



RADIESSE® (+) LIDOCAINE INJECTABLE IMPLANT SAFETY DATA SHEET (SDS)

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: RADIESSE® (+) Lidocaine Injectable Implant

Product Information: This product is a sterile, non-pyrogenic injectable soft tissue bulking agent. The implant consists of 25-45µm microspheres of synthetic calcium hydroxylapatite (CaHA) ceramic. The particles are suspended in a sodium carboxymethylcellulose gel carrier with 0.3% lidocaine HCl in a phosphate buffer solution.

Manufacturer: Merz North America, Inc.
Address: Northchase 1 Building
6501 Six Forks Road
Raleigh, NC 27615

Phone No.: 844-469-6379

Hazmat Service Emergency Number: 800-373-7542

International Shipments: +1-484-951-2432

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>
Lidocaine HCl	6108-05-0
Proprietary Ingredients	Various

4. FIRST – AID MEASURES

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

Skin Contact: Flush area with copious amounts of 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.

Specific Hazards: May emit hazardous/toxic fumes under fire conditions.



6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid contact with eyes, skin, or clothing. 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):	6.8 – 7.6
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 – 1.67g/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.

May cause irritation.



12. ECOLOGICAL INFORMATION

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

Effective Date: 28 JAN 2016

Revision: 03

The information contained in this SDS is to the best of Merz North America, Inc.'s knowledge and is believed to be accurate and reliable as of the revision date. However, no representation, warranty, or guarantee is implied or expressed regarding the accuracy, reliability, or completeness of this information. Information contained within this SDS is related to occupational exposure. See the instructions for use for more information regarding use.