SECTION 14: TRANSPORT INFORMATION

LAND TRANSPORT ADR/RID AND GGVS/GGVE (GERMANY)

ADR, RID

UN 3077 UMWELTGEFÄHRDENDER STOFF, FEST N.A.G (Zinkoxid), III, 9 SEA TRANSPORT IMDG:

IMDG-Code

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

EmS: F-A S-F

AIR TRANSPORT ICAO-TI AND IATA-DGR:

CAO, PAX

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide). 9. III

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 the products properties. However, users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.



1-800-265-3444

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Intended Use

CLING² is a non-eugenol, automix temporary cement designed as a medical device for cementing provisional crowns, bridges, inlays, and onlays.

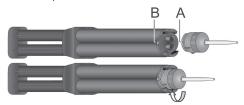
CLING² shows excellent adhesion to temporary crown and bridge materials, but it can easily be removed from prepared tooth stumps. Delivered from automix syringes, CLING² is very easy and comfortable to use. Due to its non-eugenol formulation it does not influence the setting of resin-based filling and luting materials. CLING² is based on ZnO/organic acids. Especially in cases of allergies to eugenol it is strongly recommended to use this eugenol-free type of cement.

 $\rm CLING^2$ meets the requirements of DIN EN ISO 3107 and ADA/ANSI Specification No. 30

Instructions for Use

Remove and discard the shipping cap from the syringe (do not reuse). Attach a $CLING^2$ 1:1 mixing tip (A) to the dual syringe (B). Turn the mixing tip 90° until it locks into position. $CLING^2$ is now ready for application. NOTE:

- Store used syringe with used mixing tip in place.
- Be sure to discard the first pea-sized (2-3mm) amount of cement to ensure a complete mix. This must be done for each new mix.



Cementing

CLING² can be applied directly into the temporary crown or bridge with slight pressure on the syringe plunger.

Apply a thin layer on the inside of the temporary crown or bridge and seat no later than 1:30 minutes (working time) cautiously but firmly over the prepared tooth structures.

NOTE: Do not dry the preparations. It is best to moisten them with water

A moistened preparation facilitates easy removal from the temporary crown or bridge when required.

 ${\rm CLING^2}$ sets in the mouth within 2-3 minutes. After ${\rm CLING^2}$ has set, remove any excess.

Precautions

- 1. Do not use CLING2 in cases where known allergies to the components exist.
- 2. Do not use CLING² if in some cases individual contact allergies may exist.
- In case of contact with skin and eyes, rinse immediately with plenty of water and consult a physician, if necessary.
- 4. If swallowed, seek medical advice.

Packaging

CLING² DUAL-SYRINGES MIXING TIPS 5ml (base & catalyst) 25-pack 10ml (base & catalyst) 100-pack

Storag

Store at temperatures between 47-78°F (8-25°C). Do not use after expiration date.

CLINICIAN'S CHOICE" does not accept liability for any loss or damage, direct or consequential, arising out of the use or 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.

Keep away from children!

For dental use only!

For questions or comments, please call:

CLINICIAN'S CHOICE

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SECTION 1:

MATERIAL IDENTIFICATION & INFORMATION

MATERIAL NAME: CLING2 Resin Optimized Temporary Cement

USE OF PREPARATION: Dental product

CLINICIAN'S CHOICE® DENTAL PRODUCTS INC. 167 Central Avenue, London, ON, Canada, N6A 1M6 For U.S. Distribution: Brookfield, CT, USA, 06804

TELEPHONE: For emergencies or product information 1-800-265-3444 or (519) 641-3066 (8:00am - 5:00pm EST) or email info@clinicianschoice.com

DATE OF ISSUE: 20.05.2015 **DATE OF REVIEW: 01.06.17**

SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

CLASSIFICATION ACCORDING TO REGULATION (EC) NO 1272/2008: Acute aquatic toxicity, Category 1, H400 Very toxic to aquatic life.

