

SECTION 16: OTHER INFORMATION

Relevant R-phrases and/or H-statements (number and full text):

- R11: Highly flammable.
- R22: Harmful if swallowed.
- R34: Causes burns.
- R36/37/38: Irritating to eyes, respiratory system and skin.
- R36/38: Irritating to eyes and skin.
- R43: May cause sensitization by skin contact.
- R50: Very toxic to aquatic organisms.
- Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4
- Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
- Aquatic Acute, Cat. 1: Acute Hazards to the Aquatic Environment, Category 1
- Aquatic Chronic, Cat. 1: Chronic Hazards to the Aquatic Environment, Category 1
- Eye Irr., Cat. 2B: Eye Irritation, Category 2B
- Eye Irr., Cat. 2: Eye Irritation, Category 2
- Flam. Liq., Cat. 2: Flammable Liquids, Category 2
- STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
- Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
- Skin Irr., Cat. 2: Skin Irritation, Category 2
- Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
- H225: Highly flammable liquid and vapour.
- H227: Combustible liquid.
- H302: Harmful if swallowed.
- H312: Harmful in contact with skin.
- H317: May cause an allergic skin reaction.
- H319: Causes serious eye irritation.
- H410: Very toxic to aquatic life with long lasting effects.

Prepared by: Peter G. Jordan

Revision summary: This SDS replaces the 12/22/2015 SDS. Revised: Section 1: MSDS No. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 5: EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. Section 8: . Section 11: ACUTE (DERMAL LD50 (rabbit), DERMAL LD50 (rabbit), DERMAL LD50 (rabbit), ORAL LD50 (rat), INHALATION LC50 (rat), ORAL LD50 (rat), ORAL LD50 (rat), INHALATION LC50 (rat), INHALATION LC50 (rat), ORAL LD50 (rat), ACUTE, GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC50, 96-HOUR EC50), SECTION 12: Ecological information. Section 14: VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. Section 15: GENERAL COMMENTS, RoHS. Section 16: GENERAL STATEMENTS.

General statements: NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permissible exposure limits
 MAK = Maximum Workplace Concentration
 STEL = Short-term exposure limit
 STEV = Short-term exposure value
 TWA = Time Weighted Average
 PPE = Personal Protective Equipment

Manufacturer disclaimer: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

WARRANTY: Clinician's Choice® Dental Products Inc. will replace MPa Max, free of charge, if proven to be defective and when stored according to the manufacturer's specifications. Clinician's Choice Dental Products Inc. does not accept liability for any loss or damage, direct or consequential, arising out of the use of or the inability to use this product. Before using, the user shall determine the suitability of the product(s) for its intended use and the user assumes all risk and liability whatsoever in connection therewith.

CAUTION: U.S. Federal law restricts this device to sale by, or on the order of, a dentist.

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DESCRIPTION:
 MPa Max is a bottle delivered bonding resin. It can be used with a total-etch technique. It is 7.5% filled with an ethyl alcohol solvent carrier and will cure with most high intensity lights including LEDs. MPa Max contains 0.2% chlorhexidine which may ensure long term bond strengths.

INDICATIONS FOR USE:
 Use for all bonding needs in restorative dentistry. Use MPa Max in conjunction with Max Etch, bonds to the following materials:
 • Dentin and enamel
 • Porcelain (Hydrofluoric acid and silane required)
 • Zirconia
 • Metal
 • Composite

INSTRUCTIONS FOR USE

DIRECT BONDING TECHNIQUE AND PORCELAIN/ ZIRCONIA REPAIR

- 1. PREPARE:**
 a. **Dentin/Enamel:** Isolate, clean and remove caries ensuring all non-mineral dentin is removed For abrasion/abfraction Class V preps, roughen with a diamond bur.
 b. **Composite:** Remove weakened areas of existing composite. Roughen surface with diamond bur.
 c. **Metal:** Microabrade surface.
 d. **Zirconia:** Clean surface and remove weakened zirconia with a diamond bur.
 e. **Porcelain:** Roughen and remove weakened porcelain with diamond bur. Clean fractured porcelain area for 5 seconds with Max Etch. Rinse and dry.

