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

Hydroactive AFFINITY™ VPS from Clinician’s Choice® Dental Products Inc. is the first 3rd generation vinyl poly siloxane impression material. AFFINITY’s advanced 3rd generation chemistry provides true hydroactive properties, higher tear strength and dimensional stability. In addition, each viscosity is matched to all others resulting in a superior impression, regardless of the technique utilized. AFFINITY also exhibits the most efficient working and set times to minimize chair time and the potential for inaccuracies. AFFINITY’s 3rd generation FAST MATERIALS ARE RECOMMENDED FOR SINGLE PREPARATIONS ONLY. MAY REDUCE OR EXTEND THESE TIMES. PLEASE CALL FOR QUESTIONS OR CONCERNS.

Vinyl Poly Siloxane Impression Material Considerations:
- Allow impression material to reach room temperature prior to use.
- Handling retardation cord with latex gloves may subsequently prevent proper setting prior to impression procedure, to test for compatibility.

**PLEASE NOTE**
- Sulfur-based drugs may inhibit the set time of VPS material.
- When handling AFFINITY Putty, certain gloves will inhibit the set. It is suggested the operator mix a small amount of putty to confirm proper setting prior to impression procedure, to test for compatibility.
- Keep jars closed when not in use.
- Very high viscosity (putty) materials are not suitable for detailed impressions when used alone.
- They are ideal for large impressions when used alone.

**PRODUCT INQUIRIES & ORDERING**
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**MIXING INSTRUCTIONS FOR PUTTY**
1) Using the color coded scoops provided, dispense equal portions of base and catalyst from the jars.
2) Mix finger tips until a homogenous mixture is achieved (approximately 30-45 seconds). Slight variations in the relative amounts of base and catalyst will not affect the work and set times.
3) Place the mixed putty into an adhesive coated impression material tray.

**MIXING/SETTING TIMES**

<table>
<thead>
<tr>
<th>Material</th>
<th>Putty</th>
<th>Crystal</th>
<th>Quick Bite</th>
<th>Inflex Light</th>
<th>Light R.F.</th>
<th>Light H.F.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light Blue - REGULAR SET</td>
<td>0:15 min</td>
<td>1:10 min</td>
<td>1:10 min</td>
<td>2:15 min</td>
<td>2:55 min</td>
<td>2:55 min</td>
</tr>
<tr>
<td>Light Blue - FAST SET</td>
<td>0:30 min</td>
<td>1:10 min</td>
<td>1:10 min</td>
<td>3:05 min</td>
<td>3:40 min</td>
<td>3:40 min</td>
</tr>
<tr>
<td>Light Blue - LIGHT GREEN</td>
<td>0:45 min</td>
<td>1:10 min</td>
<td>1:10 min</td>
<td>3:05 min</td>
<td>3:40 min</td>
<td>3:40 min</td>
</tr>
<tr>
<td>Light Body Blue</td>
<td>0:45 min</td>
<td>1:10 min</td>
<td>1:10 min</td>
<td>3:05 min</td>
<td>3:40 min</td>
<td>3:40 min</td>
</tr>
</tbody>
</table>

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**SPECIFICATIONS & DIRECTIONS FOR USE**

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**CAUTION:** U.S. Federal law restricts this device to sale by, or on the product(s) for its intended use and the user assumes all risk and liability for any loss or damage, direct or consequential, arising out of the use of or the inability to use these products. Before using, the user shall determine the suitability of the product(s) for its intended use and the user assumes all risk and liability whatsover in connection therewith.
SECTION 1: MATERIAL IDENTIFICATION & INFORMATION

MATERIAL NAME: Affinity™ VPS

METHOD OF MANUFACTURE: Impression Material

COMPANY: Clinician’s Choice Dental Products Inc. 167 Central Avenue, London, ON, Canada, N6A 1M6

TELEPHONE: For emergencies or product information 01800-265-3444 or (519) 641-3066 or email info@clinicianschoice.com

DATE OF ISSUE: 03.08.2015

DATE OF REVISION: October 2016

SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) 1272/2008: Void

Information concerning particular hazards for human and environment:
The product does not have to be labeled due to the classification procedure of the “General classification guideline for preparations of the EU” in the latest valid version.

