

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

	<u>VALUE</u>	<u>UNIT</u>	<u>METHOD</u>
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:	ca. 1.7 (20°C)	g/cm ³	
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 and GGVS/GGVE (Germany): 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.

California Proposition 65:

This product does not contain any chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

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.

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USA®

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Rx Only



BRASSELER
USA®

Evanesce™ Flow
Flowable Restorative

800.841.4522
BrasselerUSA.com

Evanesce™ Flow

Flowable Restorative

INSTRUCTIONS FOR USE

DATE OF ISSUE: April, 2021

DATE OF REVISION: June 2, 2021

Evanesce™ Flow is a visible light-cured flowable nano-composite for anterior and limited posterior restorations. Beside its low shrink and low abrasion Evanesce Flow shows improved mechanical properties.

Evanesce Flow is composed of urethane dimethacrylate resin and inorganic filler particles <1,0 µm. The total filler content is 62% by weight and 48% by volume.

The material properties of Evanesce Flow meet the requirements of ISO 4049.

Indications

- Anterior restorations (class III, IV, V)
- Small class I and II restorations
- Lining of cavities

Side Effects

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol as eugenol inhibits the polymerization of the composite. Evanesce Flow should not be stored in the proximity of, or come in contact with, eugenol-containing products.

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste prior to preparation and colour matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate Evanesce Flow shade.

Evanesce Flow is shaded according to VITA®-Shades.

Cavity Preparation

After isolation (we recommend the use of a rubber dam), prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material.

Condition and apply a bonding agent according to the manufacturer instructions. The total-etch technique with Max-Etch and subsequent application of a light-cure bonding agent, such as MPA Max is recommended. Otherwise use a self-etch bonding agent before application of Evanesce Flow.

Placement of Evanesce Flow

Apply Evanesce Flow in the selected shade. Place it by using a suitable instrument. Matrix strips may be used.

Curing of Evanesce Flow

For an optimum result, apply Evanesce Flow in layers of no greater than 2 mm.

Light-cure each layer separately.

By using a polymerization unit (wavelength range 400-500nm) with a light intensity of at least 1000mW/cm², cure each increment separately.

Lighter shades (e.g. A1, A2, B2): 20 seconds

Darker shades (e.g. A3.5): 30 seconds

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area, contour with finishing diamonds, flexible grinding discs or carbide burs. Polish to high gloss with polishing discs or polishing brushes.

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.

Tips are 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

Limitation of Liability

Except where prohibited by law, Brasseler U.S.A. Dental, LLC 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!

Evanesce™ Flow

Flowable Restorative

SAFETY DATA SHEET

DATE OF ISSUE: April 26, 2017

DATE OF REVISION: June 2, 2021

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

1. Product Identifier

TRADE NAME: Evanesce™ Flow

USE OF THE PREPARATION: Dental product

DETAILS OF THE DISTRIBUTOR OF THE SAFETY DATA SHEET:

DISTRIBUTOR:

Brasseler U.S.A. Dental, LLC

One Brasseler Blvd.

Savannah, GA 31419, U.S.A.

800-841-4522

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 urethane dimethacrylate-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: Seek fresh air

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

After swallowing: If symptoms persist, consult a doctor

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