

HOJA DE DATOS DE SEGURIDAD DEL MATERIAL

BESTDENT
C/ Botánica N° 137
08908 L' hospitalet de Llobregat
Barcelona, España.



GRADO DE PELIGRO	
■ SALUD	0 MINIMO
■ INFLAMABILIDAD	1 LEVE
■ REACTIVIDAD	2 MODERADO
AVISO ESPECIAL	3 SERIO
	4 EXTREMO

SECCIÓN I – IDENTIFICACIÓN DE SUBSTANCIAS

NOMBRE PRODUCTO: COMPOSITE PM MICROHIBRIDO FOTOPOLIMERIZABLE

DESCRIPCIÓN DEL PRODUCTO: COMPOSITE FOTOPOLIMERIZABLE, SOLO PARA PROFESIONISTAS DENTALES

SECCIÓN II – COMPOSICIÓN /DATOS DE LOS COMPONENTES

INGREDIENTES	%	CAS.NO.
CUARZO SILANIZADO TRATADO	70-80	----
BIS-GMA (LIBRE DE BISFENOL A)	1-10	1565-94-2
TRITILENGLICOL DIMETACRILATO (TEGDMA)	1-5	109-16-0
DIURETAN DIMETACRILATO	1-10	72869-86-4
FOTOINICIADORES	< 1	10334-26-6

(COMPONENTES NO PELIGROSOS)

SECCIÓN III – IDENTIFICACIÓN DE PELIGROS

DESCRIPCIÓN DEL RIESGO	
	IRRITANTE LEVE EN LOS OJOS Y LA PIEL. PUEDE CAUSAR SENSIBILIZACIÓN POR CONTACTO CON LA PIEL.

SECCIÓN IV – MEDIDAS DE PRIMEROS AUXILIOS

CONTACTO CON LA PIEL	LAVAR INMEDIATAMENTE CON JABON Y ABUNDANTE AGUA. SI LA IRRITACIÓN PERSISTE BUSQUE ATENCIÓN MÉDICA.
CONTACTO CON LOS OJOS	LAVAR LOS OJOS INMEDIATAMENTE CON ABUNDANTE AGUA. SI LA IRRITACIÓN PERSISTE BUSCAR ATENCIÓN MEDICA.
INHALACIÓN	PERMITIR A LA VÍCTIMA DESCANSAR EN UN ÁREA BIEN VENTILADA. SI LA IRRITACIÓN PERSISTE BUSQUE ATENCIÓN MÉDICA.
INGESTIÓN	NO INDUCIR VÓMITO A MENOS QUE SE LO INDIQUE EL PERSONAL MÉDICO. DÉ A LA VÍCTIMA DOS VASOS DE AGUA. NUNCA DAR NADA POR LA BOCA A UNA PERSONA INCONSCIENTE. SI LOS SÍNTOMAS PERSISTEN, BUSQUE ATENCIÓN MÉDICA.

SECCIÓN V – MEDIDAS CONTRAINCENDIOS

EXTINGUIDOR RECOMENDADO	2 DIÓXIDO DE CARBONO, ESPUMA, POLVO QUÍMICO.
EXTINGUIDOR A EVITAR	NINGUNO CONOCIDO
EQUIPO DE PROTECCIÓN Y PROCEDIMIENTO PARA LOS BOMBEROS	USAR EQUIPOS DE PROTECCIÓN RESPIRATORIA, GANTES Y TRAJE PROTECTOR

SECCIÓN VI – MEDIDAS EN CASO DE VERTIDO ACCIDENTAL

DERRAMES Y FUGAS	LIMPIE MECÁNICAMENTE. QUITAR CON MATERIAL ABSORBENTE INERTE (ARENA SECAS AGLUTINANTE UNIVERSAL, ASERRÍN).Y COLÓQUESE EN RECIPIENTES CERRADOS DISPONGA DE ACUERDO A LAS REGULACIONES LOCALES Y NACIONALES.
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SECCIÓN VII – MANEJO Y ALMACENAMIENTO

MANEJO Y ADVERTENCIAS	EL PRODUCTO ESTÁ DISEÑADO PARA USO DENTAL ÚNICAMENTE. EL MANEJO DE ESTE PRODUCTO DEBE SER USADO POR PROFESIONALES DE LA SALUD DENTAL SOLAMENTE.
ALMACENAMIENTO Y ADVERTENCIAS	CONSERVAR SÓLO EN EL ENVASE ORIGINAL. MANTENER EL ENVASE BIEN CERRADO. CONSERVAR EN UN LUGAR SECO. CONSERVAR LEJOS DE ALIMENTOS Y BEBIDAS. PROTEGER CONTRA EL EXCESO DE CALOR Y FRIO.

SECCIÓN VIII –CONTROLES DE EXPOSICIÓN Y PROTECCIÓN PERSONAL

CONTROLES DE EXPOSICIÓN	CON BUENA VENTILACIÓN EN GENERAL, ES SUFICIENTE
OJOS/CARA	LENTES DE SEGURIDAD (PACIENTE)
PIEL	GUANTES
INHALACIÓN	N/A
CUERPO	USAR ROPA ADECUADA PARA PROTECCIÓN PERSONAL.

