

## SECTION 15: REGULATORY INFORMATION

**15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:** No further relevant information available.

**15.2 CHEMICAL SAFETY ASSESSMENT:** A Chemical Safety Assessment has not been carried out.

## SECTION 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:

H304 May be fatal if swallowed and enters airways.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H411 Toxic to aquatic life with long lasting effects.

R20 Harmful by inhalation.

R36 Irritating to eyes.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R65 Harmful: may cause lung damage if swallowed.

R66 Repeated exposure may cause skin dryness or cracking.

**Prepared by:** Peter G. Jordan

### 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 Harmonized 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)

Acute Tox. 4: Acute toxicity, Hazard Category 4

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Asp. Tox. 1: Aspiration hazard, Hazard Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment – Chronic Hazard, Category 2



### Indication for Use

A vinyl poly siloxane material intended to be used as a medical device for the purpose of creating, via impression, a reproduction of tooth and gum structure.

### Description of Material

COUNTER-FIT™ Quick Set is an addition-vulcanising impression silicone especially for situation impressions. A short setting time in the mouth, easily removed from the mouth, unlimited shelf life of the impressions, and a highly detailed reproduction make COUNTER-FIT Quick Set an advantageous alternative to alginates.

### Technical Data According to DIN EN ISO 4823

Consistency: medium viscosity - type 2

Maximum Working Time: 1:00 min (+/- 15 sec)

Minimum Intraoral Set Time at 37°: 1:30 min (+/- 30 sec)

Total Set Time: 2:30 minutes

Deformation Under Pressure: 10.5 (+/- 0.5%)

Recovery From Deformation: >99.9%

Linear Change of Measures: <0.2%

Final Hardness: 40 Shore A

The mixing and processing times refer to a room temperature of 23°C/73°F and a relative air humidity of 50%. Lower temperatures prolong, higher temperatures shorten these times.

## INSTRUCTIONS FOR USE

### MegaMix Cartridges (380ml)

Carefully remove the 380ml cartridge from the package.

NOTE: The cartridges are heavy and accidental dropping may result in damage to the cartridge rendering it unusable.

### MegaMix Cartridge Loading

Also refer to the instructions provided by the manufacturer of your dynamic mixer.

1. Firmly hold and support the full MegaMix cartridge with dispensing nozzles up.
2. Grasp the tab in the dispensing nozzles and bend in an upward direction (90°). Do not place undue stress on the tab.
3. Firmly grasp the tab with thumb and forefinger while supporting the MegaMix cartridge and remove the cap from the cartridge. There will be some resistance when removing the cap. **NOTE:** Do not drop the MegaMix cartridge. The cartridge may break, rendering it unusable.
4. Insert the MegaMix cartridge into the dynamic mixer according to the manufacturer's instructions.

5. Following the machine's manufacturer instructions to dispense, press the control button. Bleed the material from the two nozzles of the cartridge. (This should be done prior to each use.) Wipe off the extruded material in a vertical direction to avoid cross contamination of the nozzles.
6. Place a mixing tip on the extrusion nozzles following the machine's manufacturer instructions. (**NOTE:** Do not use other manufacturer's mixing tips. They will not fit properly and can cause COUNTER-FIT Quick Set to leak.)
7. If the mixing tip does not seat easily, be sure the internal central hex of the dynamic mixing tip is aligned correctly with the drive shaft of the dynamic mixer.
8. Once the mixing tip is properly placed, place the Bayonet ring over the mixing tip and turn to the right (1/4 turn) until the Bayonet ring is locked in place.
9. Dispense COUNTER-FIT Quick Set into a suitable tray.
10. Pull back the plunger of the machine from the MegaMix cartridge immediately after dispensing the material in order to avoid the constant pressure and discharge of surplus COUNTER-FIT Quick Set from the mixing tip.
11. After each use, remove the tip, wipe each extrusion nozzle and place the supplied cap, from the manufacturer, back onto the cartridge. Remove the cartridge from the machine and store in an upright position.

**NOTE:** At the end of the day, or if the mixer will not be used for an extended period of time, it is best to remove the cartridge from the machine and store it in an upright position (with the manufacturer's supplied cap on).

### Mixing 50ml Cartridges

When using 50ml cartridges, insert the cartridge into the impression gun and attach a mixing tip; the mixing is done automatically inside the mixing tip. **Before filling the tray, it is recommended to discard the initially mixed (pea-sized) amount of the material. Leave the used mixing tip attached to the cartridge to act as a seal between uses.**

### Choosing the Impression Tray

When using a plastic or metal, perforated or non-perforated metallic tray, we recommend using a vinyl poly siloxane tray adhesive. COUNTER-FIT Quick Set will work with all commonly used impression trays.

### Impression Tray

The impression tray should be cleaned and dried carefully before use.

