

Safety Data Sheet

*** Section 1 - Commercial Product Name and Supplier***

Commercial Product Name: NuSmile BioCem Universal BioActive Cement

Application/Use: Dental Material for use by dental professional only.

Use Category: 55

Manufacturer

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*** Section 2 - Hazards Identification ***

GHS Classification

Classification According to Regulation (EC) No. 1272/2008 [CPL]

<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>
Eye Irritation	2	H319
STOT SE	3	H335
Skin Irritation	2	H315
Skin Sensitization	1	H317

Classification According to Directive 67/548/EEC

(See SECTION 16 for full text of risk phrases)

Irritant; Xi; R36/37/38-43

GHS Label Elements

Symbol(s)



Signal Word

WARNING

Hazard Statements

H319: Eye Irritation. 2. May cause eye irritation

H335: STOT SE. 3. May cause respiratory irritation.

H315: Skin irritation. 2. May cause skin irritation.

H317: Sensitization. 1. May cause an allergic skin reaction.

Precautionary Statements

Prevention

P261: Avoid breathing vapor.

P280: Wear protective gloves and eye protection

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Response

P305+P351: If in eyes, rinse cautiously with water for several minutes.

P337+P313: If eye irritation persists, get medical advice/attention.

P302+P352: If on skin, wash with plenty of soap and water.

P333+P313: If irritation or rash occurs, get medical advice/attention.

Storage

P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

*** Section 3 – Composition / Information on Ingredients ***

Chemical Characterization of the Preparation

Resin-modified glass ionomer dental material

Hazardous Ingredients

Cas Number	Name of the Ingredient	Concentration Base/ Liner	Concentration Restorative	Classification per 67/ 548/EEC	Classification per Regulation(EC) No. 1278/208 (CPL)
Proprietary	Blend of diurethane and other methacrylates with modified polyacrylic acid	53.2%	44.6%	Irritant; Xi R 3637/38-43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
112945-52-5	Silica, amorphous	30%	6.7%	Irritant; Xi R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
7681-49-4	Sodium fluoride	0.90%	0.75%	Harmful (Xn); R22-36/38	Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H319

*** Section 4 - First Aid Measures ***

General Information

May be irritating to eyes, respiratory system and skin. Avoid contact with eyes and skin.

Do not inhale vapors. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

First Aid: Eyes

Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.

First Aid: Skin

Take off contaminated clothing. Wash skin thoroughly with soap and water.

First Aid: Ingestion

Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

First Aid: Inhalation

Move to fresh air. Administer oxygen/CPR as needed. Seek medical attention.

Precautions for First Responders

Ventilate the area. Wear eye and skin protection.

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Information for Physicians

Symptoms- Irritation or redness in eyes, throat or on skin.

Hazards- May be irritating to eyes, respiratory system, skin. May be sensitizing by skin contact.

Treatment- As above under First Aid.

Section 5 - Fire Fighting Measures

General Fire Hazards

See Section 9 for Flammability Properties.

Not flammable.

Suitable Extinguishing Media

Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

Extinguishing Media to Avoid

Do not use direct water stream.

Special Exposure Hazards in a Fire

Heat may cause polymerization with rapid release of energy.

Special Protective Equipment for Fire-Fighters

A self-contained breathing apparatus should be worn by firefighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

*** Section 6 - Accidental Release Measures ***

Personal Precautions

Wear safety glasses, gloves and lab coat.

Environmental Precautions

Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.

Method for Clean Up

Contain spilled material. Absorb or wipe up spill with suitable material (e.g. paper towels). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

*** Section 7 - Handling and Storage ***

Handling

For use only by dental professionals. Practice good hygiene. Avoid direct/strong light sources, extremes of temperature (>27°C/80°F, <5°C/40°F), contamination, cross contamination of two-part materials. Recap immediately after use.

Storage

Keep container tightly closed. Store in original container at cool room temperature (<25°C). Avoid direct/strong light, sources of ignition, extremes of temperature. Shelf life for properly stored, unopened product is two years from date of manufacture.

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Specific Uses

Dental base/liner, cement or restorative

*** Section 8 - Exposure Controls / Personal Protection ***

Component Exposure Limits

PEL: Not established. TLV: Not established.

Exposure Controls

Occupational Exposure Controls

No special equipment required under normal conditions of use.

