DATE: 06/08/2019	**SURGICAL CEMENT**

Section 1 PRODUCT IDENTIFICATION

Product:	Surgical Cement (Acrylic resin with a powder component and a liquid component)
Product use:	The mixture of both components is used for the repair of cranial and facial bone defects of traumatic, surgical or tumor origin. Their reaction gives rise to a solid and rigid piece (cured cement).
Maker:	Laboratorios SL SA, Estados Unidos 4503 (B1667JHA), Area Promoción el Triangulo, Malvinas Argentinas, Buenos Aires, Argentina. (+54 11) 5272 4060 e-mail: info@subiton.com
Authorized representative to the EU:	Synimed Synergie Ingénierie Médicale SARLZA de l´Angle, 19370 Chamberet, France
Emergency telephone number:	Tel. +5411 52724060

Section 2 HAZARDS IDENTIFICATION

2.1 Classification of the mixture

Component	Description	Classes and categories of danger	Warnings
Solid	Methyl polymethacrylate	Non-hazardous	-
	Barium sulfate	Non-hazardous	-
Liquid	Methyl methacrylate	Flammable liquid (Category 2) Skin irritation (Category 2) Skin sensitization (Category 1) Specific toxicity for target organs - single exposure (Category 3)	H225 H315 H317 H335
	N, N-dimethyl p-toluidine	Specific toxicity for target organs - repeated exposure (Category 2) Toxicity for the aquatic environment (Category 3) Acute toxicity, inhalation (Category 3) Acute toxicity, Dermal (Category 3) Acute toxicity, oral (Category 3)	H373 H412 H311 H331 H301

2.1.2 Classification according to Directives 67/548 / CEE or CEE or 1999/45 / CE

Component	Description		R and S phrases
Solid	Methyl polymethacrylate	Non-hazardous	-
	Barium sulfate	Non-hazardous	-
Liquid	Methyl methacrylate	Flammable, irritant	R11 / R37 / R38 / R43
	N, N-dimethyl-p-toluidine	Toxic by inhalation, skin contact and ingestion. Danger of cumulative effects. Harmful to aquatic organisms.	R23/24/25 R33 R52/53
Notes: Carcinogenicity, teratogenicity, mutagenicity, chronic toxicity on the reproductive system and synergistic properties are not known			

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Section 3 COMPOSITION / INFORMATION ON INGREDIENTS

Component overview: powder mainly composed of methyl methacrylate polymers and liquid mainly composed of methyl methacrylate		
Chemical name	CAS No.	Concentration (%)
Solid component		
Methyl polymethacrylate	9011-14-7	~85-90
Barium sulfate	7727-43-7	~8-10
Liquid component		
Methyl methacrylate	80-62-6	~97-99
N, N-dimethyl-p-toluidine	99-97-8	~0.5-1.5

Section 4. FIRST AID MEASURES

In case of Inhalation
Remove the affected person to fresh air, get medical help if the discomfort persists.
In case of skin contact
Take off contaminated clothing and wash skin with plenty of soap and water. In case of skin reactions seek medical assistance.
In case of eye contact
Rinse with plenty of water for 15 minutes, even under the eyelids.
In case of ingestion
Rinse the mouth with water if the affected person is conscious. Do not induce vomiting and do not give the affected person anything to eat or drink.

Section 5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing media
Use Class B fire extinguishing media: Carbon Dioxide, Dry Powder, Fog, or Foam.

5.2 Fire extinguishing media that must not be used for safety reasons
High volume water jet.

5.3 Special risks of exposure derived from the substance, the products of combustion or the gases produced.
Avoid breathing combustion gases as they can be toxic after the fire
Solid component:combustible but not easily flammable at high temperatures. The minimum ignition temperature of a dust cloud is approximately 480ºC.
Liquid component:Flammable..

5.4 Special protective devices for fire-fighting staff
Advice for firefighters in case of fire, cool the containers or take them to a safe place. Use water spray to cool unopened containers. In the event of a fire wear respiratory protective equipment regardless of the surrounding air and protective clothing.

Section 6. MEASURES IN CASE OF ACCIDENTAL SPILLAGE (see also sections 8 and 13)

6.1 Personal precautions, protection devices and emergency procedures
Do not breathe dust. Provide ventilation. Eliminate any source of ignition: avoid sources of sparks and ignition. Avoid contact with skin, eyes and clothes.

