

SAFETY DATA SHEET (SDS)

1. Identification

Product identifier

Spherusol®

Other mean of identification

Product code(s): **NDC: 59584-140-01**

Synonyms: Spherusol® Skin Test Antigen
Coccidioides immitis Spherule-Derived Skin Test Antigen-Spherusol®

Recommended use of the chemical and restrictions on use

Recommended use: Intradermal Skin Test

Uses advised against: Intravenous Injection

Supplier address/information

Nielsen BioSciences, Inc.
11125 Flintkote Avenue, Suite G
San Diego, CA 92121

Emergency telephone number: 1 (855) 855-1212

This number is available only during business hours.

2. Hazards Identification

GHS Classification:**GHS Label:****Signal Words:**

Warning

Hazard Statements:

H303: May be harmful if swallowed.

Precautionary Statements:

P260: Do not breath dust/fume/gas/mist/vapor/spray.

P264: Wash potentially exposed skin after handling.

P270: Do not eat, drink, or smoke when using this product.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P281: Use personal protective equipment as required.

P301 and P310: IF SWALLOWED: Immediately call a Poison Center/doctor

P303 and P361 and P353: IF ON SKIN (or hair): Take off all contaminated clothing. Rinse with water.

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P304 and P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P332 and P313: If skin irritation occurs: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and if easy to do. Continue rinsing.
P337 and P313: If eye irritation persists: Get medical advice/attention.
P362 and P364: Take off contaminated clothing and wash it before reuse.
P501: Dispose of contents/containers in accordance with local/provincial/federal regulations.

Other hazards:

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

3. Composition / Information on Ingredients

Component	CAS Number	Weight %
Coccidioides immitis extract	NA	
Sodium Chloride	7440-23-5	0.9%,
Sodium Borate	1303-96-4	0.014%,
Phenol	108-95-2	0.4%
Water	7732-18-5	98%

(See Section 8 for Exposure Limits)

4. First Aid Measures

General: This is an investigational product and therefore information regarding the potential toxic effects of this chemical are limited or absent. Take proper precaution to ensure your own health and safety before attempting rescue and providing first aid. Show this data sheet to the doctor in attendance.

Eye: Flush immediately with large amounts of water for at least 15 minutes. Check for and remove contact lenses. Eyelids should be held away from the eyeball to ensure thorough rinsing. Consult a physician; preferably an ophthalmologist. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the materials and take precautions to protect themselves. Local allergic reactions may require treatment with either local or systemic antihistamine and/or corticosteroid.

Skin: Take off contaminated clothing and wash skin with soap and water for at least 15 minutes. If irritation persists, contact a physician. Wash clothing and shoes before reuse. Treat symptomatically and supportively. Ensure that medical personnel are aware of the materials and take precautions to protect themselves.

Inhalation: If overcome by mist or dust, move person to fresh air; if breathing difficulty or other effects occur, consult a physician. If not breathing, give artificial respiration. Get immediate medical attention. Treat symptomatically and supportively. Ensure that medical personnel are aware of the materials and take precautions to protect themselves. Systemic allergic reactions (anaphylaxis) may require epinephrine injection and possibly other supportive measures. See the Package Insert for more information.

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Ingestion: If a person vomits place them in a recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If this material is swallowed, call a physician immediately and show the container or label. Do not attempt to induce vomiting unless directed otherwise by medical personnel. Never give anything by mouth to an unconscious person. Observe for symptoms such as difficulty in breathing or swallowing, generalized itching, abdominal pain or cramps, nausea or vomiting, hives or angioedema occurs, loss of consciousness, low blood pressure. If any of these signs are observed, seek medical attention immediately. Systemic allergic reactions (anaphylaxis) may require epinephrine injection and possibly other supportive measures. See the Package Insert for more information. See the Package Insert for more information.

5. Fire Fighting Measures

Suitable Extinguishing Media: Use dry chemical, foam, carbon dioxide, or water spray to extinguish fire.

Fire Fighting Procedures: Keep people away. Isolate fire and prevent unauthorized entry. Soak thoroughly with water to cool and prevent re-ignition. Use fine water spray or foam. Cool surroundings with water to localize fire zone. Hand held dry chemical or carbon dioxide extinguishers may be used for small fires.

Special Protective Equipment for Firefighters: Exposed firefighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full-face mask and full fire fighting clothing (fire fighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fire fight from a protected location or a safe distance.

Unusual Fire and Explosion Hazards: If water is used to fight fire, contain runoff using dikes to prevent contamination of water supplies. Do not allow water runoff to enter nearby streams, ponds, or lakes.

