SAFETY DATA SHEET
Biomet Bone Cement Liquid

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product name
Biomet Bone Cement Liquid

Applications
Bone Cement


Supplier
Biomet France SARL
Boite Postale BP 75
F26903 VALENCE CEDEX 9, FRANCE
Tel: (33) 0475759100
eufrvlogindus@biomet.com

Contact person
Eric Tchelekian

Emergency telephone number
+ 49 30 19240 (24 hrs)

2. HAZARDS IDENTIFICATION

HEALTH RISK: Harmful by inhalation, in contact with skin and if swallowed. Danger of cumulative effects. May cause sensitisation by skin contact. Irritating to respiratory system and skin.

ENVIRONMENTAL RISKS. Not regarded as an environmental hazard under current legislation.

FIRE HAZARD: Highly flammable.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Name</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Content</th>
<th>Symbol</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-dimethyl-p-toluidine</td>
<td>202-805-4</td>
<td>99-97-8</td>
<td>0.5 %</td>
<td>T</td>
<td>R-23/24/25, R-33, R-52/53</td>
</tr>
<tr>
<td>methyl methacrylate</td>
<td>201-297-1</td>
<td>80-62-6</td>
<td>&gt;90 %</td>
<td>Xi,F</td>
<td>R-11, R-37/38, R-43</td>
</tr>
<tr>
<td>1,4-dihydroxybenzene</td>
<td>204-617-8</td>
<td>123-31-9</td>
<td>&lt;0.1 %</td>
<td>Xn,N</td>
<td>R-22, R-40, R-68, R-41, R-43, R-50</td>
</tr>
</tbody>
</table>

Composition comments
Section 16 contains detailed classification phrases.

Liquid with hazardous substances, and substances with occupational exposure limits.

4. FIRST AID MEASURES

General
NOTE! Effects may be delayed. Keep affected person under observation.

Inhalation
Fresh air. Get medical attention if any discomfort continues.

Ingestion
Immediately give a couple of glasses of water or milk, provided the victim is fully conscious. Contact physician if larger quantity has been consumed.

Skin
Promptly flush contaminated skin with soap or mild detergent and water. Promptly remove clothing if penetrated and flush the skin with water. Get medical attention if any discomfort continues.

Eyes
Promptly wash eyes with plenty of water while lifting the eye lids.
5. FIRE-FIGHTING MEASURES

Extinguishing media
Powder, foam or CO2. Do not use water jet as an extinguisher, as this will spread the fire.

Special fire fighting procedures
Use water to keep fire-exposed containers cool and disperse vapours. Move container from fire area if it can be done without risk. Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate.

Specific hazards
Vapours may be ignited by a spark, a hot surface or an ember. Vapours may give explosive mixture with air at temperatures below normal room temperature. Explosion risk during fire in closed containers or confined rooms. May react violently with oxidising materials.

Hazardous combustion products
Fire or high temperatures create: Toxic gases/vapours/fumes. Carbon monoxide (CO). Carbon dioxide (CO2).

Protective measures in fire
Firefighters exposed to combustion gases/decomposition products should use a respiratory protective device.

6. ACCIDENTAL RELEASE MEASURES

Personal protection
Do not breathe vapour. Provide adequate ventilation. Wear necessary protective equipment.

Environmental protection
Avoid discharge into drains, water courses or onto the ground.

Spill cleanup methods
Wear necessary protective equipment. Limit spread of spilled material. Prevent discharge to drainage systems. Remove sources of ignition. Beware of the explosion danger. Absorb spilled substance with sand or earth. Containers with collected spillage must be properly labelled with correct contents and hazard symbol. See also section 13.

7. HANDLING AND STORAGE

Usage precautions
Arrange working conditions to avoid direct contact. Containers should be kept tightly closed. Eliminate all sources of ignition. Static electricity and formation or sparks must be prevented. Provide good ventilation. Mechanical ventilation or local exhaust ventilation may be required. Eye wash must be available at the work place. Persons susceptible for allergic reactions should not handle this product.

Storage precautions
Flammable/combustible - Keep away from oxidisers, heat and flames. Keep in original container. Ground container and transfer equipment to eliminate static electric sparks. Protect from light, including direct sunrays. Avoid storing for very long periods. Do not store in uninhibited state. Keep in cool, dry, ventilated storage and closed containers. Store below 25°C.

Specific use(s)
Contact supplier for more information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>CAS no.</th>
<th>Reference</th>
<th>LT Exp 8 Hrs</th>
<th>ST Exp 15 Min</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,4-dihydroxybenzene</td>
<td>123-31-9</td>
<td>WEL.</td>
<td>0.5 mg/m3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>methyl methacrylate</td>
<td>80-62-6</td>
<td>WEL.</td>
<td>208 mg/m3</td>
<td>416 mg/m3(Sk)</td>
<td></td>
</tr>
</tbody>
</table>

Ingredient comments
WEL = Workplace Exposure Limit (GB)

Ventilation
All handling to take place in well-ventilated area. Explosion proof general and local exhaust ventilation.

