

Printing date 08.04.2020 Revision: 03.03.2020

#### 1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: UltraTemp™ Base

· Article number: 81242

· Index number: SDS 72-001.12

· Relevant identified uses of the substance or mixture and uses advised against

Professional Dental Temporary Cement

· Application of the substance / the mixture Professional Dental Temporary Cement

Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@utradent.com

EC Responsible Person Ultradent Products GmbH Am Westhover Berg 30

Am Westhover Berg 30 51149 Cologne Germany

Email: infoDe@ultradent.com

Emergency Phone: +49(0)2203-35-92-0

• Further information obtainable from: Customer Service • Emergency telephone number:

CHEMTREC (NORTH AMERICA) : (800) 424-9300

(INTERNATIONAL): +(703) 527-3887

#### 2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.



Acute Tox. 4 H332 Harmful if inhaled.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

· Hazard pictograms GHS07, GHS09

(Contd. on page 2)

(Contd. of page 1)

# Safety data sheet according to 1907/2006/EC, Article 31

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

· Signal word Warning

· Hazard-determining components of labelling:

Synthetic Amorphous Silica

· Hazard statements

H332 Harmful if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

· Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

*P271 Use only outdoors or in a well-ventilated area.* 

*P273* Avoid release to the environment.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

*P391 Collect spillage.* 

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.

#### 3 Composition/information on ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components	Dangerous components:		
CAS: 1314-13-2 Zinc Oxide		<i>≤</i> 35%	
EINECS: 215-222-5	🕸 Aquatic Acute 1, H400; Aquatic Chronic 1, H410		
	Synthetic Amorphous Silica	≤20%	
EC number: 601-214-2	♦ Acute Tox. 3, H331		

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

#### 4 First aid measures

- · Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation:

This product is a thick paste, therefore inhalation is extremely unlikely.

Seek medical treatment in case of complaints.

- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

(Contd. on page 3)

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

(Contd. of page 2)

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

#### 5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

Water spray, fog, or mist, foam, dry chemical, carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters:
- · Protective equipment:

Wear fully protective suit.

Mouth respiratory protective device.

#### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Mount respiratory protective device.

· Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/surface or ground water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

#### 7 Handling and storage

- · Handling:
- Precautions for safe handling:

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

See product labelling.

Keep container tightly sealed.

· Specific end use(s) Professional Dental Temporary Cement

CD2

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

(Contd. of page 3)

#### 8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 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.
- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

· General Information

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eve protection: Goggles recommended during refilling

· Information on basic physical and chemical properties

· Body protection: Protective work clothing

#### 9 Physical and chemical properties

· Appearance:	
Form:	Paste
Colour:	Beige
· Odour:	Not applicable
· Odour threshold:	Not determined.
77 1	37 . 1. 11 /

Not applicable (	(non-aqueous)
	Not applicable (

· Change in condition Melting point/freezing point: Initial boiling point and boiling range:	Undetermined. Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.

(Contd. on page 5)

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

		(Contd. of page
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure:	Not determined.	
Density at 20 °C:	1.8-1.9 g/cm³	
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:		
VOC (EC)	0.00 %	
· Other information	No further relevant information available.	

### 10 Stability and reactivity

- · Reactivity Stable
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- · Conditions to avoid: No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

### 11 Toxicological information

- Information on toxicological effects
- · Acute toxicity

LD/LC50	) values relevant for classification	n:	
ATE (Ac	ute Toxicity Estimates)		
Inhalativ	e LC50/4 h	>2.85 mg/l	
1314-13-	2 Zinc Oxide		
Oral	LD50	7,950 mg/kg (mouse)	
		>5,000 mg/kg (rat)	
	LC50 Fish	>320 mg/l (Fish)	
Inhalativ	e LC50/4 h	>5.7 mg/l (mouse)	
	LC50(Daphnia magna) (static)	0.098 mg/l (daphnia)	
112926-0	00-8 Synthetic Amorphous Silica	1	
Oral	LD50	>5,000 mg/kg (rat)	

CD

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

		(Contd. of page 5)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.69 mg/l (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 Based on available data, the classification criteria are not met.
- · 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.

