

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

6. Accidental release measures

Personal precautions: Not required

Environmental precautions: Do not allow to enter drains/surface water/ground-water.

Methods for cleaning up: Pick 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

7. Handling and storage

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

Information for safe handling: Observe normal care for working with chemicals.

Information about fire and explosion protection: No special measures required

Storage: Store at a dry place. Store tightly closed. Storage temperature <25°C/78°F.

Requirements at storerooms and containers: Store only in the original containers.

Further information on storage conditions: Store away from food stuffs.

Specific end uses: No further relevant information available.

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 limits of 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 foodstuffs and beverages. Avoid contact with eyes 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

9. Physical and chemical properties

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Form: paste
Color: tooth colored
Odor: odorless

VALUE UNIT METHOD

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.d.

Ignition temperature: n.d.

Danger of explosion: none

Density: 1.93 (20°C) g/cm³

Vapor pressure: n.a.

pH: neutral

Solubility in/miscibility with: Partially soluble in toluene, silicone oil

Water: insoluble

Content of solvents: none

Organic solvents: none

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, hydrides, strong oxidizing agents, radical initiators.

Hazardous decomposition products: No information available.

11. Toxicological information

Acute toxicity: No data available

Primary irritation:

Skin: Irritant

Eye: Irritant

Sensitization: Sensitization by skin contact possible

Additional toxicological information:

Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects from our experience and the information provided to us.

12. Ecological information

General information: Avoid transfer into environment

Classification of water endangerment: WGK=1 (slightly polluting substance).

13. Disposal considerations

PRODUCT:

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

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

UNCLEAN PACKAGING:

Recommendation: Disposal must be made according to official regulations.

14. Transport information

Land transport ADR/RID: Not subject to transport regulations

Sea transport IMDG: Not subject to transport regulations

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

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.

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 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.

Prepared by: Peter G. Jordan

PRODUCT INQUIRIES & ORDERING
CLINICIAN'S CHOICE
DENTAL PRODUCTS INC.

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nano-enhanced
*Evanesce*TM
universal restorative

INSTRUCTIONS FOR USE & SAFETY DATA SHEET

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DENTAL PRODUCTS INC.



EVANESCE™ Nano-Enhanced Universal Restorative is a visible light-cure nano-filled composite for anterior and posterior restorations. Beside its low shrink and low abrasion EVANESCE shows improved handling features and excellent mechanical properties. EVANESCE is based on urethanedimethacrylate resin and inorganic filler particles <1.0 µm. The total filler content is 82% (wt) and 74% (vol). Evanesce Nano-Enhanced Universal Restorative meets the requirements of DIN EN ISO 4049.

Indications

Suitable for all cavities.

Side Effects

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection the cavity floor in cases of deep excavations should be covered with a thin layer of calcium hydroxide material.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.

Determine the tooth shade while teeth are still moist and select the appropriate EVANESCE shade.

EVANESCE Nano-Enhanced Universal Restorative is shaded according to VITA®-Shades. It is also available in special shades and bleach shades.

Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction. Best pulp protection in case of deep excavations is the photo-activated disinfection (PAD). If this is not possible, deep excavations should be covered with a thin layer of calcium hydroxide material.

Etch and apply a bonding agent, such as MPa Max, according to the manufacturer's instructions. The total-etch technique with MAX-ETCH 37% Phosphoric Acid Etch and subsequent application of a light-cure bonding agent is recommended. Otherwise use a self-etching bonding agent before application of EVANESCE.

Application and Curing of EVANESCE Nano-Enhanced Universal Restorative

Place EVANESCE in the selected shade. EVANESCE Nano-Enhanced Universal Restorative is easy to model. Transparent matrix strips may be used.

In case of deep and extended cavities best results are obtained with a build-up of a base liner using a light-cure resin modified cement or a light-cure flowable composite, followed by the application of EVANESCE.

In case of small cavities EVANESCE can be placed directly.

For an optimum result, place EVANESCE in layers of max. 2 mm. Light-cure each increment separately.

By using a polymerization unit with a light intensity of at least 1000mW/cm2, cure each increment as follows:

Lighter shades (e.g. A1, A2, C2) 20 seconds

Darker shades (e.g. A3.5, B3) 30 seconds

Finishing

Contour with fine diamonds, stones or burs. Polish to high gloss with discs, such as ASAP All Surface Access Polishers or rubber points. Interproximal finishing is accomplished by fine grit finishing strips.

Storage

Do not store above 25°C (78°F). Protect from direct sunlight. Do not use after expiry date. Close syringe immediately after use to avoid exposure to light.

Single Dose compules are for single use only.

Additional Notes

- Do not use any resin to adjust viscosity of composite restorative material.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- VITA® is a registered trade mark of the VITA-Zahnfabrik, Bad Säckingen, Germany.

Warranty

Clinician's Choice Dental Products, Inc warrants this product will be free from defects in material and manufacture. Clinician's Choice makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Clinician's Choice's sole obligation shall be repair or replacement of the product.

Limitation of Liability

Except where prohibited by law, Clinician's Choice Dental Products will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Keep away from children!

For dental use only!



SAFETY DATA SHEET

Identification of the substance/mixture and of the company/undertaking


1. Product Identifier

TRADE NAME: EVANESCE™ Nano-Enhanced Universal Restorative

USE OF THE PREPARATION: Dental product

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET:

MANUFACTURER/SUPPLIER:

 Clinician's Choice Dental Products
167 Central Avenue, London, Ontario, Canada, N6A 1M6
For U.S. Distribution: Brookfield, CT, USA, 06804
1-800-265-3444
(519) 641-3066
info@clinicianschoice.com

2. Hazards identification

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

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

Skin Irrit. 2: H315 Causes skin irritation

Eye Irrit. 2: H319 Causes serious eye irritation

Skin Sens. 1: H317 May cause allergic skin reaction

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.

LABEL ELEMENTS:

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms:



Signal word:

Warning

Hazard statements:

H315 Causes skin irritation

H319 Causes serious eye irritation

H317 May cause allergic skin reaction

Precautionary statements:

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

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

3. Composition/Information on Ingredients

Chemical characterization:

Description: Mixture of urethanedimethacrylate-resin, glass fillers, silica, polymer powder, photoinitiator, accelerator, stabilizer

Hazardous components:

Methacrylates GHS07, H315, H319, H317, H335

4. First-aid measures

General information: Seek medical advice, if symptoms occur, which can be caused by the product

After skin contact: Wash with plenty of water and soap

After inhalation: Fresh air

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

After swallowing: If symptoms persist, consult a doctor