

Material Safety Data Sheet

Rev. Date
3 March 2004

UNMEDICATED BONE CEMENTS

1. PRODUCT AND COMPANY IDENTIFICATION

DePuy International Ltd
t/a DePuy CMW
Cornford Road
Blackpool, England, FY4 4QQ

EMERGENCY TELEPHONE NUMBERS

Health, Safety & Environmental Officer +44 (0) 1253 765167

PRODUCT NAME: **UNMEDICATED BONE CEMENTS**

Product Line: CMW 1 Original Bone Cement
CMW 1 Radiopaque Bone Cement
CMW 2 Bone Cement
CMW 3 Bone Cement
Endurance Bone Cement
CMW 2000 Bone Cement
Smartset MV Endurance Bone Cement

Synonyms: CMW 1 Radiopaque Bone Cement; DePuy 1; Orthoset 1
CMW 2 Bone Cement; DePuy 2; Orthoset 2
CMW 3 Bone Cement; DePuy 3; Orthoset 3

2. COMPOSITION/INFORMATION ON INGREDIENTS

CMW 1 Original Bone Cement

Powder:	Liquid:
Polymethyl Methacrylate: >50.0%	Methyl methacrylate: >50.0%
Benzoyl Peroxide: 1-3%	N,N-Dimethyl-p-toluidine: <1%

CMW 1 Radiopaque Bone Cement

Powder:	Liquid:
Polymethyl Methacrylate: >50.0%	Methyl methacrylate: >50.0%
Benzoyl Peroxide: 1-3%	N,N-Dimethyl-p-toluidine: <1%
Barium Sulphate-5-10%	

CMW 2 Bone Cement

Powder:	Liquid:
Polymethyl Methacrylate: >50.0%	Methyl methacrylate: >50.0%
Benzoyl Peroxide: 1-3%	N,N-Dimethyl-p-toluidine: 1-3%
Barium Sulphate: 10-15%	

CMW 3 Bone Cement

Powder:	Liquid:
Polymethyl Methacrylate: >50.0%	Methyl methacrylate: >50.0%
Benzoyl Peroxide: 1-3%	N,N-Dimethyl-p-toluidine: 1-3%
Barium Sulphate: 5-10%	

Material Safety Data Sheet

Rev. Date
3 March 2004

UNMEDICATED BONE CEMENTS

2. COMPOSITION/INFORMATION ON INGREDIENTS - Continued

Endurance Bone Cement

Powder:	Liquid:
Methyl Methacrylate/Styrene Copolymer: 15-30%	Methyl methacrylate: >50.0%
Polymethyl Methacrylate: >50.0%	N,N-Dimethyl-p-toluidine: 1-2%
Benzoyl Peroxide: 1-3%	
Barium Sulphate: 5-10%	

CMW 2000 Bone Cement

Powder:	Liquid:
Polymethyl Methacrylate: 50.0%	Methyl methacrylate: >50.0%
Methyl/EthylMethacrylate/Styrene Terpolymer: 10-15%	N,N-Dimethyl-p-toluidine: 1-2%
Benzoyl Peroxide: 1-3%	
Barium Sulphate: 5-10%	

Smartset MV Endurance Bone Cement

Powder:	Liquid:
Methyl Methacrylate/Styrene Copolymer: 15-30%	Methyl methacrylate: >50.0%
Polymethyl Methacrylate: >50.0%	N,N-Dimethyl-p-toluidine: 1-2%
Benzoyl Peroxide: 1-3%	
Barium Sulphate: 5-10%	

3. HAZARDS IDENTIFICATION

***** EMERGENCY OVERVIEW *****

- * These products (powder and liquid) may cause eye, skin and respiratory *
* irritation and skin sensitization. *
- * Avoid heat, sparks or open flame with liquid components. *
- * *
- * R36/37/38 *
- * R20/21/22 *
- * R10 *

POTENTIAL HEALTH EFFECTS

PRIMARY ROUTE(S) OF ENTRY

Eye, skin and respiratory tract.

EYES

Powder and liquid components may be irritating to the eyes.

SKIN

May cause skin irritation and sensitisation. The degree of reaction may vary significantly between individuals and on the amount and duration of exposure.

M a t e r i a l S a f e t y D a t a S h e e t

UNMEDICATED BONE CEMENTS

Rev. Date
3 March 2004

3. HAZARDS IDENTIFICATION - Continued

INGESTION

Liquid components may be toxic if swallowed.

INHALATION

Powder may be irritating to the respiratory system. Liquid vapour may cause irritation of the respiratory tract, dizziness, headache and anaesthetic effects based on exposure.

CHRONIC (CANCER INFORMATION)

Repeated exposure of high concentration levels of the liquid components may cause adverse effects on lungs, heart, kidney and liver.

REPRODUCTIVE EFFECTS

Unknown.

MUTAGENICITY (GENETIC EFFECTS)

Unknown.

4. FIRST AID MEASURES

EYES

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice; **S26** (Powder and Liquid).

