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Product names : C~ment<sup>™</sup>, Genta C~ment<sup>™</sup>

## **1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION**

| Product information                   | Trade mark : C~ment <sup>™</sup> , Genta C~ment <sup>™</sup><br>Cements type 1 & 3<br>Usage : Bone cement |
|---------------------------------------|---|
| Company :<br>Emergency phone number : | Trade mark and product owner : BIOMED Biomaterials<br>+33 5 61 73 67 16                                   |
| Subcontracting manufacturer :         | E.M.C.M. Middenkampweg 17. 6545 CH Nijmegen. The Netherlands. Subsidiary of AAP Germany.                  |

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical composition     | 1 vial of powder containing :<br>Polymethylmethacrylate, benzoyl peroxide, barium sulphate,<br>gentamicin sulphate<br>1 ampoule of liquid containing :<br>Methylmethacrylate, N,N dimethyl-p-toluidin, Buthylmethacrylate<br>hydroquinone |
|--------------------------|---|
| Hazardous identification | Methylmethacrylate : $C_5H_8O_2$<br>R36/37/38, R20/21/22, R10/R11   |

## **3. HAZARDOUS IDENTIFICATION**

| Principal dangers                     | Xi<br>F          | Irritations<br>Flamable                                       |
|---------------------------------------|------------------|---|
| Indications of risks<br>Environmental | R11<br>R36/37/38 | Easily flammable<br>Eye irritation, respiratory complications |
| Risks                                 | R43              | Skin irritation,  |

### 4. First aid measures

| After inhalation. | Remove to fresh air.<br>Obtain medical attention.         |
|-------------------|---|
| Skin contact.     | Wash immediately with lots of water and soap. Rinse well. |

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| Contact with eyes. | Rinse with abundant water for 10-15 minutes the seek for ophthalmologist. |
|--------------------|---|
| After ingestion.   | If swallowed do not induce vomiting. Seek medical assistance.             |

## **5. FIRE FIGHTING MEASURES**

| Method of extinguishing | Foam, powder, carbon dioxide (CO <sup>2</sup> ), sand. |
|-------------------------|--|
| Do not use              | Do not use water directly to flame.                    |
| Particular risks        | Pull away other products from danger zone.             |

## **6. ACCIDENTAL RELEASE MEASURES**

| Individual precautions   | Sufficient aeration.<br>Do not approach any ignition source.<br>If vapours are detected use masks. |
|--------------------------|--|
| Environmental protection | Do not allow spilled liquid to enter drains.   |
| Cleaning up method       | Soak up spill with inert solids and sweep into vented disposal container.                          |

## 7. HANDLING & STORAGE

| Handling precautions       | Only authorised personnel may handle this product<br>Store in closed containers away from heat, sparks, open<br>flame. Keep and store in a cool ventilated place. |
|----------------------------|---|
| Protection from explosions | Do not smoke<br>Avoid accumulation of static electricity  |
| Storage                    | Store at less than 25°C in a dark place.  |

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## 8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

| Limits                | V/L: 416mg/m <sup>3</sup> ; 100ml/m <sup>3</sup> |
|-----------------------|--|
| Individual protection | Remove soiled clothing immediately.              |

BIOMED Biomaterials 4, Place Marnac, 31520 RAMONVILLE France

## Material Safety data Sheet Directives 91/155/CEE, 93/112/CE et 2001/58/CE

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 Do not inhale vapours.

 Wash hands after handling.

 Always use protection gloves.

 9. PHYSICAL and CHEMICAL PROPERTIES

 General
 Liquid colourless pungent odour characteristics Solubility :-48°C. Boiling point :100.5°C Flash point : 10°C

 Security data
 Explosion :the product does not explode: however a mixture of vapours and air can occur.

Explosion limits : min.(2,1vol.%) : max. (12,5 Vol.%)

Vapour pressure at 20°C : 40 hPa

Density 20°V : 0,94 g/cm<sup>3</sup>  $H^2O$  solubility : 1,6 g/l

## **10. STABILITY & REACTIVITY**

| Stability | Stable at room temperatures.<br>The liquid component is stabilized. However after a long period of<br>storage or if in excessive temperatures polymerisation could be<br>induced. |
|-----------|---|
|           |   |

Avoid Excessive light or heat.

### **11. TOXICOLOGICAL INFORMATION**

| Absorption      | The liquid fraction can come into contact with, respiratory system, eyes, skin and digestive system.                 |
|-----------------|--|
| Acute toxicity  | Skin and eye irritation.<br>Harmful to the cornea if it comes into contact.<br>Irritation of the respiratory system. |
|                 | If heavily concentrated depression of the nervous system, headache, sleepiness and fainting.                         |
| Chronic effects | Breathing : damage to the nervous system. (headache, dizziness, chronic fatigue).                                    |

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#### **12. ECOLOGICAL INFORMATION**

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| General data | Water pollution class 1 (D) : low pollution |
|--------------|---|
|              | Avoid product going to a drain.             |

### **13. DISPOSAL CONSIDERATION**

| Product   | Comply to your local authority's regulations. Dispose the product in a special waste factory.  |
|-----------|--|
| Packaging | Any contaminated packaging item must be dealt with in the same manner as the product itself.<br>Non soiled packaging elements can be recycled. |

#### **14. TRANSPORT INFORMATION**

| UN classification<br>Class<br>Product description | 1247<br>3<br>Stabilized Methylmethacrylate monomer.  |
|---|--|
| Air freight                                       | The liquid component is a class 3 hazardous product and as such must be dealt with in compliance to air freight regulations. |
| Road/sea  | Transportation is not restricted providing the product class is declared to the carrier. Class 3 product UN 1247.            |

## **15. REGULATORY INFORMATION**

| EEC Guideline information | These products are medical devices or medicine depending on each<br>country. They are classed in compliance to EEC Guidelines 93/42/CEE<br>excepting in Germany where they are classed as a medicine and in<br>Italy where an illegal Italian registration is required.<br>Dangers and precautions are shown on each ampoule and vial, on the<br>IFUs and on the external packaging. |  |
|---------------------------|--|--|
| Danger code               | Xi<br>Xn   | Irritant<br>Harmful  |
| Precaution advice         | S9<br>S16<br>S29<br>S33  | Store in a ventilated place<br>Keep away from ignition. Do not smoke.<br>Don't empty in drain.<br>Precaution static discharges |

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## **16. OTHER INFORMATION**

| Data drawn up by : | BIOMED Biomaterials owner of the trade mark and product the formulation of which was elaborated for our subcontractor E.M.C.M. in 1997 by us.   |
|--------------------|---|
| Indications        | Although reasonable care has been taken in the elaboration of this<br>safety document the formulation and data go back to known<br>knowledge dating back to 1997, revised in 2001, when BIOMED first<br>marketed the product under its current and definite presentation.<br>BIOMED cannot however guarantee the accuracy of the information<br>contained herein and should be contacted in the case of any non<br>authorized modifications to the chemical composition being noticed<br>and reported back to BIOMED in France. |
|                    | For the same reason Biomed can assume no responsibility regarding<br>the suitability for the consequences of use. Each user should<br>determine the suitability of use of the product.  |

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