

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Water contaminating class (D): 1 - slightly water contaminating

15.2. Chemical safety assessment

For this substance a chemical safety assessment is not required.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms

- CAS Chemical Abstracts Service
- IATA-DGR International Air Transport Association-Dangerous Goods Regulations
- ICAO-TI International Civil Aviation Organization-Technical Instructions
- IMDG-Code International Maritime Code for Dangerous Goods
- ISO Norm der Internation Standards Organization
- OECD Organisation for Economic Co-operation and Development
- UN United Nations
- VOC Volatile Organic Compounds
- WGK Water contaminating class

Relevant H and EUH statements (number and full text)

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

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INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

Inspire™ Esthetic Provisional Composite is a highly esthetic composite for fabricating temporary restorations. The two-component system, based on a multi-functional acryl composite is produced using no Bisphenol-A or Bisphenol-A precursors in the manufacturing process. It has similar properties to a filling material and is available in the following shades: A1, A2, A3.5, and B1. Inspire temporary restorations can also be adjusted and customized using flowable light-curing composites.

INDICATIONS FOR USE

- Fabrication of temporary prostheses, such as crowns, partial crowns, bridges, inlays, onlays, and veneers for use until a permanent restoration is fabricated.
- Customization of pre-fabricated acrylic and metal crowns.
- Fabrication of long-term temporary restorations.

WARNINGS

- Do not use if there is a known allergy to methacrylic acid esters.
- Allergic reactions to the product cannot be ruled out with sensitive persons.
- Sensitization possible through skin contact.
- Inspire temporary restorations are intended for use as temporary restorations and not as permanent restorations.
- Temporary luting cements that contain eugenol can inhibit the curing of permanent composite cements, which may be used later for final cementation.

CAUTIONS

- Do not use after expiration date.
- Do not leave any residue of the temporary crown and bridge material in the sulcus, on the tooth or oral cavity.
- Do not swallow the material! If swallowed accidentally, consult a doctor if problems arise or persist.
- Avoid contact with the eyes. If accidental eye contact, rinse immediately, carefully and thoroughly with eye wash or water. Consult a doctor if problems arise or persist.
- Do not inhale grinding dust. Use safety glasses and face mask!
- Any area of the impression with severe undercuts and very wide interdental spaces should be blocked out in the usual way.
- Avoid contact with clothing, as the material cannot be removed by dry cleaning.
- Safety data sheets are available at www.clinicianschoice.com

TECHNICAL DATA

WORKING AND SETTING TIMES

0:00 - 0:40 sec	1:30 - 2:30 min	From 4:30 mins
Inject Inspire Esthetic Provisional Composite into the impression and place in the mouth.	Remove from the mouth.	Prepare the temporary restoration.

Note: Working times apply for products which have been stored and processed at a temperature of 23°C/74°F and a relative humidity of 50%. Higher temperatures shorten working time and lower temperatures extend the working time.

PRELIMINARY IMPRESSION

All standard impression materials can be used for fabrication of a temporary crown, bridge, inlay or onlay.

TEMPLATE Ultra Quick Matrix Material is ideal for taking an anatomical impression. Setting quickly, in just 30 seconds, TEMPLATE offers an ideal flow, precisely capturing the embrasure areas and fine morphology.

INSTRUCTIONS FOR USE

PREPARATION:

First, take a preliminary impression of the dentition.

A laboratory fabricated, vacuum-formed splint or, in the case of single crowns, a pre-fabricated metal or plastic crown can be used instead of an impression for forming the shape.

The impression can be cut out before use to remove any undercuts and increase the stability of the temporary restoration. A channel can be cut into the impression to create a bar-shaped connection between the spaced abutment teeth. Denture teeth can also be used as space maintainers in the anterior region before taking the impression.

DISPENSING AND MIXING:

Dispense and mix the pastes using a 10:1 dispensing gun and corresponding mixing tip. Only use the mixing tips included/recommended with Inspire Esthetic Provisional Composite

INITIAL DISPENSING:

- Insert the cartridge into the dispensing gun
- Remove the cartridge shipping cap and do not use it to reseal the cartridge in order to avoid trapping air bubbles.
- Before fitting a mixing tip for the first time, advance the plunger into the cartridge and extrude a small amount of material until both materials are dispensed uniformly. Then discard the dispensed paste.

