

SAFETY DATA SHEET

SOFRELINER TOUGH S-Paste

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name SOFRELINER TOUGH S-Paste

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 【Medical device】 Denture liner, a component of kit. For dental professionals only.

Uses Not Recommended Use only for intended applications.

1.3. Details of the supplier of the safety data sheet

Supplier Tokuyama Dental Italy S.r.l.
Via Chizzalunga, 1,
36066 Sandrigo, Vicenza, Italy
TEL: +39-0444-659650
FAX: +39-0444-750345

Contact person <http://www.tokuyama-dental.com/tdc/contact.html>

Manufacturer Tokuyama Dental Corporation
38-9, Taitou 1-chome, Taitou-ku, Tokyo
110-0016, Japan
TEL: +81-3-3835-2261
FAX: +81-3-3835-2265

1.4. Emergency telephone number

Emergency telephone Regional Medicines and Poisons Information Centre NI,
Pharmacy Department
Royal Hospital Suite, Grosvenor Road, Belfast
Emergency telephone: 844 892 0111
Telephone: +44 28 90 63 2032
Fax: +44 28 90 24 8030
E-mail address: nirdic.nirdic@belfasttrust.hscni.net

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Not Classified

Environmental hazards Not Classified

2.2. Label elements

Hazard statements NC Not Classified

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.
Endocrine disrupting properties: Not known.

SOFRELINER TOUGH S-Paste

SECTION 3: Composition/information on ingredients

3.2. Mixtures

DIMETHYL POLYSILOXANE (VINYL TERMINATED)	60-100%
CAS number: 68083-19-2	

Classification
Not Classified

SILICON DIOXIDE	10-30%
CAS number: 7631-86-9	EC number: 231-545-4

Classification
Not Classified

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
Inhalation	Move affected person to fresh air at once.
Ingestion	Try to induce vomiting. Get medical attention.
Skin contact	Wash skin thoroughly with soap and water.
Eye contact	Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

4.2. Most important symptoms and effects, both acute and delayed

General information	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	No specific recommendations.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with the following media: Foam. Carbon dioxide or dry powder.
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5.2. Special hazards arising from the substance or mixture

Specific hazards	When heated and in case of fire, irritating vapours/gases may be formed.
Hazardous combustion products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

5.3. Advice for firefighters

Protective actions during firefighting	Avoid breathing fire gases or vapours.
Special protective equipment for firefighters	Wear chemical protective suit.

SECTION 6: Accidental release measures

SOFRELINER TOUGH S-Paste

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions No specific recommendations.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation. Absorb in vermiculite, dry sand or earth and place into containers.

6.4. Reference to other sections

Reference to other sections For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions All handling should only take place in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in a cool, dark place (0-25°C, 32-77°F). Keep away from heat, sparks and open flame.

Storage class Chemical storage.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Ingredient comments No exposure limits known for ingredient(s).

8.2. Exposure controls

Appropriate engineering controls Provide adequate general and local exhaust ventilation.

Eye/face protection The following protection should be worn: Chemical splash goggles.

Hand protection Wear protective gloves.

Other skin and body protection Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures Do not smoke in work area. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

Respiratory protection No specific recommendations.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance Transparent paste

Colour Pink

Odour Not available.

SOFRELINER TOUGH S-Paste

Odour threshold	Not available.
pH	pH (concentrated solution): 7
Melting point	Not available.
Initial boiling point and range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Evaporation factor	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not applicable.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1.1
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not available.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity May polymerise.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions In contact with acids, alkalis or alcohols, generates hydrogen.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents. Acids. Alkalis. Alcohols.

10.6. Hazardous decomposition products

SOFRELINER TOUGH S-Paste

Hazardous decomposition products Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity - Ingestion

Calculation method : Not classified.

Acute toxicity - Skin Contact

Calculation method : Not classified. No data.

Acute toxicity - Inhalation

Calculation method : Not classified. No data.

Skin corrosion/irritation

Calculation method : Not classified.

Serious eye damage/irritation

Calculation method : Not classified.

Skin sensitization

Calculation method : Not classified.

Respiratory sensitization

Calculation method : Not classified.

Germ cell mutagenicity

Calculation method : Not classified.

Carcinogenicity

Calculation method : Not classified.

Reproductive toxicity

Calculation method : Not classified.

Lactation

Calculation method : Not classified.

STOT - single exposure

Calculation method : Not classified.

STOT - repeated exposure

Calculation method : Not classified.

Aspiration hazard Not classified.

Calculation method : Not classified. Not applicable.

11.2 Other information

Route(s) of entry Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2

Endocrine disrupting properties: Not known.