Combustion Products: During a fire, smoke which may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating, may be present. Combustion products may include and are not limited to: carbon monoxide and carbon dioxide.

6: Accidental Release Measures

Steps to be Taken if Material is Released or Spilled: Wear an HEPA respirator, chemical safety goggles, rubber boots, protective clothes and gloves. Keep unnecessary people away; isolate hazard area and deny entry. All recovered material should be packaged, labeled, transported and disposed of or reclaimed in accordance with applicable laws and regulations and in conformance with good engineering practices. (Also see Section 8). Do not flush to sewer or waterways. Prevent release to the environment (soil, ditches, sewers, waterways, and/or groundwater) if possible. Wash all exposed skin areas with soap and water. Launder contaminated clothing before reuse. Refer to Section 15 for spill/release reporting information.

7. Handling and Storage

Handling

Avoid contact with material. Avoid prolonged or repeated exposure. Do not handle material near food, feed, or drinking water. Keep away from heat, sparks, open flame, or any other ignition source. Use adequate ventilation. Ensure that the proper protective gloves are worn when handling the material. After handling, always wash hands thoroughly with soap and water. Replace contaminated clothing and wash thoroughly before reusing. Follow safe chemical handling procedures for handling and storage.

Storage

Keep container dry. Store away from excessive heat, direct sunlight, and away from oxidizing agents. Keep container closed. Store in a well ventilated area. Store away from food, feed, and water. Keep at 4°C. 2-8°C (35-46°F). Do not freeze.

8. Exposure Controls / Personal Protection

Exposure Limits

Component	Cal/OSHA	OSHA	ACGIH	OEL
Coccidioides immitis extract	N/A	N/A	N/A	N/A
Sodium Chloride	N/A	N/A	N/A	N/A
Sodium Borate	N/A	N/A	N/A	N/A
Phenol	5 ppm	5 ppm	5 ppm	N/A
Water	N/A	N/A	N/A	N/A

Selection of appropriate personal protective equipment should be based on an evaluation of the performance characteristics of the protective equipment relative to the task(s) to be performed, duration of use, and the hazards and/or potential hazards that may be encountered during use. Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet facilities. Promptly remove soiled clothing/wash thoroughly before reuse.

Engineering Controls

Enclose operations to prevent aerosol generation. If process generates dust, fumes, or mist, use local exhaust ventilation or other engineering control to maintain airborne levels below exposure limits and to prevent accumulation of dust. General ventilation shall not be used as the primary control system. Isolators, fume hoods, or biological safety cabinets may be used based on a risk assessment.

Personal Protective Equipment (PPE)

Eye Protection: Based on an exposure risk assessment, appropriate eyewear should be worn to prevent mechanical injury or other irritation to eyes due to airborne particles or splashes which may result from handling this product. If there is a potential for exposure to particles/liquid which could cause eye discomfort, wear chemical goggles.

Skin Protection: Wear clean body-covering clothing such as a lab coat when handling product.

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Hand Protection: Chemical (latex/nitrile) protective gloves should be worn when handling this material. Consistent with general hygienic practices for any material, skin contact should be minimized. Use gloves to protect from mechanical injury. Selection of gloves will depend on task.

Respiratory Protection: Use local exhaust ventilation or other engineering controls to keep airborne levels below regulatory/recommended exposure limits. Use appropriate respiratory protection where airborne concentrations exceed regulatory/recommended limits. If exposure limits are exceeded, NIOSH approved respiratory protection should be worn. A NIOSH approved respirator for particulate material is generally acceptable for concentrations up to 10 times the PEL. For higher concentrations, unknown concentrations and for oxygen deficient atmospheres, use a NIOSH approved air-supplied respirator. Engineering controls are the preferred means for controlling chemical exposures. Respiratory protection may be needed for non-routine or emergency situations.

9. Physical and Chemical Properties

Physical state: Liquid
Odor: Slight phenol odor
Appearance: Clear liquid

Flashpoint: N/A **Lower Flammability Limit:** N/A

Autoignition Temperature: N/A **Upper Flammability Limit:** N/A

Boiling Point: N/A **Specific Gravity:** N/A

Melting Point: N/A **% Volatile:** N/A

Vapor Pressure: <0.01mmHg **Evaporation Rate (Water=1):** N/A

Vapor Density(Air=1): N/A **Viscosity:** N/A

% Solubility in Water: 100 **Octanol/Water Partition Coefficient:** No data available

Molecular Formula: Mixture

Molecular Weight: Mixture

pH: 7.4

10. Stability and Reactivity

Stability: Under normal conditions of storage and use this product is stable. May be shipped overnight without cold pack

Reactivity: Under normal conditions of storage and use hazardous reactions of this product will not occur.