#### 12 Ecological information

- · Toxicity
- · Aquatic toxicity:

1314-13-2 Zinc Oxide

EC50 2.066 mg/kg (Fish)

- Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Very toxic for fish
- 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.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

#### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

HP14 Ecotoxic

(Contd. on page 7)

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

(Contd. of page 6)

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

Transport information		
UN-Number		
ADR, IMDG, IATA	not regulated	
UN proper shipping name ADR, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
ADR, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

### 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Seveso category El Hazardous to the Aquatic Environment
- $\cdot$  Qualifying quantity (tonnes) for the application of lower-tier requirements 100~t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

#### 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

H331 Toxic if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- · Department issuing SDS: Regulatory Affairs
- · Contact: Customer Service
- · 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

(Contd. on page 8)

Printing date 08.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Base

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)

VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 3: Acute toxicity - inhalation – Category 3 Acute Tox. 4: Acute toxicity - inhalation – Category 4

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

(Contd. of page 7)



Printing date 03.04.2020 Revision: 03.03.2020

#### 1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: UltraTemp™ Catalyst

· Article number: 81247

· Index number: SDS 22-001.13

· Relevant identified uses of the substance or mixture and uses advised against

Professional Dental Temporary Cement

· Application of the substance / the mixture Professional Dental Temporary Cement

Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@utradent.com

EC Responsible Person Ultradent Products GmbH

Am Westhover Berg 30

51149 Cologne Germany

Email: infoDe@ultradent.com

Emergency Phone: +49(0)2203-35-92-0

· Further information obtainable from: Customer Service

· Emergency telephone number:

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

#### 2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



GHS07

Acute Tox. 4 H332 Harmful if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard-determining components of labelling:

2-Methoxy-4-methylphenol

· Hazard statements

H332 Harmful if inhaled.

H317 May cause an allergic skin reaction.

(Contd. on page 2)

Printing date 03.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Catalyst

(Contd. of page 1)

#### · Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

*P312 Call a POISON CENTER/doctor if you feel unwell.* 

*P321* Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it 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.

#### 3 Composition/information on ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

#### Dangerous components:

Additional information: For the wording of the listed hazard phrases refer to section 16.

#### 4 First aid measures

- · Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation:

This product is a viscous gel, therefore chance of inhalation is extremely low.

Seek medical treatment 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.
- · After swallowing: If symptoms persist consult doctor.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Printing date 03.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Catalyst

(Contd. of page 2)

#### 5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

Water spray, fog, or mist, foam, dry chemical, carbon dioxide

*Use fire extinguishing methods suitable to surrounding conditions.* 

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters:
- · Protective equipment:

Wear fully protective suit.

Mouth respiratory protective device.

#### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

#### 7 Handling and storage

- · Handling:
- Precautions for safe handling:

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

See product labelling.

Keep container tightly sealed.

· Specific end use(s) Professional Dental Temporary Cement

#### 8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 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.

(Contd. on page 4)

*Printing date 03.04.2020 Revision: 03.03.2020* 

Trade name: UltraTemp™ Catalyst

(Contd. of page 3)

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Avoid contact with the eyes and skin.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:



#### Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye protection: Goggles recommended during refilling
- · Body protection: Protective work clothing

$\boldsymbol{n}$	7	1			
y P	I I A WAY PATIT			nroneri	I PUN

· Information on bas	ıc physical	and ch	ıemıcal	properties
----------------------	-------------	--------	---------	------------

- · General Information
- · Appearance:

Form: Gel
Colour: Clear

Odour: Not applicable
Odour threshold: Not determined.

· pH-value: Not applicable (non-aqueous)

· Change in condition

Melting point/freezing point: Undetermined. Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

Flammability (solid, gas): Not applicable.
 Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

(Contd. on page 5)

Printing date 03.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Catalyst

	(Contd. of pa
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
Density at 20 °C:	1.2-1.3 g/cm³
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:	
VOC (EC)	<i>≤</i> 1.00 %
· Other information	No further relevant information available.

#### 10 Stability and reactivity

- · Reactivity Stable
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- · Conditions to avoid: No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

#### 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity

Harmful if inhaled.

· LD/LC50	· LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)			
Oral	LD50	50,000 mg/kg	
Inhalative	LC50/4 h	1.99 mg/l (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.

(Contd. on page 6)

Printing date 03.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Catalyst

(Contd. of page 5)

- $\cdot \textbf{\textit{STOT-repeated exposure}} \ \textit{Based on available data, the classification criteria are not met.}$
- · Aspiration hazard Based on available data, the classification criteria are not met.

#### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

#### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

Transport information		
UN-Number ADR, IMDG, IATA	not regulated	
	noi reguiaca	
UN proper shipping name ADR, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
ADR, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

GB2

Printing date 03.04.2020 Revision: 03.03.2020

Trade name: UltraTemp™ Catalyst

(Contd. of page 6)

#### 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

#### 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

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

- · Department issuing SDS: Regulatory Affairs
- · Contact: Customer Service
- · 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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - oral - Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

GB2