

CAUTION: US Federal Law restricts this device to use or sale by order of a licensed professional.

Mucosoft®

Instructions for use

Not for relining nylon-based “flexible” denture materials, e.g., Flexite®, Valplast®, etc.

Store in refrigerator for longest shelf life. Use at room temperature for best results.

DESCRIPTION:

Mucosoft® is an easy-to-apply, chairside, self-curing silicone for use as a long-term soft lining material. It is taste-free, odorless, and translucent pink to complement the shade of an existing full or partial denture base.

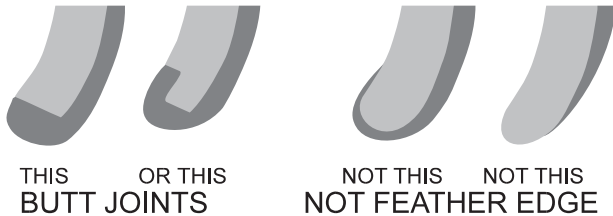
INDICATIONS:

Mucosoft® is recommended for use where retentive undercuts in edentulous ridges cause patient discomfort; where bony projections from edentulous ridges create recurring sore spots and tissue tenderness; where denture-supporting soft tissues are tender and hard denture bases cause patient discomfort, or wherever a patient might benefit from the cushioning effect of a soft silicone liner.

DIRECTIONS:

1) With a suitable acrylic bur, remove at least 1mm of hard denture base from the tissue side of the appliance. **To provide adequate space and avoid debonding or material failure, it is important to create a minimum of 1mm of relief. Anywhere from 1-3mm is suggested.**

2) The periphery of the appliance should also be shortened to permit at least 2mm of Mucosoft® to roll over the denture's borders.



Cut the acrylic border so it will form a butt-joint with the reline material. Feather-edge joints will encourage debonding.

3) Using the pipette, dispense Mucosoft® Bonding Liner into a dappen dish. Using a disposable brush, apply a thin, even layer onto all prepared, dry surfaces of the denture and let it air dry for about 2 minutes. **Only use Bonding Liner extra-orally in well-ventilated areas.**

4) Remove sealing cap from Mucosoft® cartridge and discard. **Before affixing a mixing tip, dispense about 1/4 inch of base and catalyst onto a pad to make certain that material flows freely and equally from both openings.** Attach a mixing tip and express auto-mixed Mucosoft® across the entire adhesive-treated area. To minimize air bubbles, it is suggested that you start at the posterior border, and fill the denture with a continuous overlapping, back-and-forth pattern. If necessary, a cement spatula (or similar) may be used to spread the silicone more evenly over the borders. **Be sure to cover all adhesive-treated areas with silicone. Avoid latex glove contamination that can interfere with the silicone setting reaction.** Leave used mixing tip in place as cartridge-sealer between uses.

5) Have the patient rinse with mouthwash to reduce excess saliva before seating the appliance. **When inserting the silicone-filled appliance, use appropriate technique to avoid air entrapment and direct excess material away from the throat.** Confirm proper seating of the appliance and remove any excess material.

6) Guide the patient into centric at proper vertical. Manipulate cheeks to border mold the material. Have the patient hold in centric until silicone has completely set (at least 5 minutes in the mouth). If necessary the patient may open to allow removal of excess material or evacuation, but should return to centric afterward.

7) Remove the appliance and carefully trim away excess silicone with scissors, a sharp scalpel, a single-edge razor blade or suitable burs or trimmers. Avoid leaving any loose silicone material on the denture. **Do not over-trim at the silicone/acrylic margins.**

8) Mix equal parts of A and B Mucosoft® Glaze and apply mixture to the cut surfaces of the reline with a disposable brush. Allow it to set completely, about 2 to 3 minutes @ room temperature followed by at least 1 minute in hot water, to impart a smooth, polished finish. **Do not disturb the glaze before complete set.**

Mucosoft® Glaze is not intended to smooth rough edges and surfaces. This should be accomplished with suitable instruments before glazing.

WARNINGS:

Not for internal use. Avoid swallowing. Although non-toxic, aspirated silicone materials can be harmful. Avoid contact with eyes. Seek medical advice if either should occur.

Not for use on or by individuals who are sensitive to silicone products. If signs of silicone sensitivity should develop, use of the Mucosoft® relined appliance should be discontinued.

PRECAUTIONS:

Patient must be warned of the critical importance of maintaining cleanliness of appliance to prevent fungal contamination. Bleach soaks are not indicated.

If a Mucosoft® reline shows signs of separating, cracking, loosening or other damage, it should not be worn. Repair should be made as soon as possible to avoid aspirating fragments of silicone.

REPAIRS:

Silicone reline materials will not adhere to each other. If a repair is needed, the entire soft reline must be replaced.

SUPPLIED AS:

50ml split (1:1) cartridge + mixing tips
15ml bonding liner + dispensing pipettes
6ml A & 6ml B glaze (total 12ml)
Disposable applicator brushes for bonding liner and/or glaze

WARRANTY:

Parkell will replace defective material. **This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described.

Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.

