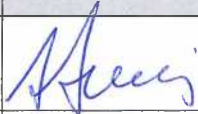


	Safety Data Sheet
	acc. to Regulation (EC) No. 1907/2006

# SAFETY DATA SHEET

OSBONE®

**Manufacturer:** curasan AG  
Lindigstraße 4  
63801 Kleinostheim  
Germany

## Document Release

FREIGABE / APPROVAL				
	Name:	Function:	Signature:	Date:
<b>Author:</b>	Dr. Alexander Huwig	Chief Scientific Officer		30. JAN. 2024
<b>Reviewer:</b>	Steffi Manig	Regulatory Affairs Manager		30. JAN. 2024
<b>Approver:</b>	Dr. Alexander Huwig	Chief Scientific Officer		30. JAN. 2024



## 1 Product Identifiers and Company Identification

### 1.1 Product identifiers

Product name	OSBONE®, IngeniOs HA
CAS No.	12167-74-7
EC No.	235-330-6
REACH No.	A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration.

### 1.2 Relevant identified uses of the substance and uses advised against

Identified Uses	Bone augmentation material being a medical device for professional use in the health services only.
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### 1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier	curasan AG Lindigstraße 4 63801 Kleinostheim Germany
Supplier of the Safety Data Sheet	QARA/RD Quality and Regulatory Affairs - Research and Development curasan AG Lindigstraße 4 63801 Kleinostheim Germany Tel.: +49 (0) 6027-40 900-0 E-Mail: qara@curasan.com

### 1.4 Emergency telephone

Central emergency call in case of toxication	Call (24 hours): +49 (0) 30 192 40
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## 2 Hazards Identification

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008, product regulated as a medical device.

### 2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008, product regulated as a medical device.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 3 Composition/Information on Ingredients


### 3.1 Substance

Formula	hydroxyapatite $\text{Ca}_5(\text{PO}_4)_3\text{OH}$
Molecular Weight	502.31 g/mol [1004.62 g/mol of the crystal unit cell formulae, which is $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ ]
CAS No.	12167-74-7
EC No.	235-330-6
Dangerous Components	No components need to be disclosed according to the applicable regulations.

## 4 First Aid Measures

### 4.1 Description of first-aid measures

After inhalation	Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.
After skin contact	Rinse skin with water/ shower
After eye contact	Rinse out with plenty of water. Remove contact lenses.
After swallowing	Make victim drink water (200-300 mL at most). Consult doctor if feeling unwell.

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

Refer to Instructions for Use information for warnings, precautions, interactions, adverse reactions, and important physician information.

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

Treat symptomatically.

### 5 Firefighting Measures

#### 5.1 Suitable extinguishing media

Use extinguishing media appropriate to the local conditions and environment. No restrictions on extinguishing media are specified for this substance.

#### 5.2 Special hazards arising from the substance

Fire may cause evolution of oxides of phosphorus. Ambient fire may liberate hazardous vapors.

#### 5.3 Advice for firefighting

In the event of fire, wear self-contained breathing apparatus.

### 6 Accidental Release Measures

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

Not required if used according to Instructions for Use

#### 6.2 Environmental precautions

Do not let product enter drains.

#### 6.3 Methods and materials for containment and cleaning up

Pick up with standard cleaning accessories and dispose of in household or organic waste.


#### 6.4 Reference to other sections

For waste disposal, see section 13.

### 7 Handling and Storage

#### 7.1 Precautions for safe handling

For professional use only in the healthcare service. Refer to Instructions for Use information for precautions.

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## 7.2 Conditions for safe storage, including any incompatibilities

No special requirements for storage according to the instructions for use.

## 7.3 Specific end use(s)

This product is a medical device. For professional use only in the healthcare service.

# 8 Exposure controls and personal protection

## 8.1 Control parameters

Ingredients with workplace	Contains no substances with occupational exposure limit values.
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## 8.2 Exposure controls

Personal protective equipment	No special requirements if used according to the instructions for use.
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# 9 Physical and chemical properties

a) Appearance	Granules
b) Color	White, opaque, blueish
c) Odor	Odorless
d) Melting point	Approx. 1670 °C
e) Boiling point	No data available
f) Flash point	Not applicable
g) Auto ignition	The product is not self-igniting.
h) Danger of explosion	The product does not present an explosion hazard.
i) Density at 20 °C	0.5-1.6 g/cm <sup>3</sup> depending on the degree of porosity and on the product modification
j) Water solubility	0.3 g/L

# 10 Stability and Reactivity

## 10.1 Reactivity

No reactivity if used according to the instructions for use.

## 10.2 Chemical Stability

The product is chemically stable under standard ambient conditions (room temperature).

## 10.3 Possibility of hazardous reactions

No possibility of hazardous reactions if used according to the instructions for use.

#### 10.4 Conditions to avoid

None if used according to the instructions for use.

#### 10.5 Incompatible materials

None if used according to the instructions for use.

#### 10.6 Hazardous decomposition products

None

### 11 Toxicological Information

#### 11.1 Information on toxicological information

##### 11.1.1 Acute Toxicity

Oral	LD50 5 000 mg/kg bw (rat)
Inhalation	LC50 (2.833 h) 2.3 mg/L air (rat)
Dermal	LD50 2 000 mg/kg bw (rabbit)

##### 11.1.2 Irritation and Corrosion

Skin	No adverse effect observed (not irritating)
Eye	No adverse effect observed (not irritating)
Respiratory	No study available

#### 11.2 Additional toxicological information:

The product is a medical device and meets the requirements of the ISO 10993 standard series regarding biocompatibility, which evaluates cytotoxicity, sensitization, irritation/intracutaneous reactivity, material-dependent pyrogenicity, acute systemic toxicity, subacute toxicity, chronic toxicity, implantation effects, genotoxicity, and carcinogenicity as endpoints.

### 12 Ecological Information

#### 12.1 Ecotoxicity


No data available

#### 12.2 Toxicity

No data available

#### 12.3 Persistence and degradability

No data available

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#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 13 Disposal Considerations

#### 13.1 Waste treatment methods

##### 13.1.1 Product

Smaller quantities can be disposed of together with domestic waste.

##### 13.1.2 Uncleaned Packaging

Disposal must be made according to local authority requirements.

### 14 Transport Regulations

The product is not classified as dangerous in the meaning of transport regulations and hence, not supposed to meet the transport regulations acc. to ARD/RID, IMDG, and IATA.

### 15 Regulations

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

EU Legislation: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

#### 15.2 Chemical Safety Assessment

For this product, a chemical safety assessment was carried out as part of the biological evaluation in accordance with the ISO 10993 standard series.





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### 16 Other Information

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability, or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

<b>Version</b>	1.0
<b>Date of Release</b>	30.01.2024