalation vapour) 50,42 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Components				
	Exposure route	Dose	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate				
	oral	LD50 >5000 mg/kg	Rat		OECD-Test-Nr. 40
	dermal	LD50 >2000 mg/kg	Rat		OECD-Test-Nr. 402
	inhalation	Data lacking			
14464-46-1	Cristobalite				
	oral	Data lacking			
	dermal	Data lacking			
	inhalation	Data lacking			
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE				
	oral	LD50 2000 mg/kg	Rat	ECHA	
	dermal	Data lacking			
	inhalation	Data lacking			
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation	Data lacking			

Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation

Serious eye damage/eye irritation: Causes serious eye irritation

Sensitizing effects

May cause an allergic skin reaction (7,7,9(or 7,9,9)

-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate; 1,12-DODECANEDIOL DIMETHACRYLATE)

Carcinogenic/mutagenic/toxic effects 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.

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): Cristobalite (CAS 14464-46-1) is listed.

Carcinogenicity (IARC): Cristobalite (CAS 14464-46-1) is listed in group 1.

Carcinogenicity (NTP): Cristobalite (CAS 14464-46-1) is listed in group Known.

Aspiration hazard

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

Further information

May cause an allergic skin reaction.

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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.

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

Other adverse effects

None known.

Further information

Do not allow to enter into surface water or drains.

13. Disposal considerations

Waste treatment methods

Disposal recommendations

Do not remove with domestic waste. Do not allow to enter drains or watercourses.
Dispose in accordance with official regulations.

Contaminated packaging

Non-contaminated packages may be recycled.

14. Transport information

U.S. DOT 49 CFR 172.101

UN number or ID number:

Proper shipping name:

Transport hazard class(es):

Packing group:

Hazard label:

UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

9

III

9



Marine transport (IMDG)

UN number or ID number:

UN proper shipping name:

Transport hazard class(es):

Packing group:

Hazard label:

UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

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III

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Special Provisions:

Limited quantity:

Excepted quantity:

EmS:

274 335 969

5 L

E1

F-A, S-F

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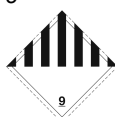
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Other applicable information (marine transport)

UN3082, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate), III, IMDG-Code segregation code: NONE, EMS: --.

Air transport (ICAO-TI/IATA-DGR)

UN number or ID number: UN 3082
UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Transport hazard class(es): 9
Packing group: III
Hazard label: 9



Special Provisions: A97 A158 A197 A215
Limited quantity Passenger: 30 kg G
Passenger LQ: Y964
Excepted quantity: E1
IATA-packing instructions - Passenger: 964
IATA-max. quantity - Passenger: 450 L
IATA-packing instructions - Cargo: 964
IATA-max. quantity - Cargo: 450 L

Other applicable information (air transport)

UN3082, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXCEPTION, (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate), III.

Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No
Danger releasing substance: This product contains a chemical which is listed as a marine pollutant according to IMDG/IMO.

Special precautions for user

No dangerous good in sense of these transport regulations.

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

No dangerous good in sense of these transport regulations.

Other applicable information

Product may be shipped as non-hazardous in suitable packages containing a net quantity of 5 L or less under the provisions of various regulatory agencies: ADR, RID, ADN: Special Provision 375; IMDG: 2.10.2.7; IATA: A197; TDG: Special Provision 99(2); 49CFR: §171.4 (c) (2) and also the Special Provision 375 in Appendix B which is regulated in China "Regulations Concerning Road Transportation of Dangerous Goods Part 3: Index of dangerous goods name and transportation requirements" (JT/T 617.3)

15. Regulatory information

U.S. Regulations

National regulatory information

SARA Section 311/312 Hazards:
 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate (72869-86-4): Immediate (acute) health hazard
 Cristobalite (14464-46-1): Delayed (chronic) health hazard
 1,12-DODECANEDIOL DIMETHACRYLATE (72829-09-5): Immediate (acute) health hazard
 silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6): Delayed (chronic) health hazard

State Regulations

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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

Changes

Revision date: 11/11/2024

Revision No: 1,03

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13,14,16.

Date of preparation / Revised on: 11/11/2024

Version number: 1,03

Replaces version number: 1,02 (22/10/(2021)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

Key literature references and sources for data

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

Other data

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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