

# SAFETY DATA SHEET

SDS for LithoClear® Gel

SECTION 1	IDENTIFICATION
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- (a) Product Identifier: LithoClear® Medical Scanning Gel for Lithotripsy
- (b) Synonyms: couplant, scanning gel, transmission gel, coupling media
- (c) Use: For dry contact ESWL (Extracorporeal Shock Wave Lithotripsy); non-sterile; for external use only. (Not for use with electromedical equipment.)
- (d) Manufacturer: NEXT Medical Products Company  
45 Columbia Road, Branchburg, NJ 08876  
800-458-4254
- (e) Emergency Phone Number: 800-458-4254 (8:30am-5pm Eastern Time)

SECTION 2	HAZARD(S) IDENTIFICATION
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- (a) Not classified as a hazardous material
- (b) Signal word: Not applicable
- (c) Eyes: Transient irritation  
Skin: No data available  
Inhalation: None expected  
Ingestion: None expected  
Note: Allergic reactions are rare, but may occur with individuals sensitive to one or more ingredients.
- (d) Not applicable

SECTION 3	COMPOSITION/INFORMATION ON INGREDIENTS
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Materials not considered to be hazardous under OSHA's Hazard Communication Standard (29 CFR 1900.1200). Product does not contain any ingredients having known health hazards in concentrations  $\geq 1\%$ , or any known or suspected carcinogens in quantities  $\geq 0.1\%$ .

SECTION 4	FIRST-AID MEASURES
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- (a) Eyes: Flush with water for at least 15 minutes  
Skin: Remove with damp towel  
Inhalation: not applicable  
Ingestion: Seek immediate medical attention if large quantity is ingested and discomfort occurs
- (b) Important symptoms: not applicable
- (c) Indication of immediate medical attention: No further relevant information available

SECTION 5	FIRE-FIGHTING MEASURES
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- (a) Extinguishing media: all types
- (b) Specific hazards: none
- (c) Special equipment precautions: none

SECTION 6	ACCIDENTAL RELEASE MEASURES
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- (a) Precaution: Material is slippery.
- (b) Method for cleaning up: Scoop or wipe up excess. Wash area with water. Sprinkle area with traction material if spill not cleaned immediately.

SECTION 7	HANDLING AND STORAGE
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- (a) Precautions: not applicable
- (b) Conditions: Store near room temperature away from sunlight to preserve viscosity.

SECTION 8	EXPOSURE CONTROLS/PERSONAL PROTECTION
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- (a) PEL limit: not applicable
- (b) Engineering controls: not applicable
- (c) Individual protection measures: protective gloves on individuals demonstrating sensitivity to this product.

SECTION 9	PHYSICAL AND CHEMICAL PROPERTIES
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- (a) Appearance: Water white, opaque gel
- (b) Odor: bland
- (c) Odor threshold: not applicable
- (d) pH: 6.0 – 8.0
- (e) Melting point/freezing point: No data available
- (f) Initial boiling point and boiling range: No data available
- (g) Flash point: No data available
- (h) Evaporation rate: No data available
- (i) Flammability: No data available
- (j) Upper/lower flammability or explosive limits: not applicable
- (k) Vapor Pressure: not determined
- (l) Vapor density: not determined
- (m) Relative density: not determined
- (n) Solubility(ies): Complete solubility in water
- (o) Partition coefficient: n-octanol/water: not determined
- (p) Auto-ignition temperature: not determined
- (q) Decomposition temperature: not determined
- (r) Viscosity: Available in high viscosity version

SECTION 10	STABILITY AND REACTIVITY
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- (a) Reactivity: Not applicable
- (b) Chemical Stability: Stable
- (c) Possibility of hazardous reactions: None known
- (d) Conditions to avoid: None known
- (e) Incompatibility: None known
- (f) Hazardous Decomposition Products: None known

SECTION 11	TOXICOLOGICAL INFORMATION
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- (a) Route of exposure: No data available
- (b) Symptoms: None known
- (c) Delayed and immediate effects: None known
- (d) Numerical measures: None known
- (e) Listing in NTP or IARC or OSHA: Not applicable

SECTION 12	ECOLOGICAL INFORMATION
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No data available

SECTION 13	DISPOSAL CONSIDERATIONS
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Follow applicable federal, state and local regulations

SECTION 14	TRANSPORT INFORMATION
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Not applicable

SECTION 15	REGULATORY INFORMATION
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All ingredients are listed on the TSCA inventory.

SECTION 16	OTHER INFORMATION
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Date of preparation: May 1, 2015.

Revision Level: D (formerly 70055C 12/27/13; 70055B 1/8/14; 70055A 10/16/13; formerly Magnaflux 7/5/11)

This SDS has been prepared in compliance with the Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200 and HCS June 1, 2015. The information contained herein is accurate to the best of our knowledge as of the date of this publication. NEXT Medical Products makes no warranty of any kind, express or implied, concerning the safe use of this product.