- 2. ETCH:**
 a. **Total-Etch Technique – dentin/enamel, composite and metal**
 i. Apply Max Etch to all surfaces of the tooth preparation for 20 seconds.
 ii. Rinse thoroughly for 5 seconds.
 iii. Lightly dry using the air/water syringe or by placing the high volume suction directly over the preparation. Leave the surface slightly damp.
 iv. Proceed to "Bond" step below.
 b. **Porcelain Etch – CAUTION – use proper isolation such as an acid neutralizing barrier when using hydrofluoric acid (HF). Do not allow hydrofluoric acid to touch gingiva or dentin.**
 i. Apply hydrofluoric acid to fractured area for 90 seconds.
 ii. Suction acid from surface THEN thoroughly rinse and dry.
 iii. Apply Max Etch for 5 seconds to remove porcelain salts and debris formed by HF etching. Rinse and dry.
 iv. Apply puddle coat of silane for 60 seconds.
 v. Dry thoroughly. DO NOT RINSE.
 vi. Proceed to "Bond" step below.
 c. **Zirconia – DO NOT ETCH OR USE SILANE**
 i. Air-abrade fractured surface of prosthesis, rinse and dry.
 ii. Apply zirconia primer to fractured area following manufacturer's instructions.
 iii. Proceed to "Bond" step below.

- 3. BOND:**
 a. Dispense 1-3 drops of MPa Max into the "B" side of the disposable dappen dish.
 b. Using the Micro Applicator Brush, apply a puddle coat of MPa Max to the preparation and gently agitate for 10 seconds.
 c. Thin/dry for 10 seconds using ¼ to ½ air pressure. Preparation should appear shiny.
 d. Light-cure for 10 seconds (20 seconds for lights with output<600mW/cm2).
 e. Restore with flowable or packable composite as per manufacturer's instructions.

**INDIRECT BONDING TECHNIQUE
INDIRECT CROWNS, INLAYS, ONLAYS, VENEERS, ZIRCONIA**

- 1. PREPARE:**
 a. Remove temporary, clean preparation, rinse, and dry.
 b. Verify prosthetic fit.
 c. Prepare inside surface of prosthesis.
 i. **Metal based:**
 1. Microabrade (sandblast) inside surface of prosthesis.
 2. Rinse and dry surface.
 ii. **Ceramic/porcelain:**
 1. Apply hydrofluoric acid (HF) to inside surface of prosthesis per manufacturer's directions, rinse and dry.
 2. Apply Max Etch for 5 seconds to remove porcelain salts and debris formed by HF etching. Rinse and dry.
 3. Apply silane to inside surface of prosthesis for 1 minute, dry and set prosthesis aside. Do not rinse.
 iii. **Zirconia: DO NOT ETCH OR USE SILANE**
 1. Air abrade internal surface of prosthesis, rinse and dry.
 2. Apply a zirconia primer as per manufacturer instructions.

- 2. ETCH – Prepare tooth surface:**
 a. **Total-Etch Technique – dentin/enamel, composite and metal.**
 i. Apply Max Etch to all surfaces of the tooth preparation for 20 seconds.
 ii. Rinse thoroughly for 5 seconds.
 iii. Lightly dry using the air/water syringe or by placing the high volume suction directly over the preparation. Leave the surface slightly damp.
 iv. Proceed to "Bond" step below.
 b. **Porcelain Etch – CAUTION – use proper isolation such as an acid neutralizing barrier when using hydrofluoric acid (HF). Do not allow hydrofluoric acid to touch gingiva or dentin.**
 i. Apply hydrofluoric acid to fractured area per manufacturer's instructions.
 ii. Suction acid from surface THEN thoroughly rinse and dry.
 iii. Apply Max Etch for 5 seconds to remove porcelain salts and debris formed by HF etching. Rinse and dry.
 iv. Apply puddle coat of silane for 60 seconds.
 v. Dry thoroughly. DO NOT RINSE.
 vi. Proceed to "Bond" step below.
 c. **Zirconia – DO NOT ETCH OR USE SILANE**
 i. Air-abrade internal surface of prosthesis, rinse and dry.
 ii. Apply zirconia primer to fractured area following manufacturer's instructions.
 iii. Proceed to "Bond" step below.

- 3. BOND**
 a. Dispense 1-3 drops of MPa Max into the "B" side of the disposable dappen dish.
 b. Using the Micro Applicator Brush, apply a puddle coat of MPa Max to the preparation and gently agitate for 10 seconds.
 c. Thin/dry for 10 seconds using ¼ to ½ air pressure. Preparation should appear shiny.
 d. Light-cure for 10 seconds (20 seconds for lights with output<600mW/cm2).

