

### 1. Identification

- **Product identifier**
- **Trade name:** [NTCem, NTCem-Violet, NTCem-Yellow, NTCem-Mixer] Powder
- **Relevant identified uses of the substance or mixture and uses advised against:**  
No further relevant information available.
- **Application of the substance / the mixture:** Antibiotic Bone cement Powder
- **Manufacturer/Supplier:**  
META BIOMED CO., LTD.  
Head Office) 270, Osongsaengmyeong 1-ro, Osong-eup,  
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea  
Tel : +82-43-218-1981 / Fax : +82-43-218-1984
- **Information department:** alex@meta-biomed.com
- **Emergency telephone number:**  
Emergency Contact (24-Hour-Phone Number)  
Meta Biomed Head office (international) : +82-43-230-8845  
Meta Biomed China : +86-10-6508-9018  
Meta Biomed Japan : +81-3-3504-0232  
Meta Biomed US Corporation : +1-267-282-5893


### 2. Hazards identification

- **Classification of the substance or mixture**  
Skin Sens. 1 H317 May cause an allergic skin reaction.

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- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Information concerning particular hazards for human and environment:**  
The product has to be labeled due to the calculation procedure of international guidelines.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**  
  
GHS07
- **Signal word:** Warning
- **Hazard-determining components of labeling:** dibenzoyl peroxide



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- **Hazard statements:** May cause an allergic skin reaction.
- **Precautionary statements**
  - Avoid breathing dust/fume/gas/mist/vapors/spray
  - Wear protective gloves.
  - If on skin: Wash with plenty of water.
  - Specific treatment (see on this label).
  - Wash contaminated clothing before reuse.
  - If skin irritation or rash occurs: Get medical advice/attention.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3. Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Dangerous components:**

94-36-0	dibenzoyl peroxide	< 2.0%
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- **Non dangerous components:**

7727-43-7	Barium sulfate	10%
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### 4. First aids measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
  - If skin irritation continues, consult a doctor.



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- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5. Fire fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fire with alcohol resistant foam.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters:** No special measures required.
- **Additional information:** -

### 6. Accidental release measures

- **Personal precautions, protective equipment and emergency procedures:**  
Wear protective equipment. Keep unprotected persons away. Avoid formation of dust.
- **Environmental precautions:**  
Do not allow to enter sewers/ surface or ground water.  
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the collected material according to regulations.
- **Reference to other sections:** See Section 8 for information on personal protection equipment.

### 7. Handling and storage

- **Precautions for safe handling**  
Wear protective equipment. Keep unprotected persons away. Prevent formation of dust.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

### 8. Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**



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· **Components with limit values that require monitoring at the workplace:**

**7727-43-7 Barium sulfate (10.0%)**

PEL	Long-term value: 10 mg/m <sup>3</sup>
REL	Short-term value: 15 mg/m <sup>3</sup>
TLV	Long-term value: 10 mg/m <sup>3</sup>
	Short-term value: 15 mg/m <sup>3</sup>
	Long-term value: 10 mg/m <sup>3</sup>

**94-36-0 Dibenzoyl peroxide (< 2.0%)**

PEL	Long-term value: 5 mg/m <sup>3</sup>
REL	Long-term value: 5 mg/m <sup>3</sup>
TLV	Long-term value: 5 mg/m <sup>3</sup>

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Avoid contact with the skin.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Protection of hands:** Check protective gloves prior to each use for their proper condition.

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **For the permanent contact gloves made of the following materials are suitable:**

for example: a glove system comprising 2 gloves with one worn inside the other:  
an inner glove made of latex and an outer glove made of polyethylene

· **Eye protection:** Safety glasses

· **Body protection:** Light weight protective clothing

### 9. Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Powder

**Color:** Light green

· **Odor:** Odorless

· **pH-value:** Not applicable.

· **Change in condition**

**Melting point/Melting range:** Undetermined.

**Boiling point/Boiling range:** Undetermined.

· **Flash point:** Not applicable.

· **Ignition temperature:**

**Decomposition temperature:** Not determined.

· **Auto igniting:** Not determined.

· **Danger of explosion:** As the product is supplied it is not capable of dust explosion; however enrichment with fine dust causes risk of dust explosion.

· **Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.



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· **Vapor pressure:** Not applicable.

· **Viscosity:**

· **Density:** Not determined.

**Dynamic:** Not applicable.

· **Relative density** Not determined.

**Kinematic:** Not applicable.

· **Vapour density** Not applicable.

· **Solvent content:**

· **Evaporation rate** Not applicable.

**Organic solvents:** 0.0 %

· **Solubility in / Miscibility with**

**Solids content:** 100.0 %

**Water:** Insoluble.

· **Other information:**

· **Partition coefficient (n-octanol/water):**

No further relevant information available.

Not determined.

### 10. Stability and reactivity

· **Reactivity**

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions:** No dangerous reactions known.

· **Conditions to avoid:** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

### 11. Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

**94-36-0 dibenzoyl peroxide**

Oral	LD50	5000 mg/kg (rat)
Inhalative	LC50/4 h	24300 mg/l (rat)

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** Sensitizing effect by skin contact is possible with prolonged exposure.

· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

94-36-0	dibenzoyl peroxide	3
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.



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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12. Ecological information

· **Toxicity**

· **Aquatic toxicity:**

**94-36-0 dibenzoyl peroxide**

EC50/48h	0.11 mg/l (daphnia)
EC50/72h	0.06 mg/l (algae)
LC50/96h	0.06 mg/l (fish)

· **Persistence and degradability:** No further relevant information available.

· **Bioaccumulative potential:** No further relevant information available.

· **Mobility in soil:** No further relevant information available.

· **Additional ecological information:**

· **General notes:** Avoid transfer into the environment.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

### 13. Disposal considerations

· **Waste treatment methods**

· **Recommendation:** Disposal must be made according to official regulations.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

### 14. Transport information

· **UN-Number**

· **DOT, ADR, IMDG, IATA:** Void

· **UN proper shipping name**

· **DOT, ADR, IMDG, IATA:** Void

· **Transport hazard class(es)**

· **DOT, ADR, IMDG, IATA**

· **Class:** Void

· **Packing group**

· **DOT, ADR, IMDG, IATA** Void

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user:** Not applicable

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable

· **UN "Model Regulation":** -

### 15. Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

94-36-0 dibenzoyl peroxide

· **TSCA (Toxic Substances Control Act):**

Medical devices are exempted from TSCA.

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

7727-43-7	Barium Sulfate	A4
94-36-0	dibenzoyl peroxide	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning



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· **Hazard-determining components of labeling:**

dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

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

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

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

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** HH-EHS-CS

· **Date of preparation / last revision:** 10/05/2016 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1