Chronic aquatic toxicity, Category 1, H410 Very toxic to aquatic life with long lasting effects.

Skin Irritation, Category 2: H315 Causes skin irritation Eve Irritation, Category 2: H319 Causes serious eve irritation.

STOT SE, Category 3, H335 May cause respiratory irritation.

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.

CLASSIFICATION SYSTEM:

The classification corresponds to actual EU-lists, and completed with details from technical literature and company data.

LABEL ELEMENTS:

LABELING ACCORDING TO REGULATION (EC) 1272/2008:

HAZARD PICTOGRAMS



SIGNAL WORD Warning

HAZARD STATEMENTS

H400 Very toxic to aquatic life

H315 Causes skin irritation

H319 Causes serious eye irritation H335 May cause respiratory irritation PRECAUTIONARY STATEMENTS:

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

LARFLING ACCORDING TO FU 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 PRT AND VPVR ASSESSMENT

PBT: Not applicable vPvB: Not applicable

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

CHEMICAL CHARACTERIZATION: Mixture

DESCRIPTION OF MIXTURE: Mixture of organic acids, zinc oxide and methacrylates

HAZARDOUS COMPONENTS:

Zinc Oxide [CAS-No. 1314-13-2] Methacrylates [Index-No. 607-134-00-4] Mixture of Organic Acids

GHS09, H410, H411 GHS07, H315, H319, H335 GHS07, H315, H319, H335

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 opened eye for several minutes under running water and consult a doctor.

AFTER SWALLOWING: Seek medical advice immediately.

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.

ACCIDENTAL RELEASE MEASURES SECTION 6:

PERSONAL PRECAUTIONS. PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

ENVIRONMENTAL PRECAUTIONS: Do not allow to enter drains/surface water/ground-water.

METHODS FOR CLEANING UP: Take up mechanically. 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.

HANDLING AND STORAGE SECTION 7:

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 at dry place. storage temperature 8 - 25°C. Store away from food.

SPECIFIC END USES: No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

COMPONENTS WITH LIMITS OF VALUES TO BE SUPERVISED AT

THE WORKPLACE: The product contains no relevant quantities of components with limit values to be supervised at the workplace.

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

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.

PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES: APPEARANCE:

FORM: Paste

SAF

Me

Boi

Flas

lani

Dar

Der

Van

Sol

Wat

Cor

Organic solvents

COLOR: White vellowish

ODO

Value	Unit	Method
n.a.		
n.a.		
n.a.		
Product is not self-igniting		
None		
1,71 (20 °C) g/cm ³		
Not applicable (non volatile)		
Slightly in	toluene, org	ganic solvent
Insoluble		
None		
	n.a. n.a. Product is None 1,71 (20 ° Not applications Slightly in Insoluble	n.a. n.a. Product is not self-igr None 1,71 (20 °C) g/cm³ Not applicable (non vo Slightly in toluene, org Insoluble

None

SECTION 10: STABILITY AND REACTIVITY

THERMAL DECOMPOSITION/CONDITIONS TO BE AVOIDED: No decomposition if used according to specifications.

POSSIBILITY OF HAZARDOUS REACTIONS: No dangerous reaction known.

CONDITIONS TO AVOID: Avoid heat, direct sunlight INCOMPATIBLE MATERIALS: Peroxides, metal powders, strong oxidizers.

free radical initiators

HAZARDOUS DECOMPOSITION PRODUCTS: No dangerous decomposition products known.

TOXICOLOGICAL INFORMATION

Allergic reactions to methacrylates by chronic exposure to the product are possible.

ACUTE TOXICITY:

PRIMARY IRRITATION:

SKIN: Slightly irritating

EYE: Irritating effect

SENSITIZATION: No sensitizing effect known.

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

ECOLOGICAL INFORMATION SECTION 12:

TOXICITY:

AQUATIC TOXICITY: May cause long term adverse effect in the aquatic environment.

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

RECOMMENDATION: Disposal must be made according to official regulations.

continued