SAFETY DATA SHEET

United States **Version 3.0; January 11, 2019**

Section 1. Product and Company Identification

Product Name: **SULFUR COLLOID®** (Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection for Subcutaneous, Intraperitoneal, Intravenous, and Oral Use)

Catalogue Number: N/A

Grade: Pharmaceutical Reagent

Tradenames and Synonyms: Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection, Sulfur Collid Kit
For active: Sodium Thiosulfate (Reaction Vial), Hydrochloric Acid (Vial A), Sodium Hydroxide (Vial B)

Recommended Use: Diagnostic Medical Agent. Diagnostic radiopharmaceutical imaging agent after reconstitution with radioactive Technetium Tc 99m.

Restrictions for Use: After reconstitution with Technetium Tc 99m, this material must be handled only by trained health care professionals qualified to handle radioactive material.

Company Identification:

Pharmalucence Inc.
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Billerica, MA 01821

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Fax: + 781.275.2634
Hours of operation: (8:30am - 5:00pm)
Web Site: **www.pharmalucence.com**

Section 2. Hazards identification

OSHA/HCS status: While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture: Does not present hazards within the GHS list of Physical Hazard Classes.

Health Hazards:
For the kit non-reconstituted:
Skin & Eyes Contact: Not established
Inhalation: Not established.
Ingestion: Not established.
Label Elements:
Symbol: Not applicable
Signal Word: Not applicable
Precautions:
Read the Package Insert prior to use.
Promptly remove any contamination from skin, eyes or clothing. Avoid all unnecessary exposure to the chemical substance.
Eye contact: Not expected to be a health hazard.
Skin contact: Not expected to be a health hazard.
Inhalation: Not expected to be a health hazard.
Ingestion: Not expected to be a health hazard.
Chronic exposure: Not expected to be a health hazard.
Aggravation of pre-existing Conditions: No information found.

Section 3. Composition/information on ingredients

Substance/mixture: Mixture.
Other means of identification: Not available.

Compostion

Sulfur Colloid Reaction Vial

Chemical Ingredients	Component (quantity per vial):	CAS #	Wt %
Sodium thiosulfate anhydrous,	(2.0 mg)	7772-98-7	9 %
Gelatin	(18.1 mg)	9000–70-8	81 %
Edetate disodium	(2.3 mg)	6381-92-6	10 %

Sulfur Colloid Solution A

Chemical Ingredients	Component (quantity per vial):	CAS #	Wt %
0.148 N Hydrochloric Acid Solution	(1.5 ml)	7647-01-0	100 %

Sulfur Colloid Solution B

Chemical Ingredients	Component (quantity per vial):	CAS #	Wt %
Sodium biphosphate anhydrous	(44.3 mg)	7558-79-4	3 %
Sodium Hydroxide	(14.2 mg)	1310-73-2	1 %
Water for Injection	(1.5 ml)	7732-18-5	96 %

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation Remove person to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion Wash out mouth with water. Remove person to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact No known significant effects or critical hazards.
Inhalation No known significant effects or critical hazards.
Skin contact No known significant effects or critical hazards.
Ingestion No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact No specific data.

Inhalation	No specific data.
Skin contact	No specific data.
Ingestion	No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	No specific treatment.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
Specific hazards arising from the chemical	In a fire or if heated, a pressure increase will occur and the container may burst.
Special protective actions for fire- fighters	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For Sulfur Colloid before reconstitution: To collect non-radioactive spills, use HEPA filtered vacuum or wet mop. Do not generate dust. Dispose of material as non-hazardous waste.

For Sulfur Colloid Reconstituted with Sodium Pertechnetate Tc-99m: If any loss or release of the radioactive contents occurs, notify your Radiation Safety Officer. All cleanup operations should be performed according to the Standard Operating Procedures (SOP) for radiation protection established for your facility and by the NRC, or other applicable local, provincial, state or federal regulations.

Section 7. Handling and storage

Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
Conditions for safe storage, including any incompatibilities	Keep container in a dark place. Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store at controlled room temperature (20 - 25 C).
For Sulfur Colloid reconstituted with Sodium Pertechnetate Tc-99m,	The shielded vial should be stored at or below room temperature but do not freeze. Refer to the package insert for specific approved storage temperatures after reconstitution. Handling devices such as syringe shields and tongs should be used. Storage and disposal of the reconstituted, radioactive product should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorised to license the use of this radionuclide.