6.2 Environmental precautions
Avoid spilling the product in the sewerage and aquifers.

6.3 Methods and material for containment and decontamination
Powder component: Minimize airborne particle suspension (eg, use industrial vacuum cleaner) or wet sweep.
Liquid component: Dry with inert adsorbent material, collect in containers and dispose of in an authorized company.
Whash the contaminated place after having collected all the material.

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid inhalation of vapours. Avoid contact with eyes, skin and clothes. Avoid prolonged exposure. Get adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities
Keep tightly sealed. Store in a cool, ventilated place, away from any sources of heat, sparks, and open flames.

Section 8. PERSONAL PROTECTION / EXPOSURE CONTROLS

8.1 Control parameters (values)
Exposure limit values
Solid component: Does not contain substances with an occupational exposure limit value
Liquid component: TLV-STEL: 100 ppm
TLV- TWA: 50 ppm

8.2 Exposure control: In case of handling: use gloves, safety glasses and mask.

Solid component: If operating procedures to limit exposure are not adequate, use P1 type filter masks)
Liquid component: Avoid inhaling liquid vapours, if necessary using full masks with combined filters.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties.

Solid Component (polymer)

Appearance: Volatile Fine Powder	Self-ignition temperature: 304 ºC
Colour: White	Explosive properties: Not applicable
Odour: Odourless	Oxidizing properties Not applicable

Olfatory threshold: Not applicable	Vapor pressure: Not applicable
pH: not applicable	Relative density: 1.2 g /cm^3
Boiling point: Not applicable	Solubility in water at 20ºC: Insoluble
Melting Point/ freezing point: Not applicable	Solubility in flax oil at 20ºC: Insoluble
Flash point: :> 250ºC	Partition coefficient:: Not applicable
Flammability limit (lower): Not applicable	Viscosity: not applicable
Flammability limit (upper): Not applicable	Vapor density: Not applicable

Liquid Component (methyl methacrylate)

Appearance: Liquid	Vapor pressure: 51.3 hPa at 25ºC
Colour: Transparent colourless	Vapor density: 3.46
Odor: Characteristic: strong and pungent	Relative density: 0.936 g / cm3 at 25ºC
Odor Threshold: No data available.	Solubility in water: 15 g / l
pH: not applicable	Partition coefficient: Log pow 1.38
Melting Point/freezing point: –48 ºC	Auto-ignition temperature: 430ºC *
Initial boiling point: 100 ºC	Decomposition temperature: No data available
Flash Point: 9ºC (closed cup)	Viscosity: No data available
Evaporation rate: No data available	Explosive properties: Does not apply
Flammability (solids, gases): No data available	Oxidative properties: Does not apply
Flammability limit (upper): 12.5%	Surface tension: 28 mN / m at 20ºC
Flammability limit (lower): 2.12%	Relative vapor density: 3.46- (Air = 1.0)

9.2 Other safety information

Liquid component:

- Ignition temperature 430 °C Method: DIN 51 794 tested substance:, methyl methacrylate
- Autoinflammability Not capable of spontaneous combustion or heating.
- Self accelerating polymerization temp (ºC) > 60ºC

Section 10. STABILITY AND REACTIVITY

10.1 Reactivity
N / A

10.2 Chemical stability
The liquid component is stable under recommended storage conditions. Avoid contact with incompatible materials.

10.3 Possibility of hazardous reactions
N / A

10.4 Conditions to avoid
The liquid component can polymerize if exposed to: heat, flames and sparks, extreme temperatures and direct sunlight, humidity and strong light, in particular fluorescent or UV.

10.5 Incompatible materials
Oxidizing agents, peroxides, bases, strong acids, reducing agents and halogens.

10.6 Hazardous decomposition products
N / A

10.7 Materials to avoid
The liquid component can polymerize: avoid organic peroxides, catalysts, free radical generators and multivalent metal oxides.