SKIN

After contact with skin, wash immediately with plenty of water and get medical attention if irritation develops or persists; **S28** (Powder and Liquid).

INGESTION

If swallowed, seek medical advice (Powder and Liquid). Do not induce vomiting.

INHALATION

If exposure occurs, remove individual to fresh air and obtain medical attention (Liquid).

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES

FLASH POINT: 10.5 C DIN 51755

M a t e r i a l S a f e t y D a t a S h e e t

Rev. Date
3 March 2004

UNMEDICATED BONE CEMENTS

AUTOIGNITION: 421 C
LOWER EXPLOSIVE LIMIT (%): 2.1 by volume
UPPER EXPLOSIVE LIMIT (%): 12.5 by volume

FIRE AND EXPLOSION HAZARDS

Combustible powder, St class 2 explosive dust, will dissolve in some solvents.
Sensitive to static discharge.

EXTINGUISHING MEDIA

Use any media which is suitable for the surrounding fire.

FIRE FIGHTING INSTRUCTIONS

Wear self-contained breathing apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Spilled or released material may polymerise and release heat/gases.
Extinguish all ignition sources and ventilate area. Wear protective equipment during clean-up. Soak up small spill with inert solids and sweep/shovel into vented disposal container. Wash spill area with detergent and water solution and rinse with water. Do not allow spilled liquid to enter drains.

7. HANDLING AND STORAGE

HANDLING AND STORAGE PRECAUTIONS

Store in tightly closed containers away from heat, sparks, open flame. Keep in a cool well ventilated area.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS

Local exhaust ventilation.

EYE/FACE PROTECTION

Wear eye/face protection;**S39**. Concentrated vapours of the liquid component may have an adverse reaction with soft contact lenses.

SKIN PROTECTION

Wear suitable gloves;**S37**. Nitrile is recommended.

RESPIRATORY PROTECTION

Respiratory protection dependent on airborne exposures. Refer to organic

Material Safety Data Sheet

UNMEDICATED BONE CEMENTS

Rev. Date
3 March 2004

solvents and particulates involved in exposure.

OTHER/GENERAL PROTECTION

Wear suitable protective clothing; **S36**

Exercise proper industrial hygiene procedures to prevent exposure by washing hands and arms thoroughly with soap and hot water after working with material. Gloves should be washed with soap and water before removal. Contaminated clothing should be promptly removed and washed before reuse.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Powder component -A white odourless free flowing powder.
Liquid component -Colourless mobile liquid with characteristic pungent odour.

BASIC PHYSICAL PROPERTIES

Powder component:

Relative density=1.14 (polymer)
Melting point=200C (polymer)

Liquid Component

BOILING POINT: 100.5 C
VAPOR PRESSURE: 28mmHg(20C)
VAPOR DENSITY (AIR=1): 0.94
SOLUBILITY (H2O): 1.59%
EVAPORATION RATE: 4(butyl acetate=1)

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID (STABILITY)

Liquid component, is a volatile flammable liquid which slowly attacks rubber. The liquid will polymerise very readily and all contamination must be avoided, particularly organic peroxides, catalysts, free radicals generators and multivalent metal oxides, especially when wet. Heat and strong light, particularly fluorescent or UV could cause polymerisation.

INCOMPATIBLE MATERIALS

Avoid high temperatures, oxidizing and reducing agents.

HAZARDOUS POLYMERIZATION: May occur

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES

Material Safety Data Sheet

UNMEDICATED BONE CEMENTS

Rev. Date
3 March 2004

Unknown for product.

Benzoyl Peroxide (CAS No.94-36-0):
LD50 Oral-Rat=7710mg/kg

Barium Sulphate (CAS No. 7727-53-7):
LD50 Oral-Rat=307-364mg/kg

Methyl Methacrylate (CAS No. 80-62-6):
LC50 Inhalation-Rat=3750ppm

EYE EFFECTS

Powder and liquid components may be irritating to the eyes.

SKIN EFFECTS

Powder and liquid components may cause irritation and sensitisation

12. ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION

Unknown. Follow all regulatory regulations. The liquid components are not readily biodegradable and could be harmful to fish and invertebrates.

13. DISPOSAL CONSIDERATIONS

In all instances this product must be disposed of in accordance with all applicable regulations.

14. TRANSPORT INFORMATION

PROPER SHIPPING NAME: Consumer Commodity
UN 1247

HAZARD CLASS: Flammable

15. REGULATORY INFORMATION

TSCA status: All components of this product are listed, or excluded from listing, on the EPA/TSCA inventory.

This product is not subject to the regulatory requirements under California Proposition 65.

International Inventory status:
Australia (AICS)-Included

M a t e r i a l S a f e t y D a t a S h e e t

UNMEDICATED BONE CEMENTS

Rev. Date
3 March 2004

Canada (DSL)-Included
European Economic Community (EINECS)-Not applicable
Japan (MITI)-Included
Korea (MOE)-Included

16. OTHER INFORMATION

REFERENCE DOCUMENTATION

Refer to package insert.

DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DePuy International Ltd