LABELS/ELEMENTS:
Labeling according to Regulation (EC) 1272/2008: Void

Labeling according to EU guidelines as defined in Directive 93/42/EEC which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP) usually if they are in the finished state and intended for the final use.

OTHER HAZARDS:

RESULTS OF PBT AND VPK ASSESSMENT

PBT: Not applicable

VPK: Not applicable

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

CHEMICAL CHARACTERIZATION:
Description: Mixture of polydimethylhydrogen siloxane and silica

Polymethyl hydrogen siloxane and silica

Hazardous components: None

SECTION 4: first aid measures

General information: No special measures required

After skin contact: Wash with plenty of water and soap

After eye contact: Rinse with plenty of water and consult a doctor

After swallowing: If symptoms persist consult a doctor

SECTION 5: Firefighting measures

Extinguishing media: CO2, water

Protective equipment: No special measures required

Methods for cleaning up: Pick up mechanically

Additional information: None

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Not required

Environmental precautions: No special measures required

Methods for cleaning up: Pick up mechanically

Additional information: None

SECTION 7: HANDLING AND STORAGE

HANDLING:

Information for safe handling: For dental use only. No special measures required

Recommendation for fire and explosion protection: No special protection required

STORAGE:

Requirements at storerooms and containers: No special measures required

Requirements for storage with other products: Not required

Further information on storage conditions: None

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with limits of values to be supervised 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.

PERSONAL PROTECTIVE EQUIPMENT:

General measures of protection and hygiene: Normal hygienic measures

Respiratory protection: Not required

Protection of hands: Not required

Eye protection: Not required

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE:

Form: Paste

Color: Different

Odor: Odorless

INFORMATION ON CHANGE IN THE PHYSICAL STATE

Melting point/melting range: n.a. °C

Boiling point/boiling range: n.a. °C

Flash point: n.a. °C

Autoignition temperature: n.a.

Danger of explosion: none

Density:

Heavy Body MegaMix 1.5 (20°C) g/cm³

Heavy Body RS/FS 1.24 (20°C) g/cm³

Light Body RS/FS 1.33 (20°C) g/cm³

Light Body XL 1.20 (20°C) g/cm³

Monophase 1.41 (20°C) g/cm³

Putty 1.53 (20°C) g/cm³

Quick Bite 1.52 (20°C) g/cm³

Vicarious:

Viscosity: paste

Density: n.a.

Solubility in/insolubility in:

Partially soluble in toluene, petrol ether

Water: insoluble

Content of solvents: none

Organic solvents: -----.

Water: Content of solids: n.a.

SECTION 10: STABILITY AND REACTIVITY

Conditions to avoid: No decomposition if used according to specification

Hazardous decomposition products: None under normal conditions of storage and use

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Primary irritation: Skin: none

Eye: No irritating effect

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

SECTION 12: ECOLOGICAL INFORMATION

General information: Avoid transfer into environment

CLASSIFIED AS HARMFUL (VESSEL): WSK 1 (German regulation) slightly hazardous for water

SECTION 13: DISPOSAL CONSIDERATIONS

PRODUCT:

Recommendation: Small quantities can be disposed of with household waste.

Recommendation: Must be disposed or incinerated in accordance with local, state and federal regulations.

UNCLASSIFIED PACKAGING:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport ADR, RID: Not subject to transport regulations

Maritime transport: IMDG-Code: Not subject to transport regulations

Air transport ICAO-TI/IATA-DGR: Not subject to transport regulations

SECTION 15: REGULATORY INFORMATION

Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42/EEC.

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

SECTION 16: OTHER INFORMATION

Changes compared with the previous version: Adaptation according to 1907/2006/EC, Article 31

Prepared by: Peter G. Jordan

The above information is based on our present day knowledge and relates solely to the polydimethylhydrogen siloxane of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

N/D: NOT DETERMINED

N/A: NOT APPLICABLE