4. CEMENT:
 a. Apply light-cure cement for translucent veneers or dual-cure resin cement to other prostheses and follow manufacturer's instructions for use.

NOTE: Immediate Dentin Sealing requires Direct Technique steps 2a and 3 at left. Apply glycerin over MPa Max and light-cure 10 seconds. Rinse glycerin. Make final impression. Re-apply glycerin to preparation as a separating medium prior to cementing the temporary in place.

POST AND CORE

- 1. PREPARE:**
 a. Drill post hole using a rubber stop and appropriate size Macro-Lock Illusion XRO drill.
 b. Thoroughly rinse the post space for 10 seconds and dry from the bottom of the preparation up.
 c. Verify post (Macro-Lock Illusion X-RO) fit and cut to desired length using a high speed diamond disc. **NOTE:** Carbide and operative burs may fray the fibers.
2. ETCH:
 a. **Total-Etch Technique:**
 i. Attach a tip to the Max Etch syringe.
 ii. Start apically and fill post space coronally. Apply to coronal preparation. Etch for 20 seconds.
 iii. Suction off excess etchant.
 iv. Rinse thoroughly and lightly air dry, leaving the post space slightly damp.
 v. Proceed to "Bond" step below.

- 3. BOND:**
 a. Dispense 1-3 drops of MPa Max into the "B" side of the disposable dappen dish.
 b. Apply MPa Max to the post space and gently agitate the full length of the canal and tooth preparation for 10 seconds.
 c. Thoroughly remove excess.
 d. Thin/dry the outer preparation for 10 seconds using ¼ to ½ air pressure. Preparation should appear shiny. Remove excess MPa Max in the depths of the canal with a paper point.
 e. Light-cure down the post space for 20 seconds (40 seconds for lights with output <600mW/cm2).

POST CEMENTATION AND CORE BUILD-UP

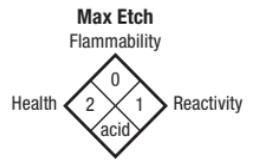
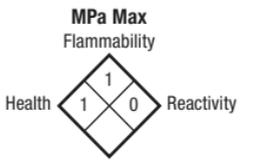
1. Remove cap from the Zircules cartridge.
2. Place a mixing tip onto the dual barrel cartridge lining up the two ports. Twist clockwise until locked in place.
3. Attach the flexible intraoral tip to the mixing tip for delivery directly into the canal from the cartridge.
4. Express a small amount before placing in the post space.
5. Insert the tip into the post space to full depth.
6. Using even pressure deliver Zircules starting apically and moving coronally.

7. **Immediately** insert the post (Macro-Lock Illusion X-RO) slowly, displacing the excess cement.
8. Place curing light directly above the post and light-cure 20 seconds to stabilize the post; 40 seconds for lights with output <600mW/cm2) (Zircules self-cures in 3:30 minutes).
9. Continue building layers of Zircules around post as needed. **NOTE:** Light-cure for 20 seconds per layer to gel and form core. Do a final cure on core for 40 seconds.

Do not remove mixing tip until next use. Disinfect syringe and mixing tip.

PRECAUTIONS AND WARNINGS:

1. Carefully read and understand all instructions before using MPa Max.
2. For professional use only.
3. Re-cap immediately following use to avoid polymerization.
4. Always verify material flow of syringe materials prior to applying intraorally. If resistance is met, replace tip and re-check.
5. Keep caps on the bottle until use.
6. Clinician and patient should wear UV protective eyewear when curing resin materials.
7. If not used daily, refrigerate product.
8. Bring refrigerated products to room temperature before using.
9. To optimize bond strengths use oil-free and moisture-free air.
10. Redirect overhead light to prevent premature polymerization of all resin based materials.
11. Resins can be sensitizing. Avoid repeated contact of uncured dental resin with skin. Do not use on patients with a known sensitivity to acrylates or other resins. If allergic reaction, dermatitis or rash develops, consult a physician.
12. Dispose of tips, empty syringes and bottles properly.
13. Keep out of reach of children.
14. Do not use after expiration date noted on containers.
15. Re-cap, disinfect and wipe syringe with an intermediate level disinfectant between uses. If disposable syringe cover is used, remove tip, re-cap, and discard syringe cover.
16. Tips are disposable. To avoid cross-contamination, do not re-use tips.
17. Keep products out of direct heat/sunlight.
18. Isolate strong chemicals to area of treatment.



