SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance Form: liquid

Color: slightly yellow Odor: sweetish

SAFETY RELEVANT BASIC DATA

Melting point/melting range: Value Unit Method n.a.

°F/°C

DIN 51755

Boiling point/boiling range: approx. 77/171
Flash point: -4/24.5

Flash point: -4/24.5 °F/°C Ignition temperature: No information available

Danger of explosion: Lower limit of explosion: 2.1 Vol% KühnUpper limit of explosion: 11.5 Vol% Birett

Density: ca. 0,93 (68°F/20°C) g/cm³

Vapor pressure: n.d.

Solubility in/miscibility with:

Water: soluble

Content of solvents: ethylacetate

SECTION 10: STABILITY AND REACTIVITY

THERMAL DECOMPOSITION / CONDITIONS TO BE AVOIDED

Possibility of hazardous reactions: no information available

Conditions to avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hybrids, strong oxidizing agents, radical initiators

Hazardous decomposition products: No information available.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY: (ETHYLACETATE)

LD₅₀ (oral, rat) 5600 mg/kg LD₅₀ (dermal, rabbit) >18000 mg/kg LD₅₀ (inhal., rat) 5,86 mg/l (8h)

PRIMARY IRRITATION:

Skin: Repeated exposure may cause skin dryness or cracking

Eye: Strong irritating effect

Inhalation and swallowing: Irritation of mucous membranes, loss of appetite, headache, drowsiness

ADDITIONAL TOXICOLOGICAL INFORMATION:

Allergic reactions to acrylates after long-term exposure are possible. 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

TOXICITY:

Aquatic toxicity: No further relevant information available

Persistence and degradability: No further relevant information available

BEHAVIOR IN ENVIRONMENTAL SYSTEMS:

Bioaccumulative potential: No further relevant information available

Mobility in soil: No further relevant information available

General information: Do not flush into surface water or sanitary sewer system

SECTION 13: DISPOSAL CONSIDERATION

PRODUCT:

Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations,

UNCLEANED PACKAGING:

Recommendation: Disposal must be made according to official regulations

SECTION 14: TRANSPORT INFORMATION

Land transport ADR/RID and GGVS/GGVE (Germany): UN 1173 ETHYLACETAT, 3, II Sea transport IMDG: UN 1173 ETHYLACETAT. 3, II

Air transport ICAO-TI and IATA-DGR: UN 1173 ETHYLACETATE, 3, II

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

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/EG, Article 31

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

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 for its intended use and the user assumes all risk and liability whatsoever in connection therewith.

Prepared by: Peter G. Jordan



Affinity Tray Adhesive

Clinician's Choice®

Distributed by Clinician's Choice, a division of Den-Mat Holdings, LLC 1017 W. Central Avenue, Lompoc, CA 93436 USA 800 433 6628, clinicianschoice.com



800.433.6628 www.clinicianschoice.com

988227 R:1 10/24SN

Affinity Tray Adhesive

INTENDED USE:

A liquid adhesive used as a medical device to provide a bond between the impression material and tray when fabricating dental impressions.

INSTRUCTIONS

- Paint a thin layer of Affinity™ Tray Adhesive onto tray.
- 2. Allow to dry for 30 seconds.
- 3. Load the tray and take the impression.

NOTE: Use only Affinity™ Tray Adhesive with hydroactive Affinity™ VPS Impression Material.

ATTENTION: Close bottle immediately after each use to avoid evaporation of the solvent!

Affinity Tray Adhesive should be used in a well-ventilated room. In case of contact with skin, wash off with soap and water.

STORAGE: Do not store above 77°F/25°C. Do not use after expiry date.

KEEP AWAY FROM CHILDREN!

ONLY FOR USE BY DENTISTS AND DENTAL TECHNICIANS!

SAFETY DATA SHEET

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

PRODUCT DETAILS

TRADE NAME: Affinity™ Tray Adhesive USE OF THE PREPARATION: Tray Adhesive

COMPANY: Distributed by Clinician's Choice, a division of Den-Mat Holdings, LLC 1017 W. Central Avenue. Lompoc. CA 93436 USA

For emergencies or product information, please call 800.433.6628 (8:00am - 5:00pm ET) or email info@clinicianschoice.com.

DATE OF ISSUE: 26.05.2015

SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Classification according to Regulation (EC) No 1272/2008:

Flam. Liq. 2, H225 Higly flammable liquid and vapour Eve Irrit. 2, H319 Causes serious eve irritation

STOT SE 3. H336 May cause drowsiness or dizziness

Information concerning particular hazards for human and environment: The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

LARFI FLEMENTS

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms



Signal word Danger

Hazard statements

H225 Highly flammable liquid and vapour

H319 Causes serious eve irritation

H336 May cause drowsiness or dizziness

Precautionary statements

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking. P305+P351+P338 IF IN EYES. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and 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/GHS) usually if they are in the finished state and intended for the final user.

OTHER HAZARDS

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL CHARACTERIZATION:

Description of the mixture: Solution of modified polyacrylate in ethylacetate Hazardous components:

CAS-No. [141-78-6], EC-No.2005-500-4

Ethylacetate GHS02, GHS07 H225, H319, H336

SECTION 4: FIRST-AID MEASURES

General information: no special measures required After skin contact: wash with plenty of water and soap

After inhalation: fresh air

After eye contact: Rinse opened eye for several minutes under running water and consult a doctor

After swallowing: Caution if victim vomits. Risk of aspiration. Keep airways free. Consult a physician. Subsequently administer: activated charcoal (20 – 40 g in 10% slurry). Laxative: Sodium sulfate (1 tablespoon / ½ L water).

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media: CO2, powder, water spray.

Use extinguishing method and media suitable to surrounding fire. Special hazards arising from the substance or mixture:

No further relevant information available

Protective equipment: Wear self-contained respiratory protective equipment

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms

Environmental precautions: Do not allow to enter drains/surface water/ ground-water. Methods for cleaning up: Absorb with liquid binding material. Clean up affected area.

Reference to other sections: 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

HANDLING:

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Precautions for safe handling: Observe normal care for working with chemicals Information about fire and explosion protection: No special measures required STORAGE:

Requirements at storerooms and containers: Store only in the original containers Further information on storage conditions:

Store in well ventilated place at 59°F/15°C to 77°F/25°C, protected from light. Store away from food. Store tightly closed. Keep away from heat and sources of ignition. Specific end uses: No further relevant information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

CAS-No.	Name	Art	Value	Unit	
COMPONENT	S WITH LIMIT	s of values to) be super	RVISED AT	THE WORKPLACE:

[141-78-6] Ethylacetate TRGS900 400 ml/m3 or 1500 mg/m3

Additional information: The lists valid during the making were used as basis PERSONAL PROTECTIVE EQUIPMENT:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from food and beverages, Avoid contact with eves or skin

Hand protection: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Safety glasses

Respiratory protection: Required, when aerosols are generated

continued...