10.8 Decomposition products
Carbon monoxide, carbon dioxide. In case of fire see section 5

Section 11. TOXICOLOGICAL INFORMATION

Solid Component

Possible health consequences:
Inhalation: can be harmful if inhaled, causing irritation of the respiratory tract.
Ingestion: May be dangerous if swallowed.
Skin: can cause irritation
Eyes: can cause irritation

Additional Information
RTECS: Methyl Polymethacrylate TR0400000
RTECS: Barium Sulfate: No Data Available

Liquid Component

Inhalation
Irritating to respiratory system. High concentrations in the atmosphere can lead to irritation of the respiratory tract, vertigo, headache and anesthetic effects.

Skin contact:
May cause sensitization by skin contact. Irritating to skin. Repeated or prolonged contact can cause dermatitis.

Eye contact:
Irritating to eyes. A high concentration of steam will produce irritation.
Ingestion.
Low oral toxicity, but ingestion can irritate the gastrointestinal tract.

Long-term exposure
Repeated exposure to high concentrations produces adverse effects on the heart, lungs, liver and kidneys.
Repeated exposure by inhalation of animals at concentrations equal to or greater than the occupational exposure limit produces adverse effects on the nasal epithelium (concentrations of 100 and 400 ppm)
Based on animal studies, appropriate mutagenicity studies and adequate epidemiology studies in representative cohorts, there is no reason to believe that methyl methacrylate represents a carcinogenic or mutagenic risk to man.
Studies have revealed that high exposures do not produce toxic effects for the embryo or fetus, nor teratogenic effects in the presence of maternal toxicity.
None of these effects are likely to occur in humans, provided that the exposure is maintained at or below the Occupational Exposure Limit level.

Section 12. ECOLOGICAL INFORMATION

Component Powder and Cured Cement:

Ecotoxicity: Non-toxic
Mobility: The product is insoluble in water. It is foreseeable that it has low mobility on the ground.
Persistence and Degradability: Not easily biodegradable. Persistent.
Bioaccumulative Potential: The product has a low bioaccumulation potential**.**
Other Harmful Effects: They don't know each other.

Liquid Component

Ecotoxicity
Low toxicity to fish. LC50 (fish) Typically:> 100mg / L
Harmful to aquatic invertebrates: EC50 (Daphnia magna) (48 hours) 69 mg / L
Low toxicity to algae. EC50 (selenastrum capricornutum) 170 mg / L
Mobility: The product is limitedly soluble in water. It is expected that it will have high mobility on the ground.
Persistence and Degradability: Not easily biodegradable. Chemical Oxygen Demand (COD) 88% (28 days) Inherent biodegradation: Elimination of dissolved organic carbon (Elimination of COD)> 95% (28 days)
Bioaccumulative Potential: The product has a low bioaccumulation potential.
Other Harmful Effects They don't know each other.

Section 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Mix the powder with the liquid from a plane to obtain a non-hazardous product and / or dispose of the product in accordance with current local or national legislation.
Dispose of as contaminated container.

Section 14. TRANSPORT CONSIDERATIONS

14. 1 UN number:
Solid component: Non-hazardous
Liquid component: ADR / RID: 1247, IMDG: 1247, IATA: 1247

14.2 UN regulations
Solid component: Non-hazardous
Liquid component: ADR / RID: Methyl Methacrylate Monomer Stabilized, IMDG: Methyl Methacrylate Monomer Stabilized, IATA: Methyl Methacrylate Monomer Stabilized

14.3 Hazard classes for transport materials
Solid component: Non-hazardous
Liquid component: ADR / RID: 3, IMDG: 3, IATA: 3

14.4 Packaging unit
Solid component: Non-hazardous
Liquid component: ADR / RID: II (Liquid Component), IMDG II: (Liquid Component), IATA II (Liquid Component)

14.5 Environmental hazards
Solid component: ADR / RID: No IMDG Marine Pollutant: No IATA: No
Liquid component: ADR / RID: No IMDG Marine Pollutant: No IATA: No

Section 15. REGULATORY INFORMATION

Cementos Ortopédicos de Laboratorios SL SA are approved and CE marked, under European regulations, as a class llb medical device (medical device).

This safety sheet meets the requirements of the regulation (CE) No. 1907/2006

Section 16. OTHER INFORMATION

Laboratorios SL SA hereby authorize the printing of an unlimited number of copies exclusively for internal use. The information contained in this safety data sheet is considered correct; however, it may not be exhaustive and should therefore be considered for information only. Laboratorios SL SA is not responsible for any damage derived from the use or contact with the product described in this safety data sheet.