



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

## 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product name : Sorbone

Product code : 8806387898009

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Bone grafting materials.

### 1.3. Details of the supplier of the safety data sheet

Registered company name : METABIOMED CO., LTD.

Address : Head Office & Osong Factory) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu,  
Cheongju-si, Chungcheongbuk-do, Korea

Cheongju Factory) 136, Mochung-ro, Seowon-gu, Cheongju-si, Chungcheongbuk-do, Korea

Telephone : (82-43) 216-0433, 0434

Fax : (82-43) 216-0438

e-mail : info@meta-biomed.com

Manufacturer : METABIOMED CO., LTD.

### 1.4. Emergency telephone number

(82-43) 216-0433, 0434

## 2. Hazards identification

### 2.1. Classification of the substance or mixture

#### **Classification according to Regulation (EC) No 1272/2008**

Skin irritation, Category 2(Skin Irrit. 2, H315)

Eye irritation, Category 2(Eye Irrit. 2, H319)

### 2.2. Label elements

#### **Labelling according to Regulation (EC) No 1272/2008**

The product does not need to be labelled in accordance with EC directives or respective national laws.GHS label elements including precautionary statements

- Hazard Pictograms



GHS07

- Signal word : Warning

- Hazard statement(s) : H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

- Precautionary Statement(s) : P261 Avoid breathing vapours.
- Prevention : P264 Wash hands thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/protective clothing/eye protection/ face protection.
- Response : P302+P352 IF ON SKIN: Wash with plenty of water.  
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in position comfortable for breathing.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.  
P312 Call a POISON CENTER/doctor/if you feel unwell.  
P332+P313 If skin irritation occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P362+P364 Take off contaminated clothing and wash it before reuse.
- Disposal : P501 Dispose of contents/container according to the related regulations

### 2.3. Other hazards (according to the NFPA Rating System)

- Health : 1
- Flammability : 0
- Reactivity : 0

## 3. Composition/information on ingredients

### 3.1. Substances

Chemical Name	CAS No.	EC No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008[CLP]
$\beta$ -tricalcium phosphate	7758-87-4	231-840-8	95%<	-	H315, H319, H335

### 3.2. Mixtures

Not Applicable



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

## 4. First aids measures

### 4.1. Description of first aid measures

- Eyes : Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.  
If there is any redness, pain or visual impairment, consult an ophthalmologist.
- Skin : Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.  
Watch out for any remaining product between skin and clothing, watches, shoes, etc. If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.
- Inhalation : In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest. If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.  
If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor.
- Ingestion : Do not give the patient anything orally.  
In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.  
Seek medical attention immediately, showing the label.

### 4.2. Most important symptoms and effects, both acute and delayed

- Eyes : N/A
- Skin : N/A
- Inhalation : N/A
- Ingestion : N/A

### 4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician : N/A

## 5. Fire fighting measures

### 5.1. Extinguishing media

- Extinguishing media : In the event of a fire, use: water, carbon dioxide, dry chemical agents

### 5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products : None Known.
- Explosion hazards : Not Determined
- Fire explosion : Not Determined



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

- Sensitive to static discharge : Not Determined
- Sensitivity to impact : Not Determined

### 5.3. Advice for firefighters

- Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when product is involved in fire.
- Fire fighting equipment : Non-combustible

## 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Give special attention to chemical materials and conditions that must be avoided.

### 6.2. Environmental precautions

Prevent the inflow of this product to waterways, drains, basements, and confined spaces.

### 6.3. Methods and material for containment and cleaning up

Clean up spills immediately, observing precautions in Protective Equipment section.

### 6.4. Reference to other sections

Not Applicable

## 7. Handling and storage

### 7.1. Precautions for safe handling

Follow all prevention measures on the SDS/labels.

Handle and store with care.

Give special attention to chemical materials and conditions that must be avoided.

Wear personal protective equipment while handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed in a dry, well-ventilated place.

### 7.3. Specific end use(s)

No data available.