SECTION 12: Ecological Information

12.1 Toxicity

Toxicity - Aquatic invertebrates Not classified.

Toxicity - Fish Not classified.

Toxicity - Algae Not classified.

Toxicity - Sediment Compartment Not classified.

Toxicity - Terrestrial Compartment Not classified.

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12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6 Endocrine disrupting properties

Not known.

12.7 Other adverse effects

Not known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/ regional/ national/ international regulations. Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: Transport information

General

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

SOFRELINER TOUGH S-Paste

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation (EC) No 1907/2006 (REACH).
(EC) No 1272/2008 (CLP).
(EU) No 2015/830.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008 Not Classified for Physical: Based on available data the classification criteria are not met. Not Classified for Health: Based on available data the classification criteria are not met. Not Classified for Environmental: Data lacking.

Training advice Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

Revision comments

Revision date 15/12/2022

Revision 4

The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be relied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such information.

SAFETY DATA SHEET

SOFRELINER TOUGH Primer

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name SOFRELINER TOUGH Primer

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 【Medical device】 Denture Liner, a component of kit. For dental professionals only.

Uses Not Recommended Use only for intended applications.

1.3. Details of the supplier of the safety data sheet

Supplier

Tokuyama Dental Italy S.r.l.
Via Chizzalunga, 1,
36066 Sandrigo, Vicenza, Italy
TEL: +39-0444-659650
FAX: +39-0444-750345

Contact person

<http://www.tokuyama-dental.com/tdc/contact.html>

Manufacturer

Tokuyama Dental Corporation
38-9, Taitou 1-chome, Taitou-ku, Tokyo
110-0016, Japan
TEL: +81-3-3835-2261
FAX: +81-3-3835-2265

1.4. Emergency telephone number

Emergency telephone Regional Medicines and Poisons Information Centre NI,
Pharmacy Department
Royal Hospital Suite, Grosvenor Road, Belfast
Emergency telephone: 844 892 0111
Telephone: +44 28 90 63 2032
Fax: +44 28 90 24 8030
E-mail address: nirdic.nirdic@belfasttrust.hscni.net

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Flam. Liq. 2 - H225

Health hazards Eye Irrit. 2 - H319: STOT SE 3 - H336

Environmental hazards Not Classified

2.2. Label elements

Pictogram



Signal word

Danger

Hazard statements

H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

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Precautionary statements	<p>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P271 Use only outdoors or in a well-ventilated area.</p> <p>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P403+P235 Store in a well-ventilated place. Keep cool.</p> <p>P501 Dispose of contents/ container in accordance with local regulations.</p>
Supplemental label information	EUH066 Repeated exposure may cause skin dryness or cracking.
Contains	ETHYL ACETATE
Supplementary precautionary statements	<p>P240 Ground/ bond container and receiving equipment.</p> <p>P241 Use explosion-proof electrical equipment.</p> <p>P242 Use only non-sparking tools.</p> <p>P243 Take precautionary measures against static discharge.</p> <p>P261 Avoid breathing vapour/ spray.</p> <p>P264 Wash contaminated skin thoroughly after handling.</p> <p>P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.</p> <p>P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312 Call a POISON CENTER/ doctor if you feel unwell.</p> <p>P337+P313 If eye irritation persists: Get medical advice/ attention.</p> <p>P370+P378 In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish.</p> <p>P403+P233 Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405 Store locked up.</p>
2.3. Other hazards	<p>This product does not contain any substances classified as PBT or vPvB.</p> <p>Endocrine disrupting properties: Not known.</p>

SECTION 3: Composition/information on ingredients
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3.2. Mixtures

ETHYL ACETATE	60-100%
CAS number: 141-78-6	EC number: 205-500-4
Classification	
Flam. Liq. 2 - H225	
Eye Irrit. 2 - H319	
STOT SE 3 - H336	

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
Inhalation	Move affected person to fresh air at once.
Ingestion	Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if any discomfort continues.
Skin contact	Wash skin thoroughly with soap and water.

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Eye contact Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation Vapours may cause drowsiness and dizziness.

Skin contact Repeated exposure may cause skin dryness or cracking.

Eye contact May cause severe eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor No specific recommendations.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with the following media: Foam. Carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

Specific hazards Highly flammable liquid and vapour. Irritating gases or vapours.

Hazardous combustion products No known hazardous decomposition products.

5.3. Advice for firefighters

Protective actions during firefighting Avoid breathing fire gases or vapours.

Special protective equipment for firefighters Wear chemical protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions Avoid the spillage or runoff entering drains, sewers or watercourses.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation. Absorb in vermiculite, dry sand or earth and place into containers. Avoid the spillage or runoff entering drains, sewers or watercourses.

