

Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

## 1 Identification

- · Product identifier
- Trade name: SR Nexco Pontic Fill
- · Application of the substance / the mixture Light-curing labside composite
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

USA

Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada

Phone: +1 905 670 8499 Fax: +1 905 670 3102

- · Information department: Quality Assurance / Regulatory Affairs
- Emergency telephone number: 24 Hour Emergency Assistance:

Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

### 2 Hazard identification

· Classification of the substance or mixture

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labeling:

aromatic aliphatic urethane dimethacrylate 1,10-decandiol dimethacrylate urethane dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 2)

Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

# Trade name: SR Nexco Pontic Fill

(Contd. of page 1)

Wash contaminated clothing before reuse.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



0 Health = 0Fire = 0

### 3 Composition/Information on ingredients

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

· Dangerous components:					
CAS: 6701-13-9	1,10-decandiol dimethacrylate	3-5% w/w *			
CAS: 43048-08-4	tricyclodocane dimethanol dimethacrylate	1-<3% w/w *			
CAS: 72869-86-4	urethane dimethacrylate	1-<3% w/w *			

<sup>\*</sup> Actual concentration ranges are withheld as a trade secret.

# 4 First-aid measures

- · Description of first aid measures
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Rinse with water.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · 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.

#### 5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

## 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures Not required.

(Contd. on page 3)

Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

## Trade name: SR Nexco Pontic Fill

(Contd. of page 2)

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

Only adequately trained personnel should handle this product.

For use in dentistry only.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Protect from exposure to the light.

Protect from heat and direct sunlight.

Keep receptacle tightly sealed.

· Specific end use(s) No further relevant information available.

#### 8 Exposure controls/ Personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Keep away from foodstuffs, beverages and feed.

- · Breathing equipment: Not required.
- · 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 the 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 (Contd. on page 4)

Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

#### Trade name: SR Nexco Pontic Fill

(Contd. of page 3)

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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

9 Physical	and	chem	ııcal	pro	pert	ies

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· General Information

· Appearance:

Form: Pasty

Color: According to product specification

· Odor: Characteristic
· Odor threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not applicable.

· Auto igniting: Product is not selfigniting.

• **Danger of explosion:** Product does not present an explosion hazard.

· Explosion limits:

Lower:Not determined.Upper:Not determined.

· Vapor pressure: Not determined.

Density at 20 °C:
 Relative density
 Vapor density
 Evaporation rate
 1.56 g/cm³
 Not determined.
 Not determined.
 Not determined.

· Solubility in / Miscibility with

Water: Nearly insoluble.

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic:Not determined.Kinematic:Not determined.

• Other information No further relevant information available.

### 10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability

Photoreactive (Danger of polymerization).

Stable under normal handling and storage conditions.

(Contd. on page 5)

Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

#### Trade name: SR Nexco Pontic Fill

(Contd. of page 4)

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid

Protect from exposure to the light.

Keep away from heat and direct sunlight.

- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

### 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Specific symptoms in biological assay:
- · on the skin: No irritant effect.
- on the eye: No irritating effect.
- Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

CAS: 7631-86-9 silicon dioxide, chemically prepared

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

#### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- Behavior 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 2 (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.

- · 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:

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. on page 6)

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Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

Trade name: SR Nexco Pontic Fill

(Contd. of page 5)

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

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UN-Number DOT/TDG, ADR, ADN, IMDG, IATA	Void
UN proper shipping name DOT/TDG, ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
DOT, ADR, ADN, IMDG, IATA	
Class	Void
Packing group	
DOT/TDG, ADR, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II	of
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN "Model Regulation":	Void

# 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara

Suru			
Section 355 (extremely hazardous substances):			
None of the ingredients is listed.			
· Section 313 (Specific toxic chemical listings):			
None of the ingredients is listed.			
· TSCA (Toxic Substances Control Act):			
CAS: 6701-13-9	1,10-decandiol dimethacrylate		
CAS: 43048-08-4 tricyclodocane dimethanol dimethacrylate			

# GHS label elements

CAS: 72869-86-4 urethane dimethacrylate

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



· Signal word Warning

(Contd. on page 7)

Printing date 07/16/2021 Version number 3 Reviewed on 07/15/2021

Trade name: SR Nexco Pontic Fill

(Contd. of page 6)

#### · Hazard-determining components of labeling:

 $aromatic\ aliphatic\ ure than e\ dimethac rylate$ 

1,10-decandiol dimethacrylate urethane dimethacrylate

#### · Hazard statements

May cause an allergic skin reaction.

#### · Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

#### · National regulations:

#### Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## 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.

#### · Contact:

Date of the latest revision of the safety data sheet 07/16/2021 / 2

#### · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

\* Data compared to the previous version altered.

-CA