APPLICATION:

To ensure optimal results, we recommend using vinyl or latex gloves.

Place the mixing tip on the cartridge, turn the cap clockwise by 90° until it engages.

With the mixing tip in place, the material requires a certain time before flowing out. The material stops flowing immediately once the pressure on the dispenser handle is reduced. Do not use force to press out any material that has set in the mixing tip, as it may damage the cartridge and mixing tip. Compomer, resin-modified glass ionomers or composite preparation surfaces must be isolated before the application of Inspire eg: Vaseline.

- Extrude an approximately pea-sized amount of material before each use and discard.
- Fill the dried impression, vacuum-formed splint or preformed crown, beginning at the base. Leave the mixing tip immersed in the material during filling to avoid trapping air bubbles.
- The filled mold must be placed in the mouth using light pressure within 40 seconds.
- The material attains an elastic consistency in the mouth 1 minute 30 seconds after the beginning of mixing and should be removed from the mouth together with the impression or vacuum-formed splint by 2 minutes 30 seconds after the beginning of mixing.
- Check the condition of the material in the mouth using the excess material, eg: with a probe, to avoid it curing too much before removal.
- Leave the filled mixing tip on the cartridge after use as a seal.
- Remove the used mixing tip and dispose of it before reusing the cartridge. Fit a new mixing tip and proceed as instructed.

FINISHING:

- Completely wipe off the inhibition layer after the material has fully cured (with alcohol).
- Once the material has cured fully, finish the temporary restoration using cross-cut burs and polishers (eg: EDGE Carbides, Shape & Shine Single Step Diamond Polishers).

CLEANING/DISINFECTING:

If required, the Inspire temporary can be disinfected using standard aqueous disinfectant solutions.

CUSTOMIZATION/RECONTOURING:

The use of a bonding agent is not necessary when using a filling composite in conjunction with Inspire Esthetic Provisional Composite for customization and adjusting the shape. Please adhere to the respective instructions for use with other products.

CEMENTATION:

- Remove any residual separating agent from the prepared tooth before temporary cementation.
- Standard temporary luting materials can be used for cementation.
- Residue of temporary cements that contain eugenol can impair the curing of composite cements used for subsequent permanent luting. If the plan is to use composite cements, the use of a eugenol-free temporary cement, such as Cling², is recommended.

AFTER CEMENTATION:

Carefully check the sulcus and surrounding areas and remove any remaining residue of the temporary material or cement.

REPAIR:

- Roughen the fracture site and create mechanical retention on the adjoining sections.
- Clean using alcohol and then air dry.
- Join or add to newly fabricated restorations using Inspire Esthetic Provisional Composite or a flowable, light-cured filling composite.
- Join or add to existing restorations using Inspire Esthetic Provisional Composite or the combination of a flowable, light-cured filling composite and a bonding agent.
- Cure Inspire or composite according to the respective instructions for use.
- Prepare in the usual way after curing.

STORAGE CONDITIONS

Store in a dry place at room temperature; do not expose to sunlight and avoid exposure to extreme temperature fluctuations.

Do not store in refrigerator.

DISPOSAL

Dispose of the product in accordance with local regulations.



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Inspire™
 Esthetic Provisional Composite

800.433.6628
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SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1. Product Identifier:** Inspire Esthetic Provisional Composite (A1; A2; A3.5; B1)
1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

See Directions for Use for the individual products.

1.3. Details of the supplier of the safety data sheet

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Further information

For dental use only!

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Aliphatic Dimethacrylate

Poly(alkyleneglycol)diacrylate

Signal word: Warning

Pictograms:



Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Precautionary statements

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

2.3. Other hazards

Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Chemical characterization

Preparation of multifunctional methacrylates, filler materials and additives

Hazardous Components

CAS No	Chemical Name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
confidential	Aliphatic Dimethacrylate			5 - < 10 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
confidential	Poly(alkyleneglycol)diacrylate			5 - < 10 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			

Full text of H and EUH statements: see section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

After inhalation

Provide fresh air. Seek medical attention if problems persist.