6.4. Reference to other sections

Reference to other sections For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions All handling should only take place in well-ventilated areas. Use explosion-proof electrical, ventilating and lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharges. Avoid contact with skin, eyes and clothing. Avoid breathing vapour/spray.

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Advice on general occupational hygiene Do not eat, drink or smoke when using this product. Wash promptly if skin becomes contaminated. Wash at the end of each work shift and before eating, smoking and using the toilet.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Keep away from heat, sparks and open flame. Store at temperatures between 0°C/32°F and 25°C/77°F.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

ETHYL ACETATE

Long-term exposure limit (8-hour TWA): WEL 200 ppm

Short-term exposure limit (15-minute): WEL 400 ppm

WEL = Workplace Exposure Limit

8.2. Exposure controls

Appropriate engineering controls Provide adequate general and local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.

Eye/face protection The following protection should be worn: Chemical splash goggles.

Hand protection Wear protective gloves.

Other skin and body protection Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures Do not eat, drink or smoke when using this product. Promptly remove any clothing that becomes contaminated. Wash promptly with soap and water if skin becomes contaminated. Wash at the end of each work shift and before eating, smoking and using the toilet. Use appropriate skin cream to prevent drying of skin.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Clear liquid
Colour	Colourless
Odour	Characteristic
Odour threshold	Not available.
pH	Not available.
Melting point	Not available.
Initial boiling point and range	77°C
Flash point	-4°C
Evaporation rate	Not available.
Evaporation factor	Not available.
Flammability (solid, gas)	Not available.

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Upper/lower flammability or explosive limits	Lower flammable/explosive limit: 2 % Upper flammable/explosive limit: 11.5 %
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	427°C
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not available.
<u>9.2. Other information</u>	
Other information	Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity There are no known reactivity hazards associated with this product. See the other subsections of this section for further details.

10.2. Chemical stability

Stability The product is highly flammable.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Not known.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame. Avoid exposure to high temperatures or direct sunlight.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity - Ingestion

Calculation method : Not classified.

Acute toxicity - Skin Contact

Calculation method : Not classified. No data.

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Acute toxicity - Inhalation

Calculation method : Not classified. No data.

Skin corrosion/irritation

Calculation method : Not classified.

Serious eye damage/irritation

Calculation method : Causes serious eye irritation.

Skin sensitization

Calculation method : Not classified.

Respiratory sensitization

Calculation method : Not classified.

Germ cell mutagenicity

Calculation method : Not classified.

Carcinogenicity

Calculation method : Not classified.

Reproductive toxicity

Calculation method : Not classified.

Lactation

Calculation method : Not classified.

STOT - single exposure

Calculation method : May cause drowsiness or dizziness.

STOT - repeated exposure

Calculation method : Not classified.

Aspiration hazard Not classified.

Calculation method : Not classified. Not applicable.

11.2 Other information

Route(s) of entry Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.

Endocrine disrupting properties: Not known.

SECTION 12: Ecological Information

Ecotoxicity No data on possible environmental effects have been found

12.1 Toxicity

Toxicity - Aquatic invertebrates Not classified.

Toxicity - Fish Not classified.

Toxicity - Algae Not classified.

Toxicity - Sediment Compartment Not classified.

Toxicity - Terrestrial Compartment Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

SOFRELINER TOUGH Primer

12.6 Endocrine disrupting properties

Not known.

12.7 Other adverse effects

Not known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/ regional/ national/ international regulations. Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: Transport information

14.1. UN number

UN No. (ADR/RID)	1133
UN No. (IMDG)	1133
UN No. (ICAO)	1133

14.2. UN proper shipping name

Proper shipping name (ADR/RID)	ADHESIVES
Proper shipping name (IMDG)	ADHESIVES
Proper shipping name (ICAO)	ADHESIVES
Proper shipping name (ADN)	ADHESIVES

14.3. Transport hazard class(es)

ADR/RID class	3
ADR/RID label	3
IMDG class	3
ICAO class/division	3

Transport labels



14.4. Packing group

ADR/RID packing group	II
IMDG packing group	II
ICAO packing group	II

14.5. Environmental hazards

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Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

EmS F-E, S-D

Emergency Action Code •3YE

Hazard Identification Number 33
(ADR/RID)

Tunnel restriction code (D/E)

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78
and the IBC Code

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation (EC) No 1907/2006 (REACH).
(EC) No 1272/2008 (CLP).
(EU) No 2015/830.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC) 1272/2008 Flam. Liq. 2 - H225: On basis of test data. Eye Irrit. 2 - H319: Calculation method. STOT SE 3 - H336: Calculation method.

Training advice Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

Revision comments

Revision date 15/12/2022

Revision 4

Hazard statements in full H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be relied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such information.