SECCIÓN IX – PROPIEDADES FÍSICAS Y QUÍMICAS

APARIENCIA	PASTA SUAVE	GRAVEDAD ESPECIFICA	N/A
COLOR	VITA (A1-D4)	SOLUBILIDAD (AGUA)	N/A
OLOR	SUAVE OLOR A ACRILATO	PRESIÓN DE VAPOR (mm Hg)	N/A
PUNTO DE EBULLICIÓN	N/A	PUNTO DE FUSIÓN	N/A

SECCIÓN X – ESTABILIDAD Y REACTIVIDAD

ESTABILIDAD	EL PRODUCTO ES ESTABLE. BAJO CONDICIONES NORMALES Y CONDICIONES DE ALMACENAMIENTO
INCOMPATIBILIDAD (MATERIALES A EVITAR)	ÁCIDOS FUERTES Y AGENTES OXIDANTES
PRODUCTOS PELIGROSOS DURANTE LA DESCOMPOSICIÓN	MONÓXIDO Y DIÓXIDO, HIDROCARBUROS DE BAJO PESO MOLECULAR.
CONDICIONES A EVITAR	MANTENER ALEJADO DEL CALOR, LA LUZ SOLAR Y LA LUZ DIRECTA INTENSA.

SECCIÓN XI – INFORMACIÓN TOXICOLÓGICA

TOXICIDAD AGUDA	CONTACTO DIRECTO PUEDE PROVOCAR IRRITACIÓN OCULAR PIEL: UNA EXPOSICIÓN REPETIDA O PROLONGADA PUEDE CAUSAR LEVES IRRITACIONES. POSIBILIDAD DE SENSIBILIZACIÓN EN CONTACTO CON LA PIEL EVALUACIÓN BASADA EN LA PRUEBA REAL O EN DATOS DE MATERIALES SIMILARES.
MAS INFORMACIÓN	NO EXISTE PELIGRO ANTICIPADO POR INGESTIÓN DE PEQUEÑAS CANTIDADES POR LA MANIPULACIÓN NORMAL.

SECCIÓN XII – INFORMACIÓN ECOLÓGICA

SIN PROBLEMAS ECOLÓGICOS QUE ESPERAR SI SE MANEJAN Y UTILIZAN COMO SE INDICA

SECCIÓN XIII – CONSIDERACIONES DE DISPOSICIÓN

LEGISLACIONES: NO SE PUEDE DESECHAR CON LA BASURA DOMÉSTICA. DISPONGA DEL MATERIAL COMO RESIDUO SOLIDO EN UN RECIPIENTE CERRADO.
DISPONGA DE ACUERDO A LAS REGULACIONES NORMATIVAS FEDERALES, ESTATALES Y LOCALES.

SECCIÓN XIV – INFORMACIÓN SOBRE TRANSPORTE

NO REQUERIDA

SECCIÓN XV – INFORMACIÓN REGLAMENTARIA

ESTE PRODUCTO ES UN DISPOSITIVO MEDICO Y NO ESTA SUJETO A LOS REQUERIMIENTOS DE NOTIFICACIÓN QUÍMICA.
REGULADO PARA EMBARQUE: NO REGULADO.
SIMBOLO: N/D
CATEGORIA DE PELIGRO: N/D

SECCIÓN XVI – OTRA INFORMACIÓN

LA INFORMACIÓN EN ESTA HOJA DE DATOS DE SEGURIDAD ESTA BASADA EN NUESTRO PRESENTE CONOCIMIENTO. ESTA INFORMACIÓN ES PRESENTADA CON LA INTENCIÓN DE DESCRIBIR LA SEGURIDAD EN EL MANEJO DEL PRODUCTO. LA HOJA DE DATOS DE SEGURIDAD NO SE DEBE CONSIDERAR COMO UNA DESCRIPCIÓN QUÍMICA COMPLETA DE EL PRODUCTO.

* N/E: NO ESTABLECIDO, N/D: NO DISPONIBLE, N/R: NO REGULADO POR IARC, N/A. NO APLICA

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SECTION 1: Identification

1.1 Product Identifier

MICROHYBRID LIGHT CURE COMPOSITE BESTDENT

1.2 Recommended use and restrictions on use

Recommended use

Dental Product, Restorative

Restrictions on use

For use only by dental professionals

SECTION 2: Hazard Identification

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

2.1. Hazard classification

Skin Sensitizer: 1. H317

Aquatic Chronic 3; H412

2.2. Label elements

Signal word

Warning

Symbols

Exclamation mark !

Read instructional before use

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Pictograms



Hazard Statements

H317: May cause an allergic skin reaction

H412: Harmful to aquatic life with long lasting effects

Precautionary Statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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

P333+ P313 If skin irritation or rash occurs: Get medical advice/ attention.

P273 Avoid release to the environment.

P501 Dispose of contents/container to Hazardous to the aquatic environment

P272 Contaminated work clothing should not be allowed out of the workplace.

P321 Specific treatment. Skin sensitization.

