

MSDS
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MATERIAL SAFETY DATA SHEET

SECTION I - IDENTITY

Product Name: SUPARTZ™
NDC Number: "Medical Device Listing Number B091961" "FDA Product Code 89MOZ" "PMA Number P980044 - FDA Approved January 24, 2001"
Product Class: Medical Device, significant risk, class 3
Description: ● SUPARTZ™ is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight sodium hyaluronate (620,000-1,170,000 daltons) having a pH of 6.8-7.8. Each one mL of SUPARTZ™ contains 10mg of sodium hyaluronate dissolved in a physiological saline (1.0% solution). The sodium hyaluronate is extracted from chicken combs. Sodium hyaluronate is a polysaccharide containing repeating disaccharide units of glucuronic acid and N-acetyl-glucosamine.

SECTION II – PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance/Odor: Colorless and clear, odorless and viscous
Specific Gravity: 1.008
Acid/Alkaline (pH): 6.8 - 7.8
Solubility in Water: NA
Melting Point: NA
Evaporation Point: NA
Boiling Point: NA
Vapor Pressure: NA
Vapor Density: NA

SECTION III – FIRE/EXPLOSION DATA

Flash Point: NA
LEL/UEL* (see notes): NA
Extinguishing Media: NA
Special Fire Fighting Precautions: NA

SECTION IV – REACTIVITY DATA

Stability: Stable for 42 months below 25°C, not freezing
Hazardous Decomposition or Byproducts: NA
Hazardous Polymerization: NA
Conditions to Avoid: Avoid freezing and high temperature

SECTION V – HEALTH HAZARD DATA

Route of Entry: Intra-articular injection
Health Hazard: <ul style="list-style-type: none">● Animal studies, post-marketing experience with other sodium hyaluronate-based products in this indication suggest that adverse events with SUPARTZ™ are usually infrequent, mild and transient.
Toxicity (toxicology): <ul style="list-style-type: none">● The safety of sodium hyaluronate has been established in a series of studies designed to comply with the ISO 10993 standard.
Medical Conditions Aggravated by Exposure: Not expected
Effects of Overexposure: Not expected
Emergency First Aid:
<ul style="list-style-type: none">• Eyes: Immediately flush with lots of running water (if necessary)• Inhalation: Gargle with lots of water (if necessary)• Ingestion: Wash mouth and gargle with lots of water and drink lots of water (if necessary)• Skin: Wash with soap and lots of water (if necessary)
Regulated Exposure Limits: ND

SECTION VI – PRECAUTIONS FOR SAFE HANDLING

Spill/Leakage Procedures: Clean up by absorption with materials such as a cloth.
Waste Disposal: Follow local, state and federal regulations
Handling and Storage Precautions: <ul style="list-style-type: none">● Do not freeze and store below 25°C.
Other Precautions: <ul style="list-style-type: none">● Do not use if the package or syringe is opened or damaged.

SECTION VII – CONTROL MEASURES

Ventilation: NA
Personal Protective Equipment: NA
Clothing: NA
Gloves: NA
Eye Protection: NA
Respiratory Protection: NA
Work Practices: The administration is to be performed by a physician.
Hygienic Practices: Standard aseptic administration technique must be followed.

DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES

Notes:

1. If the item has not been determined, the abbreviation “ND” may be used.
2. If the item is not applicable to the product, the abbreviation “NA” may be used.
3. UEL = upper explosive limit
4. LEL – lower explosive limit