HAZARD RATING

- 4 = Severe
- 3 = Serious
- 2 = Moderate
- 1 = Slight
- 0 = Minimal



MPa™ Max
Maximum Performance Adhesive

1.800.265.3444

519.641.3066

www.clinicianschoice.com

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER

Product name: MPa Max Maximum Performance Adhesive

Product description: Light-Cured Adhesive With Chlorhexidine (0.2%)

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Relevant identified uses: Professional Dental Adhesive

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Manufacturer

Clinician's Choice Dental Products, Inc

167 Central Avenue, London, ON, Canada, N6A 1M6

1.800.265.3444

519.641.3066

info@clinicianschoice.com

1.4 EMERGENCY TELEPHONE NUMBER

1.800.265.3444

519.641.3066

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Directive 1999/45/EC: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Danger symbols: F, Xi

R phrases: R36/38, R43, R11

Classification according to Regulation (EC) No 1272/2008 [CLP]

Health:

Eye Irritation, Category 2

Skin Irritation, Category 2

Target Organ Toxicity (Single exposure), Category 3

Acute Toxicity (Inhalation), Category 4

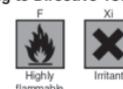
Skin Sensitization, Category 1B

Physical: Flammable Liquids, Category 2

2.2 LABEL ELEMENTS

Classification according to Directive 1999/45/EC

Hazard pictogram(s):



R& statement(s): R36/38: Irritating to eyes and skin.

R43: May cause sensitization by skin contact.

R11: Highly flammable.

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram(s):



Signal Word: DANGER

Hazard statement(s): H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

H225: Highly flammable liquid and vapour.

Precautionary statement(s)

Prevention: P280: Wear protective gloves/protective clothing/eye protection/face protection.

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Response: P305: IF IN EYES:

P351: Rinse cautiously with water for several minutes.

P337+P313: If eye irritation persists: Get medical advice/attention.

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

P332+P313: If skin irritation occurs: Get medical advice/attention.

P301: IF SWALLOWED:

P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330: Rinse mouth.

P331: Do NOT induce vomiting.

P304: IF INHALED:

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Storage: P273: Avoid release to the environment.

Disposal: P501: Dispose of in compliance with governmental regulation.

(EC)1975L0442-20/11/2003)

2.3 OTHER HAZARDS

Conclusion: The substance does not fulfill the vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Not applicable

3.2 MIXTURES

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl alcohol	64-17-5	200-578-6	< 20	F,R11	Flam. Liq., Cat. 2; Eye Irr., Cat 2; Skin Irr., Cat. 2; STOT SE, Cat. 3; H225; H319
2-hydroxyethyl Methacrylate	868-77-9	212-782-2	≤ 16	Xi; R43;R36/38	Eye Irr., Cat. 2B; Skin Sens., Cat. 1B; H317; H319
Methacrylic Acid	79-41-4	201-204-4	≤ 6	C; R34	Skin Corr., Cat. 1A; Acute Tox. (O), Cat. 4; Acute Tox. (D), Cat. 4; H302; H312; H227
Chlorhexidine di(acetate)	56-95-1	200-302-4	< 0.3	Xn; R22: R36/37/38;R50	Acute Tox. (O), Cat. 4; Aquatic Acute, Cat. 1; Aquatic Chronic, Cat. 1; H302; H410

(Full text of R-Phrases can be found under heading 16)

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

Following eyes: Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

Following skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion: If swallowed, rinse mouth with water. Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.

Following inhalation: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Eyes: Irritating to eyes.

Skin: May cause skin irritation and sensitization.

Ingestion: May be harmful if swallowed.

Inhalation: Maybe harmful if inhaled.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Notes to physician: Irritating to eyes and skin.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Extinguishing media: Foam, dry chemical, carbon dioxide (CO2).

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Explosion hazards: Keep away from heat, sparks, and flames.

5.3 ADVICE FOR FIRE FIGHTERS

Firefighting procedures: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

General procedures: Refer to Section 8 for Personal Protective Equipment.

6.2 ENVIRONMENTAL PRECAUTIONS

Water spill: Do not allow to enter sewers or drains that may lead to waterways.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Small Spill: Absorb liquid and place in sealed container for disposal. Vapors can travel to an ignition source.

Large Spill: Absorb with inert, damp non-combustible material, then flush area with water.