## 8. Exposure controls and personal protection

### 8.1. Control parameters

Not determined

### 8.2. Exposure controls

**Personal protection measures, such as personal protective equipment**

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection : Avoid contact with eyes.
  - Use eye protectors designed to protect against liquid splashes
  - Before handling, wear safety goggles with protective sides accordance with standard EN166.
  - In the event of high danger, protect the face with a face shield.
  - Prescription glasses are not considered as protection.
  - Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.
  - Provide eyewash stations in facilities where the product is handled constantly.
- Hand protection : Wear suitable protective gloves in the event of prolonged or repeated skin contact.
  - Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.
  - Gloves must be selected according to the application and duration of use at the workstation.
  - Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.
  - Recommended properties :
    - Impervious gloves in accordance with standard EN374
- Body protection : Avoid skin contact.
  - Wear suitable protective clothing.
  - Suitable type of protective clothing :
    - In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605 to prevent skin contact.
    - In the event of a risk of splashing, wear protective clothing against chemical



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

risks (type 6) in accordance with EN13034 to prevent skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection : Avoid breathing vapours.

If the ventilation is insufficient, wear appropriate breathing apparatus.

When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection device.

Anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387 : - A1 (Brown)

## 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

- Appearance	: Solid, Powder	- Vapor pressure	: N/A
- Odor	: N/A	- Vapor density	: N/A
- Color	: White	- Relative density	: 3.14g/cm <sup>3</sup>
- pH	: N/A	- Solubility(ies)	: 0.002g/100g
- Melting/freezing point	: 1391°C <	- Partition coefficient :	: N/A
- Initial boiling point and boiling range	: N/A	n-octanol/water	
- Flash point	: N/A	- Auto-ignition temperature	: N/A
- Evaporation rate	: N/A	- Decomposition temperature	
- Flammability(solid, gas)	: N/A	- Viscosity	: N/A
- Upper/lower flammability or explosive limits	: N/A	- Explosive properties	: N/A
		- Oxidising properties	: N/A

### 9.2. Other information

None

## 10. Stability and reactivity

### 10.1. Reactivity

Stable

### 10.2. Chemical stability

Stable when stored and handled under recommended conditions.



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

## 10.3. Possibility of hazardous reactions

None

## 10.4. Conditions to avoid

Extreme heat, direct light and humidity

## 10.5 Incompatible materials

N/A

## 10.6. Hazardous decomposition products

N/A

## 11. Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	Device is biocompatible when used as directed by ISO 10993-1.
Irritation and corrosiveness	May be irritating to eyes or skin on contact
Sensitization	N/A
Sub-acute, sub chronic and prolonged toxicity	None known
Carcinogenicity, Mutagenicity,	None known
Reproductive toxicity	
Empirical data	None known
Clinical experience	None known

## 12. Ecological information

### 12.1. Toxicity

- Toxicity : Not determined
- Aquatic toxicity(acute) : Not determined

### 12.2. Persistence and degradability

Not determined

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined

### 12.5. Results of PBT and vPvB assessment

Not determined

### 12.6. Other adverse effects

None known



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

## 13. Disposal considerations

### 13.1. Waste treatment methods

Do not pour into drains or waterways.

#### Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

#### Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

## 14. Transport information

### 4.1. UN Number

UN Number : 3266

### 14.2. UN proper shipping name

Corrosive liquid, basic inorganic, N.O.S.(Calcium hydroxide mixture)

### 14.3. Transport hazard class(es)

Hazard classification : 8

### 14.4. Packing Group

Packing group : III

### 14.5. Environmental hazards

Marine pollutant #1 : N/A

### 14.6. Special precautions for user

- ADR - road : N/A

- RID - rail : N/A

- IMDG - sea : N/A

- IATA - air : N/A

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk : N/A



# Material Safety Data Sheet

- Sorbone -

METABIOMED CO., LTD.

## 15. Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**Federal and State Regulations:** TSCA 8(b) inventory: Calcium phosphate tribasic

**Other Regulations:** OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

**Other Classifications:**

**WHMIS (Canada):** CLASS D-2A: Material causing other toxic effects (VERY TOXIC).

**DSCL (EEC):** R36/38- Irritating to eyes and skin.

**HMIS (U.S.A.):** (Health Hazard: 2, Fire Hazard: 0, Reactivity: 0, Personal Protection: E)

**National Fire Protection Association (U.S.A.):** (Health: 2, Flammability: 0, Reactivity: 0)

### 15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

## 16. Other information

The information contained in the Safety data sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.

### HISTORY

- **Date of creation** : 08-01-2015
- **Revision number and Revision date**
  - \* Revision number : 2
  - \* Date of last revision : 20-02-2017
- **Prepared by** : METABIOMED CO., LTD.