



COAPTITE SAFETY DATA SHEET (SDS)

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Coaptite

Product Information: Coaptite is a sterile, non-pyrogenic, semi-solid, cohesive implant, whose principle component is synthetic calcium hydroxylapatite suspended in a gel carrier of sterile water for injection, glycerin and sodium carboxymethylcellulose.

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2. HAZARD(S) IDENTIFICATION

This product is not considered to be hazardous per the Occupational Safety & Health Administration's (OSHA's) Hazard Communication Standard 29CFR1910.1200.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Substance Name</u>	<u>CAS#</u>
Calcium Hydroxylapatite	1306-06-5
Glycerin	56-81-5
Sodium Carboxymethylcellulose	9004-32-4
Sterile Water	7732-18-5

4. FIRST – AID MEASURES

Oral Exposure: If swallowed, wash out mouth with water if conscious; consult a physician.

Skin Contact: Wash affected skin thoroughly with soap and water.

Eye Contact: Flush with copious amounts of water for at least 15 minutes; consult a physician.

5. FIRE FIGHTING MEASURES

Extinguishing media: Water, Dry Chemical, Carbon Dioxide, or Appropriate Foam

Fire Fighting Protective Equipment:

As in any fire, wear self-contained breathing apparatus (SCBA) pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.



6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Protective gloves recommended

Method for cleaning up: Clean up with dry, absorbent material such as paper towel

7. HANDLING AND STORAGE

Handle in accordance with good industrial hygiene and safety practices.

Store at a controlled room temperature between 15°C and 32°C (59°F and 90°F)

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Personal protective equipment: Protective gloves recommended, safety glasses recommended if risk of eye contact during handling

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Opaque/White
Form:	Colloidal
Odor:	None
pH (Value):	7.4 ±0.6
Melting Point/Freezing Point:	No data available
Initial Boiling Point and Boiling Range:	No data available
Flashpoint:	No data available
Evaporation Rate:	No data available
Upper/Lower Flammability or Explosive Limits:	No data available
Vapor Pressure:	No data available
Relative Density:	1.64 – 1.67 g/cc
Solubility:	No data available
Partition Coefficient:	No data available
Auto-Ignition Temperature:	No data available
Decomposition Temperature:	No data available
Viscosity:	No data available

10. STABILITY AND REACTIVITY

Reactivity	No data available
Chemical Stability:	Stable under recommended storage conditions
Conditions to Avoid:	No data available
Incompatible Materials:	Strong bases, strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Health effects are not known or expected during normal use



12. DISPOSAL CONSIDERATIONS

Ecological data is not available

13. DISPOSAL CONSIDERATIONS

Dispose of this product according to all local, state, and federal regulations

Used and partially used syringes and injection needles may be considered regulated medical waste

14. TRANSPORT INFORMATION

Non-hazardous for transport

15. REGULATORY INFORMATION

All ingredients are listed on the TSCA inventory or exempt

SARA Listed: No

RCRA Hazardous Waste: No

16. OTHER INFORMATION

Revision Date: 03 JUN 2016

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