Respirators
In case of inadequate ventilation use suitable respirator. GMAGS, Gas mask with acid gas canister protecting against the specific compound.
Protective gloves Use protective gloves made of: Polyvinyl alcohol (PVA). Multi-layer material (eg 4H, Saranex). Other types of gloves can be recommended by the glove supplier.

Eye protection If risk of splashing, wear safety goggles or face shield.

Other Protection Protective clothing as needed.

Environmental exposure See section 6 and 7.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Fluid.</td>
</tr>
<tr>
<td>Colour</td>
<td>Green.</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristic.</td>
</tr>
<tr>
<td>Solubility description</td>
<td>Slightly soluble in water. Miscible with: Acetone.</td>
</tr>
<tr>
<td>Boiling point (°C, interval)</td>
<td>100</td>
</tr>
<tr>
<td>Density (g/cm³)</td>
<td>0,94</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>4,7 kPa</td>
</tr>
<tr>
<td>Flash point (°C)</td>
<td>430</td>
</tr>
<tr>
<td>Flammability limit (%)</td>
<td>2,1 - 12,5</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable under the prescribed storage conditions.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Polymerises when heated. Avoid heat, flames and other sources of ignition.</td>
</tr>
<tr>
<td>Hazardous polymerisation</td>
<td>May polymerise.</td>
</tr>
<tr>
<td>Polymerisation description</td>
<td>Monitor inhibitor content and polymer formation in stored material. Avoid light. Avoid heat. Avoid storing for very long periods.</td>
</tr>
<tr>
<td>Materials to avoid</td>
<td>Strong oxidising agents. Strong alkalies. Nitrates Peroxides</td>
</tr>
<tr>
<td>Hazardous decomp. products</td>
<td>Carbon monoxide (CO). Carbon dioxide (CO2).</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitization</td>
<td>May cause allergic skin reaction.</td>
</tr>
<tr>
<td>Genotoxicity</td>
<td>Contains small amount of hydroquinone, a substance that is mutagenic.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Contains small amount of hydroquinone, a substance that can cause cancer.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Harmful by inhalation. Irritating to respiratory system. Symptoms like headache, fatigue and nausea may appear. N,N-Dimethyl-p-toluidine: LC50 Inh. rat 4h, 1,4 mg/l Methyl methacrylate: LC50 Inh. rat 4h, 78 mg/l</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Harmful: possible risk of irreversible effects if swallowed. May cause liver and/or renal damage. May irritate and cause stomach pain, vomiting and diarrhoea. Oral rat LD50 500 mg/kg</td>
</tr>
<tr>
<td>Skin</td>
<td>May cause sensitisation by skin contact. May be absorbed through the skin. Harmful in contact with skin. Dermal rat LD50 3 mg/kg</td>
</tr>
<tr>
<td>Eyes</td>
<td>May irritate and cause redness and pain.</td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

Ecotoxicity The product contains a component(s) classified as harmful to the environment. There are no data on the ecotoxicity of this product.
13. DISPOSAL CONSIDERATIONS

**Mobility**
The product is partly miscible with water and may spread in the aquatic environment.

**Bioaccumulative potential**
Is not expected to be bioaccumulable.

**Persistence and degradability**
The chemical is readily biodegradable.

**Other adverse effects**
Not known.

14. TRANSPORT INFORMATION

**General/cleaning**
Allocation of EWC code to be based on the source generating the waste. When handling waste, consideration should be made to the safety precautions applying to handling of the product. Disposal to licensed waste disposal site in accordance with local Waste Disposal Authority.

**Waste class**
18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans 18 01 06* chemicals consisting of or containing dangerous substances

15. REGULATORY INFORMATION

**Symbol(s)**
- Contains: N,N-dimethyl-p-toluidine, methyl methacrylate
- Risk phrases: R-11 Highly flammable. R-20/21/22 Harmful by inhalation, in contact with skin and if
swallowed.
R-33 Danger of cumulative effects.
R-37/38 Irritating to respiratory system and skin.
R-43 May cause sensitisation by skin contact.

**Safety phrases**

- S-15 Keep away from heat.
- S-23 Do not breathe vapour.
- S-24/25 Avoid contact with skin and eyes.
- S-37 Wear suitable gloves.

**EU directives**

EU 1907/2006

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### 16. OTHER INFORMATION

**Explanations to R-phrases in section 3**

- R-11 Highly flammable.
- R-22 Harmful if swallowed.
- R-23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
- R-33 Danger of cumulative effects.
- R-37/38 Irritating to respiratory system and skin.
- R-40 Limited evidence of a carcinogenic effect.
- R-41 Risk of serious damage to eye.
- R-43 May cause sensitisation by skin contact.
- R-50 Very toxic to aquatic organisms.
- R-52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- R-68 Possible risk of irreversible effects.

**Revision comments**

Changes made in section 1. Supplier and contact person.

**Issued by**

Farligt Gods Center AB, Gothenburg Sweden

**Date of issue**

2009-06-29

**Revision date**

2010-09-24

**Revision no.**

2

**Signature**

AO

**Disclaimer**

The information in this Safety Data Sheet is in compliance with Regulation (EC) 1907/2006, based largely on information from the manufacturer/distributor, and assumes that the product is being used within the prescribed area of usage.