European Authorized Representative: (Not a dealer/distributor)
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MATERIAL SAFETY DATA SHEET	PARKELL, INC. 300 EXECUTIVE DRIVE EDGEWOOD, NY 11717 Phone: 631-249-1134, Fax: 631-249-1242	24-HOUR EMERGENCY TELEPHONE 1-800-535-5053
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SECTION I - PRODUCT IDENTIFICATION

PRODUCT NAME:	Mucosoft™ Adhesive Agent	STOCK NO:	S494	
DOT HAZARD LABEL		UN NUMBER:	UN1247,	UN1593
DOT/UN SHIPPING NAME:	Dichloromethane; Methyl Methacrylate monomer, inhibited	DATE PREPARED:	05/01/09	
NFPA CODES:	HEALTH - 2	FLAMMABILITY - 3	REACTIVITY - 3	

SECTION II - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

HAZARDOUS COMPONENTS	CAS NUMBER	PEL	TLV	%
Proprietary Compound	NA	ND	ND	
Methyl Methacrylate	80-62-6	100 ppm	100 ppm	
Methylene Chloride	75-09-2	25 ppm	50 ppm	

SECTION III - PHYSICAL & CHEMICAL CHARACTERISTICS

BOILING POINT:	Proprietary Compound	Methyl Methacrylate	Methylene Chloride
SPECIFIC GRAVITY	NA	100°C (212°F)	39.75°C (103.5°F)
VAPOR PRESSURE	0.952	0.936	1.3266
VAPOR DENSITY (Air = 1):	NA	29MM Hg (20°C)	349mm Hg (20°C)
APPEARANCE AND ODOR:	>1	3.45	2.93
	Clear Liquid	Liquid	Liquid

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (TCC):	Proprietary Compound	Methyl Methacrylate	Methylene Chloride
AUTOIGNITION TEMP.:	>110°C (>230°F)	55.4°C (13°F)	ND
UPPER FLAMMABLE LIMIT IN AIR:	ND	421°C (789.8°F)	556°C (1033°F)
LOWER FLAMMABLE LIMIT IN AIR:	ND	2.1%	12%
EXTINGUISHER MEDIA:	ND	12.5%	23%

Use water spray, fog, dry chemical, carbon dioxide or foam. Wear self-contained breathing apparatus, and full protective gear. Use water spray to cool containers.

EXPLOSION HAZARD: Fight fire from protected location.

SECTION V - REACTIVITY DATA (PHYSICAL HAZARDS)

STABILITY: ☒ STABLE ☐ UNSTABLE

CONDITIONS TO AVOID: Heat and ignition sources, moisture, aging and contamination.

INCOMPATIBILITY (Materials to avoid): Avoid contact with acids, alkalis, oxidizing agents and chemically active metals.

HAZARDOUS DECOMPOSITION PRODUCTS: None under normal conditions; oxides of carbon, phosgene gas and hydrochloric acid when burned.

HAZARDOUS POLYMERIZATION: ☐ MAY OCCUR ☒ WILL NOT OCCUR

SECTION VI - HEALTH HAZARD DATA

PRIMARY ROUTE(S) OF ENTRY ☒ EYES ☒ SKIN ☒ INHALATION ☒ INGESTION

HEALTH HAZARDS (Acute & Chronic): Over exposure from liquid or high vapor concentrations can irritate eyes, respiratory system and cause skin rashes. Prolonged exposure can lead to headaches, nausea, drowsiness, and unconsciousness.

SIGNS & SYMPTOMS OF EXPOSURE: Irritation of eyes and respiratory system, skin rash, headaches, nausea, drowsiness, coughing, chest pain, and unconsciousness.

CARCINOGENECITY: Methylene Chloride is Classified by OSHA/NIOSH and Classified 2B by IARC. Cytotoxicity tests on the proprietary compound were negative.

EMERGENCY AND FIRST AID PROCEDURES:

INHALATION: Remove individual to fresh air. If discomfort persists, seek immediate medical attention.

EYES: Flush with water for 15 minutes, including under eyelids. Seek medical attention.

SKIN: Wash with soap and water.

INGESTION: Induce vomiting. Seek immediate medical attention.

SECTION VII - SPECIAL PRECAUTIONS AND SPILL OR LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING & STORAGE: Keep in a cool, well-ventilated place, away from heat and sources of ignition. Ground all equipment containing material. In case of insufficient ventilation, wear suitable respiratory equipment. Keep away from incompatibles.

OTHER PRECAUTIONS: NA

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Dilute with water and mop up, or absorb with an insert dry material and place in an appropriate waste disposal container. Stop leak if without risk. Do not touch spilled material. Prevent entry into sewers, basements or confined areas. Dike, if needed.

WASTE DISPOSAL METHODS (Consult federal, state, and local regulations): Waste should be handled as hazardous waste and sent to an RCRA approved incinerator or disposed in an RCRA approved waste facility. Dispose of container and unused contents in accordance with federal, state and local requirements.

SECTION VII - SPECIAL PROTECTION INFORMATION/CONTROL MEASURES

RESPIRATORY PROTECTION: Use self-contained breathing apparatus when needed.

VENTILATION: Use local ventilation with a minimum capture velocity of 100 ft./min. (20m/min.) at point of adhesive release.

PROTECTIVE GLOVES: Impervious.

EYE PROTECTION: Safety glasses or goggles.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Provide eyewash station.

WORK/HYGIENIC PRACTICES: Wash hands before eating, drinking or smoking.

For additional non-emergency health, safety, or environmental information, telephone (800) 243-7446, or write to: Manager, Quality Assurance and Regulatory Affairs, Parkell Inc., 300 Executive Drive, P.O. Box 9004, Edgewood, NY 11717. The information contained herein is based on the data available to us and is believed to be correct. However, Parkell makes no warranty, express or implied, regarding the accuracy of these data or the results to be obtained from the use thereof. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances.