SECTION 9:

PHYSICAL AND CHEMICAL PROPERTIES

APPFARANCE Form: Liquid Color: Different Odor: Sweetish

Information on Change in the Physical State

Method approx. -86/-123 Melting point/melting range: Boiling point/boiling range: approx 40/104 Flash point: Autoignation temperature: 505/941 DIN 51794 Danger of explosion: 1.8 % Kiihn-Lower limit of explosion Upper limit of explosion 11.5 % Birett Density: approx. 0.93 (20°C/68°F) g/cm3 approx 100 Vapor pressure: Viscosity: Slightly viscous Solubility in/miscibility with: Soluble in acetone and toluene, slightly in petrol ether Water: Insoluble Content of solvents:

Water:

Organic solvents: Ethyl methyl ketone, dichloromethane None

Content of solids: None

SECTION 10: -STABILITY AND REACTIVITY

Conditions to Avoid:

Avoid heat. The product is stable by proper use.

Avoid contact with oxidation agents (e.g. Cr(VI) compounds: H2O2 etc.). Avoid contact with alkali metals, alkaline earth metals, metals in powder form.

Hazardous Decomposition Products: In case of fire: phosgene.

hydrochloric acid

SECTION 11: -

TOXICOLOGICAL INFORMATION

Acute toxicity: Small effects of toxicity

Primary irritation:

Skin: Repeated or prolonged exposure may cause skin irritation or dermatitis.

due to degreasing properties of the product. Resorption possible. Eve: Severe irritation. Risk of corneal clouding.

Inhalation: Mucosal irritations: inebriation, narcosis, unconsciousness.

Sensitization of Product: Not observed

Additional Toxicological Information: The following applies to halogenated hydrocarbons in general; systemic effect; narcosis, cardiovascular disorders. Toxic effect

on liver, kidneys. Handle in accordance with good industrial hygiene and safety practice. SECTION 12: -

FCOLOGICAL INFORMATION

General information: Do not allow to enter the environment or sewerage system. Classification of Water Endangerment: WGK 2 (German regulation) hazardous for water.

SECTION 13: -

DISPOSAL CONSIDERATION

Product:

Recommendation: Use proper landfill disposal or incineration in accordance with local

state and federal regulations. Uncleaned Packaging

Recommendation: Handle contaminated packaging in the same way as the substance itself.

SECTION 14: -

TRANSPORTATION INFORMATION

Land Transport ADR, RID:

ENTZÜNDBARE FLÜSSIGKEIT. TOXISCH N.A.G. (Ethylmethylketon / Dichlormethan), 3 (6.1), II

Maritime Transport: IMDG-Code: UN 1992

FLAMMABLE LIQUID. TOXIC. N.O.S.

(Ethyl methyl ketone / Dichloromethane), 3 (6.1), II FmS: F-F S-A/S-F

Air Transport ICAO-TI/IATA-DGR: UN 1992

FLAMMARI E LIQUID TOXIC NOS

(Ethyl methyl ketone / Dichloromethane), 3 (6.1), 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

082017

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

DENTAL PRODUCTS INC.

1-800-265-3444 • Phone: (519) 641-3066 www.clinicianschoice.com



Prinsessegracht 20 2514 AP The Hague







1-800-265-3444

(519) 641-3066 www.clinicianschoice.com



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

1. Paint a thin layer of AFFINITY™ Tray Adhesive onto tray.

2. Allow to sit for 1:00 minute.

NOTE: Use only AFFINITY[™] Tray Adhesive with hydroactive AFFINITY[™] VPS Impression Material.

SAFETY DATA SHEET

PRODUCT IDENTIFICATION/PREPARATION/COMPANY LINDERTAKING

PRODUCT DETAILS

Trade Name: AFFINITY™ Tray Adhesive

Use of the Preparation: Tray Adhesive

Company: ... CLINICIAN'S CHOICE® Dental Products, Inc.,

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

For U.S. Distribution: Brookfield, CT, USA, 06804 For emergencies or product information, please call 1-800-265-3444

(519-641-3066) (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) 1272/2008: Carc. 2. H351 Suspected of causing cancer.

Flam, Lig. 2, H225 Highly flammable liquid and vapor. 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 the calculation procedure of the "General classification guideline for preparations of the EU" in the latest valid version. LABEL ELEMENTS:

Labeling according to Regulation (EC) 1272/2008:





Hazard statements

H351 Suspected of causing cancer

H225 Highly flammable liquid and vapor

H319 Causes serious eve irritation

H336 May cause drowsiness or dizziness

Precautionary statements

P403 Store in a well ventilated place.

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P262 Do not get in eyes, on skin or on clothing.

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

P281 Use personal protective equipment as required.

P235 Keep cool.

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 OF INGREDIENTS

Chemical Characterization:

Description: Solution of modified polyacrylates in ethyl methyl ketone and dichloromethane

Hazardous Components:

CAS-No [78-93-3] EC-No 201-129-0 Ethyl methyl ketone GHS02, GHS07 H225, H319, H336

CAS-No [75-09-2] EC-No 200-838-9 Dichloromethane GHS08, H351

SECTION 4: -

FIRST-AID MEASURES

After Inhalation: Fresh air

After Skin Contact: Wash with plenty of water. Remove contaminated clothing. Consult a physician.

After Eve Contact: Rinse with plenty of water with the evelid held wide open. Consult an ophthalmologist, if necessary.

After Swallowing: Caution if victim vomits. Risk of aspiration, Keep airways free. Drink plenty of water, but no milk or castor oil, Call a physician immediately.

SECTION 5: -

FIRE FIGHTING MEASURES

Extinguishing media: Water, CO2, foam, powder,

Protective equipment: Do not stay in dangerous zone without suitable chemical protection clothing and self-containing breathing apparatus.

SECTION 6: ---

ACCIDENTAL RELEASE MEASURES

Personal Precautions: Do not inhale vapors/aerosols. Ensure supply of fresh air in enclosed rooms.

Environmental Precautions: Observe local bylaws. Do not allow to enter sewerage system.

Methods for Cleaning Up: Wipe up with absorbent material, Dispose, Clean up affected area

Additional Information: None

SECTION 7: -

HANDLING AND STORAGE

Handling: The product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information for Safe Handling: For dental use only. Work under hood. Do not inhale substance/mixture. Avoid generation of vapors/aerosols.

Recommendation for Fire and Explosion Protection: Keep away from sources of ignition.

Storage:

Requirements at Storerooms and Containers: Tightly closed. Protected from light. Store in well ventilated place at 15°C/59°F to 25°C/77°F.

Requirements for Storage with Other Products: Keep away from food. Further Information on Storage Conditions: None

SECTION 8: -

EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with Limits of Values to be Supervised at the Workplace:

CAS-No.	Name	Art	Value	Unit
[78-93-3]	ethyl methyl ketone	TRGS900	200	ml/m ³
[75 00 0]	diablaramathana	TDCCOOO	or 600	mg/m ³ ml/m ³
[75-09-2]	dichloromethane	TRGS900	75 or 260	mg/m ³

Preanancy: Group C

Additional Information: The lists valid during the making were used as basis. Personal Protective Equipment: Change contaminated clothes. After finishing of work wash hands

General measures of Protection and Hygiene: Do not eat, drink or smoke during handling: avoid contact with eves or skin.

Respiratory Protection: Required when vapors/aerosols are generated. Protection of Hands: Wear gloves.

Eve Protection: Glasses recommended.

continued