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

After ingestion

Do NOT induce vomiting. Rinse mouth immediately and drink plenty of water.

Medical treatment necessary.

4.2. Most important symptoms and effects, both acute and delayed

Not applicable.

4.3. Indication of any immediate medical attention and special treatment needed

Not applicable.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

SUITABLE EXTINGUISHING MEDIA

Water spray. Extinguishing powder. Sand. Foam. Carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

Not applicable.

5.3. Advice for firefighters

No special technical protective measures are necessary.

Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Avoid contact with skin.

6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up

Take up mechanically. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Not applicable.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

ADVICE ON SAFE HANDLING

Store cartridge at ambient temperatures. Avoid heat sources and direct sunlight.

FURTHER INFORMATION ON HANDLING

The usual precautions when handling chemicals have to be obtained.

When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

7.3. Specific end use(s)

Not applicable.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

8.2. Exposure controls

PROTECTIVE AND HYGIENE MEASURES

The usual precautions when handling chemicals have to be obtained.

Eye/face protection

Safety glasses.

Hand protection

Protective gloves.

Suitable material:

Butyl rubber, NR (Natural rubber (Caoutchouc), Natural latex), PVC (Polyvinyl chloride).

Unsuitable material:

NBR (Nitrile rubber).

Skin protection

Protective clothing.

Respiratory protection

Not required.

Respiratory protection

Not required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Paste

Color: light beige

Odor: nearly odorless

Changes in the physical state

Flash point:

Sustaining combustion: > 100 °C / >212 °F

Not sustaining combustion

Density (at 20 °C):

ca. 1,4 g/cm³

Water solubility:

Viscosity / dynamic:

(at 23 °C)

9.2. Other information

Not applicable.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Not applicable.

10.2. Chemical stability

Not applicable.

10.3. Possibility of hazardous reactions

None by intended use.

10.4. Conditions to avoid

None by intended use.

10.5. Incompatible materials

Radical former. Reducing agents.

10.6. Hazardous decomposition products

None by intended use.

Test method

> 100 °C / >212 °F

Not sustaining combustion

ca. 1,4 g/cm³

practically insoluble

ca. 9000 mPa·s

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Toxicological data are not available.

Irritation and corrosivity

Irritant effect on the skin: Irritant effect on the eye.

Sensitizing effects

Sensitization through skin contact possible.

Carcinogenic/mutagenic/toxic effects for reproduction

No experimental indications of mutagenicity in-vitro exist.

No experimental indications of mutagenicity in-vivo exist.

Practical experience

Observations relevant to classification

No data available

Further information

May cause an allergic skin reaction.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Do not allow uncontrolled leakage of product into the environment.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

None by intended use.

12.4. Mobility in soil

None by intended use.

12.5. Results of PBT and vPvB assessment

None by intended use.

12.6. Other adverse effects

None by intended use.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

Carry out a burning of hazardous waste according to official regulations.

Waste disposal number of waste from residues/unused products

070799 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fine chemicals and chemical products not otherwise specified; wastes not otherwise specified

Waste disposal number of used product

200301 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; mixed municipal waste

Waste disposal number of contaminated packaging

200301 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; mixed municipal waste

SECTION 14: TRANSPORT INFORMATION

Land transport (ADR/RID)

14.1. UN number: N/A

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

14.3. Transport hazard class(es): N/A

14.4. Packing group: N/A

Inland waterways transport (ADN)

14.1. UN number: N/A

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

14.3. Transport hazard class(es): N/A

14.4. Packing group: N/A

Marine transport (IMDG)

14.1. UN number: N/A

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

14.3. Transport hazard class(es): N/A

14.4. Packing group: N/A

Segregation group: ammonium compounds

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: N/A

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

14.3. Transport hazard class(es): N/A

14.4. Packing group: N/A

Danger releasing substance: N/A

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

Danger releasing substance: No risks worthy of mention.

14.6. Special precautions for user

N/A

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

N/A

Other applicable information

No dangerous good in sense of these transport regulations.