### COUNTER-FIT Quick Set Single-Phase Impression Technique

COUNTER-FIT Quick Set should be mixed to a uniform color and consistency, then immediately placed into the impression tray followed by immediate intraoral placement. The working time is approximately 1:00 minute. The recommended intraoral removal time is at least 1:30 minutes, for a total set time of 2:30 minutes. Afterward, the material can be demolded. The flexible recovery processes are finished after approximately 30 minutes. The impression should be stored at room temperature (max. 25°C/77°F). COUNTER-FIT Quick Set is best poured up with dental stone after 30 minutes (degassing process). COUNTER-FIT Quick Set remains stable indefinitely.

### Disinfecting

For disinfecting, the impression should be immersed in disinfecting solution. The use of a 2% glutaraldehyde solution is recommended. Please make sure that the disinfecting solution is compatible with addition-reaction silicones. After removing the impression from the mouth it should be rinsed with water for 15 seconds. The disinfecting process time for the impression is about 10-15 minutes, afterwards it must be rinsed with water for another 15 seconds.

### Casting and Galvanization

After disinfecting, dry the impression and store it at normal room temperature (max. 25°C/77°F). The impression should be poured 30 mins. at the earliest after removal from the mouth. Using special purpose hard plaster (ISO 6873, type 3) respectively an ultra hard plaster (ISO 6873, type 4) for the forms is recommended. COUNTER-FIT Quick Set can be copper or silver galvanized.

### Important Advice

- When using 50ml cartridges, the mixing tip should remain on after use to seal the cartridge.
- COUNTER-FIT Quick Set is not to be used in combination with condensation impression materials.
- Residues from hemostatic agents must be removed by water spray prior to taking an impression. Polymerization may be inhibited by use of latex gloves, creams, cleaning agents, resins, etc.

### Keep away from children! Only for dental use!

### Storage Conditions

At room temperature, i.e. 18°C/64°F - 28°C/82°F

### Durability

See date of expiry. COUNTER-FIT Quick Set is not to be used when expiry date has passed.

### WARRANTY

Clinician's Choice® Dental Products, Inc. will replace COUNTER-FIT Quick Set, 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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**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING**

**1.1 PRODUCT IDENTIFIER**  
**Trade name:** Counter-Fit Quick Set Multi-Purpose Replication Silicone

**1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST**  
 No further relevant information available.

**APPLICATION OF THE SUBSTANCE/THE MIXTURE:** Impression material

**1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET**  
**Manufacturer/Supplier:**

CLINICIAN'S CHOICE® Dental Products  
 167 Central Avenue, London, ON, Canada, N6A 1M6  
 For US Distribution: Brookfield, CT, USA, 06804  
 Emergency Telephone Number:  
 1-800-265-3444, (519) 641-3066  
 info@clinicianschoice.com

**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE**  
**CLASSIFICATION ACCORDING TO REGULATION (EC) NO 1272/2008**  
 The product is not classified according to the CLP regulation.

**CLASSIFICATION ACCORDING TO DIRECTIVE 67/548/EEC OR DIRECTIVE 1999/45/EC:**  
 Not applicable.

**Information concerning particular hazards for human and environment:**  
 The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

**Classification System:** The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

**2.2 LABEL ELEMENTS**  
**Labelling according to Regulation (EC) No 1272/2008:** Void  
**Hazard pictograms:** Void  
**Signal word:** Void  
**Hazard statements:** Void  
**Additional information:** Safety data sheet available on request.

**2.3 OTHER HAZARDS**  
**Results of PBT and vPvB assessment**  
**PBT:** Not applicable  
**vPvB:** Not applicable

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.2 CHEMICAL CHARACTERIZATION: MIXTURES**  
**Description:** Mixture of the substances listed below with non-hazardous additions.  
**Dangerous Components:**

Isoparaffin-mixture C12, C16 and C20	2.5%-10%
Xn R65 R66	
Asp. Tox. 1, H304	

Paraffinum Perliquidum DAB	≤2.5%
Xn R65	
Asp. Tox. 1, H304	
27306-78-1 Heptamethyltrisiloxan, Polyalkylenoxid modifiziert	≤2.5%
Xn R20; Xi R36; N R51/53	
Aquatic Chronic 2, H411; Acute Tox. 4, H332; Eye Irrit. 2, H319	

**Additional Information:** For the wording of the listed risk phrases refer to section 16.

**SECTION 4: FIRST AID MEASURES**

**4.1 DESCRIPTION OF FIRST AID MEASURES**  
**General information:** No special measures required.  
**After inhalation:** Supply fresh air; consult doctor 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. If symptoms persist, consult a doctor.  
**After swallowing:** If symptoms persist, consult doctor.

**4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**  
 No further relevant information available.

**4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED**  
 No further relevant information available.

**SECTION 5: FIRE FIGHTING MEASURES**

**5.1 EXTINGUISHING MEDIA**  
**Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
**For safety reasons unsuitable extinguishing agents:** Water with full jet

**5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE**  
 No further relevant information available.

**5.3 ADVICE FOR FIREFIGHTERS**  
**Protective equipment:** No special measures required.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:**  
 Avoid contact with eyes.

