

Date of update: 18th March 2023

Version: 1.0

1. Identification of the substance and company's information

Compound name: Hydroxyapatite (HA)

Chemical formula: $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ or $[\text{Ca}_5(\text{PO}_4)_3 \text{OH}]$

Chemical family: Inorganic compound

Particle size: 45 to 200 μm

Application of the substance: Used in thermal spray coatings for biomedical implants.

Manufacturer/Supplier:

Ceramat Private Limited

Site1: Unit No.- 105, Krishna Industrial Estate, Dhumalnagar, Near Waliv, Vasai East, 401208, India

Site2: Unit No. 14, Sethia Industrial Park, S.No. 39/1, Bilalpada, Vasai East-401208, Maharashtra,

Emergency telephone number: +91-8857861496, 9665888516

2. Hazards identification

The substance is not classified according to Globally Harmonized System (GHS)

Hazard description: Not applicable

Information concerning particular hazards for human and environment: Not applicable

3. Composition/Information on ingredients

Chemical characterization:

CAS No.: 12167-74-7; Hydroxyapatite $[\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2]$

4. Chemical/Physical properties & General Information

Colour: White

Physical state: Solid

Chemical Formula: $[\text{Ca}_5(\text{PO}_4)_3(\text{OH})]$, usually written as $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$

Formula Mass: 502.31 g/mol

Crystallite size: 15 to 60 nm

Crystal system: Hexagonal

Form: Powder, finer and coarser particles

Particle size: 45- 200 μm

Odour: Odourless

Melting point: 1670°C

Note: During plasma spray coating the thermal spray grade powder can decompose in Tricalcium Phosphate [$\text{Ca}_3(\text{PO}_4)_2$]; Tetra-calcium Phosphate [$\text{Ca}_4\text{P}_2\text{O}_9$], Calcium Oxide [CaO] and amorphous HA.

Boiling point: Undetermined

Flash point: Not applicable

Flammability: Product is not flammable.

Danger of explosion: Product does not present an explosion hazard.

Theoretical density: 3.18 gm/cc

Apparent specific weight: (no compacted powder) 0.5 to 1 gm/cc.

Solubility: 0.1M HCL, complete colourless; not soluble in water.

pH-value (100g/l) at 20°C: 7-9

5. Proposed First-aid measures

General information: No special measures

After inhalation: Inhale fresh air; consult doctor in case of respiratory complaints.

After skin contact: No known irritation as it is biocompatible.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult a physician.

Most important symptoms and effects, both acute and delayed: Not known.

Indication of any immediate medical attention and special treatment needed:
Not known.

6. Fire -fighting measures

Suitable extinguishing agents: Not inflammable.

Special hazards arising from the substance: No further relevant information available.

Protective equipment: No special measures required.

7. Accidental release measures

Personal precautions, protective equipment and emergency procedures: For bulk handling wear protective clothing.

Environmental precautions: Not known.

Method and material for containment and cleaning up: Pick up mechanically.

Additional information: No dangerous substances are leached.

8. Handling and storage

The powder is packed in sterilized and sealed High-Density Polyethylene (HDPE) containers.

Information for safe handling: No special measures required.

Information about fire-and explosion protection: No special measures required.

Storage: No special requirements.

Information about storage in one common storage facility: No issues in such storage.

Further information about storage conditions: Store as supplied until used.

9. Exposure controls/personal protection

Additional information about design of technical facilities: Some sub-micron particles may be suspended in the air. Therefore, adapted ventilation in this zone is recommended otherwise the operator must wear a dust mask.

Personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling thermal spray powders.

Respiratory protection:

Dust mask during the filling up of the powder feeder if the ventilation is not sufficient.

Protection of hands:

Protective gloves/prolonged handling of the powder tends to remove oils from the skin and lead to dryness.

Eye protection: Wear the safety glasses as airborne dust may cause eye irritation.

10. Stability and reactivity

Thermal decomposition: See section 4 (thermal decomposition during the plasma spray coating process).

Dangerous reactions: No dangerous reactions known.

Dangerous decomposition products: Not known.

11. Toxicological information

Biocompatible (*in vitro*, *in vivo* (mice)) according to ISO10993-11/12.

Acute toxicity: non-toxic up to 100mg/kg if injected intraperitoneally.

Primary irritant effect:

On the skin: None

On the eye: None

Sensitisation: None

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects to our experience.

12. Ecological information

General notes:

Do not allow product to reach ground water, water course or sewage system in its unused form.

Toxicity

Aquatic toxicity: No further relevant information available.

Persistence and degradability: No further relevant information available.

Mobility in soil: No further relevant information available.

13. Disposal considerations

Waste treatment methods

Recommendation: Follow local regulation.

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary other cleansing agents.

14. Transport information

Land transport ADR/RID (cross-border)

ADR/RID class: No dangerous goods.

Maritime transport IMDG:

IMDG class: No dangerous goods.

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA class: No dangerous goods

Special precautions for user: Not applicable

Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:

Not applicable

Transport /Additional information: Not dangerous according to the above specifications.

15. Regulatory information

Labelling according to EU guidelines:

The substance is not subject to classification according to EU lists and sources of literature known to us. Safety, health and environmental regulations/legislation specific for the substance or mixture SARA (Superfund Amendments and reauthorization Act of 1986-USA).

Section 302/304 (40CFR355.30/40CFR355.40): Substance not listed.

Section 313 (40CFR372.65): Substance not listed.

TSCA (Toxic Substances Control Act): Substance is not listed carcinogenic categories.

EPA (Environmental Protection Agency): Substance is not listed.

TLV (Threshold Limit Value established by ACGIH): Substance is not listed.

MAK (German Maximum Workplace Concentration): Substance is not listed.

Material Safety Data Sheet-Hydroxyapatite (Thermal Spray Grade)

NIOSH-Ca (National Institute for Occupational Safety and Health): Substance is not listed.

16. Other Information:

The above information is believed to be correct to our knowledge but does not purport to be all inclusive and shall be used as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product and shall not establish a legally valid contractual relationship.