6.4 REFERENCE TO OTHER SECTIONS

Reference to Other Sections: Not applicable

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Handling: Keep away from heat, sparks and flame

Storage: See product labeling.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Shelf Life: See product labelling

7.3 SPECIFIC END USE(S)

Specific end use(s): Professional Dental Adhesive

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Control parameters: HEMA CAS: 868-77-9

Control Parameters	Exposure Limits
TLV	Not Established
MAK	Sensitization of skin (Sh); DFG 2008

Methacrylic Acid CAS:79-41-4

Control Parameters	Exposure Limits
NIOSH REL	TWA 20 ppm (70 mg/m3) [skin]
OSHA PEL	none
ACGIH TLV	20 ppm; 70 mg/m3 TWA

Aluminum Oxide (Respirable Fraction & Total Dust) CAS: 1344-28-1

Control Parameters	Exposure Limits
OSHA PEL General Industry	5mg/m3
OSHA PEL - Maritime	5mg/m3
ACGIH TLV	1mg/m3 TWA; Respirable fraction
NIOSH REL	Substances With No Established RELs

Ethyl Alcohol CAS: 64-17-5

Control Parameters	Exposure Limits
OSHA PEL General Industry	1000 ppm (1900 mg/m3) TWA
OSHA PEL - Construction Industry	1000 ppm (900 mg/m3) TWA
OSHA PEL Shipyard Employment	1000 ppm (1900 mg/m3) TWA
NIOSH REL	1000 ppm (1900 mg/m3) TWA
ACGIH TLV	1000 ppm (1880 mg/m3) STEL
CAL/OSHA PEL	1000 ppm (1900 mg/m3) TWA

8.2 EXPOSURE CONTROLS

Eye/face protection: Wear eye protection

Skin protection: Wear suitable protective clothing and gloves.

Respiratory protection: Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON THE BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Appearance: Light yellow opaque resin.

Odor: Acrylic, pungent

Flash point: < 27°C

9.2 OTHER INFORMATION

Percent volatile: Not determined

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Reactivity: Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

10.2 CHEMICAL STABILITY

Chemical stability: Stable when stored and handled under recommended conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Hazardous polymerization: None

10.4 CONDITIONS TO AVOID

Conditions to avoid: Heat, flames, ignition sources, direct light.

10.5 INCOMPATIBLE MATERIALS

Incompatible materials: Ignition sources

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute

Dermal LD50: > 2100 mg/kg (rabbit/rat)

Notes: ~61% of the mixture consists of components of unknown toxicity (dermal).

Oral LD50: > 4000 mg/kg rat/mouse

Notes: ~37% of the mixture consists of components of unknown toxicity (oral)

Inhalation LC50: > 11.0 mg/L/4H Vapor Rat

Notes: ~54% of the mixture consists of components of unknown toxicity (inhalation)

Other information: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

12.2 PERSISTENCE AND DEGRADABILITY

Persistence and degradability: Not classified

12.3 BIO ACCUMULATIVE POTENTIAL

Bio accumulative potential: Not classified

12.4 MOBILITY IN SOIL

Mobility in soil: Not Available

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

Results of PBT and vPvB assessment: Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6 ENVIRONMENTAL DATA

Environmental Data: Harmful to aquatic life with long lasting effects.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

Disposal method: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

SECTION 14: TRANSPORT INFORMATION

14.1 UN NUMBER

UN Number: 1987

14.2 UN PROPER SHIPPING NAME

UN Proper Shipping Name: Alcohols, n.o.s. (Ethyl alcohol mixture)

14.3 TRANSPORT HAZARD CLASS(ES)

Primary hazard class/division: 3

Hazard classification: 3

14.4 PACKING GROUP

Packing Group: III

14.5 ENVIRONMENTAL HAZARDS

Marine Pollutant #1: NAP

14.6 SPECIAL PRECAUTIONS FOR USER

ADR - road: NAP

RID - rail: NAP

IMDG - sea: NAP

IATA - air: NAP

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OR MARPOL73/78 AND THE IBC CODE

Transport in bulk: NAP

SECTION 15: REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

General comments: Please refer to Medical Devices Directive 93/42/EEC.

15.2 CHEMICAL SAFETY ASSESSMENT

Chemical safety assessment: See Section 11

15.3 US STATE REGULATIONS

California Proposition 65: This product does not contain any chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.