Section 8. Exposure controls/personal protection

Control parameters

Chemical Identity	Type	Exposure Limit Values	Source
HYDROCHLORIC ACID	Ceiling	2 ppm	US. ACGIH Threshold Limit Values (2011)
	Ceiling_Time	5 ppm 7 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2010)
	Ceiling	5 ppm 7 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
	Ceiling	5 ppm 7 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)

Airborne Exposure Limits	OSHA Permissible Exposure Limit (PEL)	ACGIH ® Threshold Limit Value (TLV®)
Sodium Hydroxide	2 mg/m^3 (TWA), as Sn	2 mg/m^3 (TWA), as Sn

TWA = Time Weighted Average
For Tc-99m: NRC occupational concentration limit is 6 x 10E-3 µCi/mL of air.

Appropriate engineering controls Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures
Engineering Controls: Not expected to require any special ventilation.
Eye/face protection: Safety glasses with side-shields.
Skin protection: Wear protective gloves and clean body-covering clothing.
Respiratory protection: Not expected to require personal respirator usage.

Section 9. Physical and chemical properties

Appearance
Physical state Lyopholized solid. (RX Vial), Liquid (A Solution Vial), Liquid (B Solution Vial).
Color White (RX Vial), Liquid (A Clear solution), Liquid (B Clear solution).
Odor Odorless.
Odor threshold Not available.
pH Not available.
Melting point ca. 0 ºC (32 ºF) reconstituted
Boiling point ca. 100 ºC (212 ºF) reconstituted
Flash point Not applicable.
Burning time Not applicable.
Burning rate Not applicable.
Evaporation rate Not available.
Flammability (solid, gas) Not available.
Lower and upper explosive(flammable) limits Not available.
Vapor pressure Not available.
Vapor density Not available.
Relative density Not available.
Solubility Soluble
Solubility in water Soluble
Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.

Section 10. Stability and reactivity

Reactivity	No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	The product is stable.
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	No specific data.
Incompatible materials	No specific data.
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

The product is contained within an hermetically sealed glass serum vial and direct exposure is not likely to occur under normal handling and using the precautions described. Unusual events may lead to exposure through skin or eye contact. The information below pertains to the individual ingredients found in this product.

Information on toxicological effects

Edetate Disodium
Acute Toxicity:
Oral Data
LD 50 (Rat): > 2,000 mg/kg

Sodium Hydroxide
Acute Toxicity:
Oral LD50 2000 mg/kg (Rat)

Hydrochloric Acid
Acute Toxicity:
Oral Data
ATEmix (Rat): 581 mg/kg
Dermal Data
LD 50 (Mouse): 1,449 mg/kg
Inhalation Data
LC 50 (Mouse, 1 h): 1108 ppm
LC 50 (Rat, 1 h): 3124 ppm

Carcinogenicity: When this kit is reconstituted with Sodium Pertechnetate Tc-99m, this product contains a substance known to the State of California to cause cancer.

Section 12. Ecological information

Toxicity	Not available.
Persistence and degradability	Not available.
Bioaccumulative potential	Not available.
Mobility in soil	
Soil/water partition coefficient (KOC)	Not available.
Other adverse effects	No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe

way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer and follow spill control and waste management procedures for radioactive material spills in the Technetium Tc-99m SDS.

Section 14. Transport information

Product is not regulated as dangerous goods for transport.

Section 15. Regulatory information

CERCLA Reportable Quantities:
When this kit is reconstituted with radioactive material, the Reportable Quantity for Tc-99m = 100 Ci (3.7 E 12 Bq)
Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported.

SARA Title III
302 Extremely Hazardous Substances: None
311/312 Hazard Categories: None
313 Toxic substances subject to annual release reporting requirements: None
RCRA Hazardous Waste Status: Non-hazardous (See Section 13 for additional details.) California Proposition 65: Warning

When this kit is reconstituted with radioactive material, this product contains a substance known to the State of California to cause cancer.

Section 16. Other information

This document pertains, in most part, to the non-radioactive, non-reconstituted, lyophilized product. Once reconstituted with radioactive 99mTc, the material falls under the regulation of the NRC, or other local, provincial, state, or federal agencies. Only trained professionals in licensed facilities are permitted to handle the radioactive reconstituted product.

DISCLAIMER: This above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Pharmalucence shall not be held liable for any damage resulting from handling or from contact with the above material.