SECTION 14: TRANSPORT INFORMATION

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

ADR, RID
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III
EMG: F-A S-F
AIR TRANSPORT ICAO-TI AND IATA-DGR:
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.

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.

CLING2 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 CLING2 1:1 mixing tip (A) to the dual syringe (B). Turn the mixing tip 90º until it locks into position. CLING2 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.

CLING2 sets in the mouth within 2-3 minutes. After CLING2 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.
3. 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
1ml (base & catalyst) 100-pack

Storage
Store at temperatures between 47-78ºF (8-25ºC). 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 questions or comments, please call:
1-800-265-3444
1-800-265-3444

For dental use only!

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

EXPOSURE CONTROLS/PERSONAL PROTECTION

PHYSICAL AND CHEMICAL PROPERTIES

DISPOSAL CONSIDERATION

FIRE FIGHTING MEASURES

FIRST-AID MEASURES

TOXICOLOGICAL INFORMATION

PRECAUTIONARY STATEMENTS:
F292 Do not get in eyes, on skin or on clothing.

LABELING ACCORDING TO EU GUIDELINES:
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct 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 7: HANDLING AND STORAGE

HANDLING: This product should only be supplied or handled to dentists or dental technicians or upon their instructions. Use proper landfill disposal or incineration in accordance with official regulations. Disposal must be made according to official regulations.

SECTION 8: PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:
APPEARANCE: Mixture
INFORMATION CONCERNING PARTICULAR HAZARDS FOR HUMAN HEALTH 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) NO 1272/2008:

Hazard Pictograms

SECTION 2: HAZARD 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.

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

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

MIXTURE: Mixture of organic acids, zinc oxide and methacrylates

HAZARDOUS COMPONENTS:
Zinc Oxide [CAS-No. 1314-32-3] GHS08, H410, H411
Methacrylates [Index-No. 607-134-00-4] GHS08, H410, H119, H335
Mixture of Organic Acids GHS08, H410, H119, H335

SECTION 4: FIRST-AID MEASURES

GENERAL INFORMATION:
No special measures required.

AFTER INHALATION:
Seek medical advice immediately.

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 INGESTION:
Do not induce vomiting. 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:
The product contains no relevant components of hazardous decomposition products to be Supervised at the workplace. The lists valid during the making were used as basis.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PROTECTIVE EQUIPMENT:
HAND PROTECTION: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

EYE PROTECTION: Protective glasses.

RESPIRATORY PROTECTION: Required, when aerosols are generated.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

SAFETY RELEVANT BASIC DATA

Melting point/range:
Product is not self-igniting

Flash point:
Dampens the inflammation.

Density:
Water:

Vapor pressure:
Not applicable (not volatile).

Solubility in/Miscibility with:
Slightly soluble in solvents, organic solvents
Insoluble

Sensitization:
No sensitizing effect known.

SKIN:
No further relevant information available.

ACUTE TOXICITY:
Absorbs through skin, nose, eyes and throat.

BEHAVIOR IN ENVIRONMENTAL SYSTEMS:
PERSISTENCE AND DEGRADABILITY:
No further relevant information available.

BEHAVIOR IN ENVIRONMENTAL SYSTEMS:
Bioaccumulative Potential:
No further relevant information available.

PAINTING:
Absorbs through skin, nose, eyes and throat.

MOBILITY IN SOIL:
No further relevant information available.

GENERAL INFORMATION:
No further relevant information available.

BEHAVIOR IN ENVIRONMENTAL SYSTEMS:
Bioaccumulative Potential:
No further relevant information available.

PRODUCT:
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.

PRODUCT:
Recommends use of personal protective equipment on the product.

SOLUBILITY:
Slightly soluble in organic solvents

CONTAMINANTS:
Water:

ORGANIC SOLVENTS:
Not further relevant information available.

RECOMMENDATION:
No decomposition if used according to specifications.

SECTION 10: STABILITY AND REACTIVITY

THERMAL DECOMPOSITION/CONDITIONS TO AVOID:
No dangerous reaction known.

POSSIBILITY OF HAZARDOUS REACTIONS:
No dangerous reaction known.

CONDITIONS TO AVOID:
Avoid heat, direct sunlight

INCOMPATIBLE MATERIALS:
Peroxydases, metal powders, strong oxidizers, free radical initiators.

HAZARDOUS DECOMPOSITION PRODUCTS:
No dangerous decomposition products known.

PECULIAR SENSITIVITY:
Slight irritation eye, irritant effect

SENSITIZATION:
No sensitizing effect known.

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

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICITY:
Acute 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.

GENERAL INFORMATION:
No further relevant information available.

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