P363 Wash contaminated clothing before reuse.

Prevention:

Avoid breathing dust/fume/gas/mist/vapors/spray.

Contaminated work clothing must not be allowed out of the workplace.

Response:

IF ON SKIN: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

Disposal:

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

2.3. Hazards not otherwise classified

None. 31% of the mixture consists of ingredients of unknown acute oral toxicity.

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SECTION 3: Composition/information on ingredients

Ingredient	CAS No.	% by Wt.	Classification
SILANIZED QUARTZ	-----	70-80*	Substance not classified as hazardous
Bis-GMA (BISPHENOL A FREE)	1565-94-2	1-10*	Skin Sens, 1B, H317
DIURETHANE DIMETHACRYLATE (UDMA)	72869-86-4	1-10*	Hazardous to the aquatic environment, 2, H411
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	109-16-0	1-5*	Skin Sens, 1, H317
PHOTOINITIATOR	10373-78-1	<1*	Skin Irrit. 2, H315 Eye Irrit. 2, H319
STABILIZER	128-37-0	<1*	Aquatic Chronic 1 H:410

* The specific chemical identity and / or exact percentage (concentration) of this composition has been withheld as a trade secret

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:

Allow the victim to rest in a well ventilated area. if irritation persists , seek medical attention

Skin Contact:

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye Contact:

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If Swallowed:

Rinse mouth. If you feel unwell, get medical attention.

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

See Section 11.1. Information on toxicological effects.

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

Not applicable.

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SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

5.3. Special protective actions for fire-fighters

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Contain spill. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid breathing of dust created by cutting, sanding, grinding or machining. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, dust/fume/gas/mist/vapors/spray. Do not get in eyes,

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on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.)

7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Store away from oxidizing agents.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Ingredient	CAS No.	Agency	Limit type	Additional Comments
FLUORIDES	13760-80-0	ACGIH	TWA(as F):2.5 mg/m ³	A4: Not class. as human carcin
FLUORIDES	13760-80-0	OSHA	TWA(as dust):2.5 mg/m ³ ;TWA(as F):2.5 mg/m ³	

ACGIH : American Conference of Governmental Industrial Hygienists

OSHA : United States Department of Labor - Occupational Safety and Health Administration

TWA: Time-Weighted-Average

8.2. Exposure controls

8.2.1. Engineering controls

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure

Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment.

The following eye/face

protection(s) are recommended:

Safety Glasses with side shields

Skin/hand protection

See Section 7.1 for additional information on skin protection.

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Respiratory protection

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Physical Form:	Solid
Specific Physical Form:	Paste
Odor, Color, Grade:	Slight acrylate odor, tooth colored
Odor threshold	<i>No Data Available</i>
pH	<i>Not Applicable</i>
Melting point	<i>No Data Available</i>
Boiling Point	<i>Not Applicable</i>
Flash Point	No flash point
Evaporation rate	<i>Not Applicable</i>
Flammability (solid, gas)	Not Classified
Flammable Limits(LEL)	<i>Not Applicable</i>
Flammable Limits(UEL)	<i>Not Applicable</i>
Vapor Pressure	<i>Not Applicable</i>
Vapor Density	<i>Not Applicable</i>
Density	<i>Not Applicable</i>
Specific Gravity	<i>Not Applicable</i>
Solubility in Water	Negligible
Solubility- non-water	<i>No Data Available</i>
Partition coefficient: n-octanol/ water	<i>Not Applicable</i>
Autoignition temperature	<i>No Data Available</i>
Decomposition temperature	<i>No Data Available</i>
Viscosity	<i>No Data Available</i>

SECTION 10: Stability and reactivity

10.1. Reactivity

When exposed to light it begins to polymerize.

10.2. Chemical stability

Stable when stored and handled following the recommended conditions.

10.3. Possibility of hazardous reactions

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Hazardous polymerization will not occur.

10.4. Conditions to avoid

Heat

High shear and high temperature conditions

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
None known	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:

Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin Contact:

May cause an allergic skin reaction. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye Contact:

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion:

May be harmful if swallowed.

Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Aspiration Hazard

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For the components, there is no data available

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

Harmful to aquatic life with long lasting effect

Ecotoxicological information

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

Chemical fate information

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

12.1 Persistence and degradability

Name	No. CAS	Type of test	Duration	Type of study	Test result	Protocol
Bis-GMA (BISPHENOL A FREE)	1565-94-2	estimated biodegradation	28 days	biological oxygen demand	33% in weigh	OECD 301C-MITI(1)
TRIETHYLENE GLIYCOL DIMETHACRYLATE (TEGDMA)	109-16-0	estimated biodegradation	28 days	biological oxygen demand	60% in weigh	Other methods

SECTION 13: Disposal considerations

13.1. Disposal methods

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

Incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

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SECTION 14: Transport Information

Not required

SECTION 15: Regulatory information

This product is a medical device and not subject to chemical notification requirements.

regulated for shipping: not regulated

symbol: n/a

categories of danger: n/a

SECTION 16: Other information

NFPA Hazard Classification

Health: 2 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.