Respiratory Protection

None required. Good general ventilation is sufficient to control any airborne vapors.

Personal Protective Equipment: Hands

No special requirements other than the usual surgical gloves.

Personal Protective Equipment: Eyes

No special requirements other than the usual safety glasses worn by dental staff.

Personal Protective Equipment: Skin and Body

No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to uncured material.

Other Controls

Emergency eye wash fountain should be available. Wash hands after use.

Environmental Exposure Controls

Cure material before disposing.

*** Section 9 - Physical and Chemical Properties ***

Appearance / Color:	Part A	Part B
Physical State / Color:	Yellowish	Off-white
Specific Gravity:	1.460 +/- 0.02 g/mL	1.380 +/- 0.02 g/mL
Odor:	Faint, characteristics	

Important Health, Safety and Environmental Information

pH:	Not determined
Boiling Point:	Not determined
Flash Point:	Not determined
Flammability (solid, gas):	Not applicable
Explosive Properties:	Not applicable
Oxidizing Properties:	Not determined
Vapor Pressure:	< 1 mm Hg
Solubility in Water:	Nil
Partition Coefficient:	Not determined
Viscosity:	Not determined
Vapor Density:	Not determined
Evaporation Rate:	Not determined

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*** Section 10 – Chemical Stability and Reactivity Information ***

Conditions to Avoid

Temperature > 38°C, intense light, cross-contamination.

Materials to Avoid

Reducing and oxidizing agents, peroxides, amines.

Hazardous Decomposition Products

Under fire conditions, amounts greater than that supplied in this product may polymerize with heat build-up, release of oxides of carbon and nitrogen.

Further Information

Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

*** Section 11 – Toxicological Information ***

Acute Toxicity

Finished products in paste form present a minimal health hazard under normal conditions of use and in the quantities necessary for dental procedures.

Sodium fluoride: Oral rat LD50: 180 mg/kg

Silica, amorphous: Oral rat LD50: 3160 mg/kg

Irritation and Corrosiveness

May be irritating to eyes, respiratory tract, mucous membranes or skin on contact or with prolonged exposure.

Sensitization

May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.

Sub-acute, Sub-chronic and Prolonged Toxicity

Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) may cause eye and respiratory irritation.

Carcinogenicity, Mutagenicity, Reproductive Toxicity

None known

Empirical Data

Biocompatibility has been tested and found to be acceptable.

Clinical Experience

NuSmile BioCem is a new product that has been evaluated by dentist consultants. There have been no reports of adverse events.

*** Section 12 - Ecological Information ***

Ecotoxicity

A. General Product Information

Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert.

B. Component Analysis- Ecotoxicity- Aquatic Toxicity

No ecotoxicity data are available for this product's components.

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*** Section 13 - Disposal Considerations ***

Waste Disposal Instructions

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

Disposal of Contaminated Containers or Packaging

Dispose of contents/container in accordance with local/regional/national/international regulations.

*** Section 14 - Transport Information ***

DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

EU	Class IIa medical devices under MDD 93/42/EEC.
US FDA	Class II medical devices.
Health Canada	Class III medical devices

*** Section 16 - Other Information ***

List of Relevant R Phrases

R36/37/38: Irritating to eyes, respiratory system and skin.

R43: Sensitizing by skin contact.

Hazard Statements

H319: Eye irritation. Hazard category 2.

H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation.

H315: Skin irritation. Hazard category 2.

H317: Skin Sensitization. Hazard category 1.

Precautionary Statements

P261: Avoid breathing vapor.

P280: Wear protective gloves and eye protection

P305 + P351: If in eyes, rinse cautiously with water for several minutes.

P337 + P313: If eye irritation persists, get medical advice/attention.

P302 + P352: If on skin, wash with plenty of soap and water.

P333 + P313: If irritation or rash occurs, get medical advice / attention.

P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

Restrictions on Use

NuSmile BioCem is to be sold to and used by dental professionals only.

Further Information

The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which NuSmile LTD bears

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legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

Sources of Key Data

National Institute for Occupational Safety (NIOSH)

US Occupational Safety and Health Administration (OSHA)

Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).

Guidance on the compilation of safety data sheets. Version 1.1; December 2011.

European Chemicals Agency

Information which has been added, deleted or revised.

This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.