Hazardous Reactions/Decomposition Products: None known.

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Incompatibility: Alcohols.

Conditions to Avoid: Heat. Do not freeze. Do not use after expiration date.

11. Toxicological Information

Acute Effects

Eye Contact: No data available.

Skin Contact: No data available.

Inhalation: No data available.

Ingestion: No data available.

Carcinogenicity: No data available.

Target Organ Effects: No data available.

Genetic Effects: No data available.

Reproductive Effects: No data available.

Developmental Effects: No data available.

Chronic Effects: No data available.

Repeated Dose Toxicity: No data available.

Acute Toxicity Values: No data available.

Other Toxicology Information

Specific testing has not been performed on this product. Hazard evaluation is based on information from similar products, raw material data, and technical literature. Exposure may cause irritation to the eyes, mucous membranes, upper respiratory tract and skin. As this is an investigational new product, the chemical, physical and toxicological properties have not been thoroughly investigated. May be harmful by inhalation, ingestion or skin absorption.

12. Ecological Information

EcoToxicity Information: Do not allow product to enter drinking water supplies, wastewater, or soil.

Biodegradability: No data available.

Stability in Water: No data available.

Bioaccumulation: No data available.

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Microorganisms: No data available.

Algae: No data available.

Daphnia: No data available.

Fish: No data available.

13. Disposal Considerations

Do not dump into any sewers, on the ground, or into any body of water. Sweep up spilled material and place in suitable container for disposal. Use only licensed transporters and permitted facilities for waste disposal. Comply with Federal, State, or local regulations for disposal. Do not reuse containers. For additional guidance, we recommend that you contact your local Department of Health Services for information on the disposal of this product, or arrange for disposal by an EPA licensed & permitted disposal company.

14. Transport Information

U.S. Department of Transportation (DOT):

This material is not classified as hazardous for transport.

International Maritime Organization (IMDG):

This material is not classified as hazardous for transport.

International Air Transport Authority (IATA):

This material is not classified as hazardous for transport.

International Civil Aviation Organization (ICAO):

This material is not classified as hazardous for transport.

International Carriage of Dangerous Goods by Road (ADR):

This material is not classified as hazardous for transport.

International Carriage of Dangerous Goods by Rail (RID):

This material is not classified as hazardous for transport.

Maritime Pollutant: Not listed as a Marine Pollutant

Hazardous Substances Reportable Quantity: Not applicable

**Consult Appropriate ICAO/IATA/DOT/IMDG/ADR/RID regulations for specific requirements based on shipping quantities.*

15. Regulatory Information

U.S. Federal Regulations

Hazard Communication Classification: This product is not a “hazardous chemical” as defined by the OSHA Hazard Communication Standard, 29CFR 1910.1200.

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Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):

No CERCLA listed chemicals.

Toxic Substances Control Act (TSCA): Not subject to TSCA reporting.

EPA Registry Number: N/A

Clean Water Act (CWA): This product does not contain components listed as Priority Pollutants under the Clean Water Act. (40 CFR 122.21 and 40 CFR 122.42)

Clean Air Act (CAA): This product does not contain components listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA 302/304) Title III Information: This product does not contain components regulated under SARA section 302/304.

SARA Section 311/312 (40 CFR 370) Hazard Categories:

This product is not a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29CFR 1910.1200, and as such does not require reporting under the requirements of 40CFR 370, Hazardous Chemical Reporting; Community Right to Know.

SARA Section 313 (40 CFR 372)

This product does not contain components regulated under SARA section 313.

State Regulations

California: This product does not contain chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm.

Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components: No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components: No components are subject to the New Jersey Right to Know Act.

International Inventories

Canadian Workplace Hazardous Materials Information System (WHMIS): Not controlled under WHMIS (Canada).

EU Classification: According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

****This product is not classified according to the EU regulations. Supervisors of personnel handling this product must comply with applicable communication requirements under TSCA. This is an investigational product and therefore is not fully regulated under TSCA.***



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National Fire Protection Association (NFPA) Ratings: This information is intended solely for the use of individuals trained in the NFPA system.

Health: 1 Flammability: 0 Reactivity: 0

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Prepared by: Nielsen BioSciences, Inc.

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Rev.2

End of Safety Data Sheet