**6.2 ENVIRONMENTAL PRECAUTIONS:** Do not allow to enter sewers/surface or ground water.

**6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP:**  
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

**6.4 REFERENCE TO OTHER SECTIONS:**  
 No dangerous substances are released  
 See section 7 for information on safe handling.  
 See section 8 for information on personal protection equipment.  
 See section 13 for disposal information.

**SECTION 7: HANDLING AND STORAGE**

**7.1 PRECAUTIONS FOR SAFE HANDLING:** When using do not eat, drink or smoke.  
**Information about fire and explosion protection:** No special measures required.

**7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:**  
**Storage:**

**Requirements to be met by storerooms and receptacles:** Keep container tightly sealed.

**Information about storage in one common storage facility:** Not required.  
**Further information about storage conditions:** None.

**7.3 SPECIFIC END USE(S):** No further relevant information available.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Additional information about design of technical systems:**  
 No further data; see item 7

**8.1 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.

**8.2 EXPOSURE CONTROLS**  
**Personal protective equipment:**  
**General protective and hygienic measures:** The usual precautionary measures are to be adhered to when handling chemicals.

**Respiratory protection:** Not required.

**Protection of hands:** Not required.

**Material of gloves:** Not applicable.

**Penetration time of glove material:** Not applicable.

**Eye protection:** Goggles recommended during refilling

**Body protection:** Protective work clothing

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 PHYSICAL AND CHEMICAL PROPERTIES**  
**General Information**  
**Appearance:**  
**Form:** Viscous  
**Color:** Pinkish  
**Odor:** Characteristic  
**Odor threshold:** Not determined.  
**pH-value:** Not determined.

**Change in condition:**  
**Melting point/Melting range:** Undetermined.

**Boiling point/Boiling range:** 275°C (527°F)

**Flash point:** 130°C (266°F)

**Flammability (solid, gaseous):** Not applicable.

**Ignition temperature:** 375°C (707°F)

**Decomposition temperature:** Not determined.

**Self-igniting:** Product is not self-igniting.

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

**Explosion limits:**  
**Lower:** Not determined.  
**Upper:** Not determined.

**Oxidizing properties:** Not determined

**Vapour pressure at 20°C (68°F):** 100 hPa

**Density at 20°C (68°F):** 1.7 g/cm<sup>3</sup>

**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:**  
**Organic solvents:** 0.0 %

**9.2 OTHER INFORMATION:** No further relevant information available.

**SECTION 10: STABILITY AND REACTIVITY**

**10.1 REACTIVITY:** No dangerous reactions if used according to specifications.

**10.2 CHEMICAL STABILITY:** Stable if used according to specifications.

**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**10.3 POSSIBILITY OF HAZARDOUS REACTIONS:** No dangerous reactions known.

**10.4 CONDITIONS TO AVOID:** No further relevant information available.

**10.5 INCOMPATIBLE MATERIALS:** No further relevant information available.

**10.6 HAZARDOUS DECOMPOSITION PRODUCTS:** No dangerous decomposition products known.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:**  
**Acute toxicity:**  
**Primary irritant effect:**  
**On the skin:** No irritant effect.  
**On the eye:** No irritant effect.  
**Sensitization:** No sensitizing effects known.  
**Additional toxicological information:** The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 TOXICITY**  
**Aquatic toxicity:** No further relevant information available.  
**12.2 PERSISTENCE AND DEGRADABILITY:** No further relevant information available.  
**12.3 BIOACCUMULATIVE POTENTIAL:** No further relevant information available.  
**12.4 MOBILITY IN SOIL:** No further relevant information available.

**Additional ecological information:**  
**General notes:** Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**12.5 RESULTS OF PBT AND VPVB ASSESSMENT:**  
**PBT:** Not applicable.  
**vPvB:** Not applicable.

**12.6 OTHER ADVERSE EFFECTS:** No further relevant information available.

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1 WASTE TREATMENT METHODS**  
**Recommendation:** Disposal must be made according to official regulations.  
**Uncleaned packaging:**  
**Recommendation:** Disposal must be made according to official regulations.

**SECTION 14: TRANSPORT INFORMATION**

**14.1 UN-NUMBER:**  
**ADR, ADN, IMDG, IATA:** Void  
**14.2 UN PROPER SHIPPING NAME:**  
**ADR, ADN, IMDG, IATA:** Void  
**14.3 TRANSPORT HAZARD CLASS(ES):**  
**ADR, ADN, IMDG, IATA Class:** Void  
**14.4 PACKING GROUP:**  
**ADR, IMDG, IATA:** Void  
**14.5 ENVIRONMENTAL HAZARDS:**  
**Marine pollutant:** No  
**14.6 SPECIAL PRECAUTIONS FOR USER:** Not applicable.  
**14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE:** Not applicable.  
**UN "Model Regulation":** –