CIS-US, Inc.

Material Safety Data Sheet

PULMOLITE®

Revised 17-Sep-1999
Issued 02-NOV-2006

CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification

Grade: CLINICAL

Tradenames and Synonyms

MACRO AGGREGATED ALBUMIN
MAA
PULMOLITE® Kit for the preparation of Technetium Tc99m Albumin Aggregated for Injection

Company Identification

MANUFACTURER/DISTRIBUTOR

CIS-US, Inc.
10 DeAngelo Drive
Bedford, MA 01730

PHONE NUMBERS

Product Information: 1-800-221-7554
Medical Emergency: 781/275-7120

COMPOSITION/INFORMATION ON INGREDIENTS

Components

Material	CAS Number	%
NORMAL HUMAN SERUM ALBUMIN	9048-46-8	47.5
AGGREGATED HUMAN ALBUMIN		4.7
STANNOUS CHLORIDE DIHYDRATE	7772-99-8	<0.3
INACTIVE INGREDIENTS		47.5

HAZARDS IDENTIFICATION

Potential Health Effects

Approximately 21 mg of materials is contained in each glass, septum-sealed vial. Normal handling of this product in the workplace should not constitute an occupational hazard. The following information is provided for those circumstances where handling of this product in the workplace may result in uncontrolled exposure and dust generation.

The toxicologic properties of this material have not been characterized, however, mild to severe allergic reactions including anaphylactic shock have occurred in individuals exposed to protein-containing materials such as Human Serum Albumin, the active ingredient of PULMOLITE.

Effects of exposure to stannous chloride, dihydrate are as follows:

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin.

Inhalation may be fatal as a result of spasm, inflammation, and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema.

Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting.

Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

FIRST AID MEASURES

First Aid

INHALATION

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SKIN CONTACT

In case of contact, wash skin with soap and water. Call a physician. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INGESTION

If swallowed, immediately give two glasses of water and induce vomiting. Never give anything to an unconscious person. Call a physician.

Notes to Physicians

PULMOLITE, when reconstituted with Technetium Tc-99m eluate, becomes a radiopharmaceutical suitable for intravenous administration by a qualified physician. Its use is indicated as a lung imaging agent and may be used as an adjunct in the evaluation of pulmonary perfusion, as well as an imaging agent to aid in the evaluation of peritoneo-venous (LeVeen) shunt patency.

Treatment in case of overexposure should be supportive and symptomatic. If vomiting occurs prevent aspiration.

Whenever humans are exposed to protein-containing materials, hypersensitivity reactions are possible. Immediate use of epinephrine, antihistamines, or corticosteroids may be indicated.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious. An activated charcoal slurry may be used. To prepare, suspend 50 grams of activated charcoal in 400 mL of water in a plastic bottle and shake well. Orally administer 5 mL/kg, or 350 mL for an average adult (70 kg or 154 lbs).

FIRE FIGHTING MEASURES

Flammable Properties

Not a fire or explosion hazard.

Extinguishing Media

Water Spray, Foam, Dry Chemical, CO2.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Spill Clean Up

Use HEPA filtered vacuum or wet mop. Do not generate dust.

Accidental Release Measures

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 Technelite MSDS.

HANDLING AND STORAGE

Handling (Personnel)

Avoid breathing dust. Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling. Wash clothing after use.

Handling (Physical Aspects)

Do not generate dust.

Storage

Store 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 before reconstitution.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Handle in a laboratory fume hood, or other suitably ventilated work area.

Personal Protective Equipment

Wear safety glasses with side shields. Wear full face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Acceptable Exposure Limits

PULMOLITE

PEL (OSHA):	None Established
TLV (ACGIH):	None Established

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Solubility in Water:	Soluble.
pH:	5.0-8.0 @ Reconstitution.
Form:	Lyophilized solid.

The **PULMOLITE**® KIT for the preparation of Technetium Tc99m Albumin Aggregated is packaged as sterile and non-pyrogenic.

The contents of the vial are lyophilized and stored under sterile filtered air.

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

Incompatibility with Other Materials

None reasonably foreseeable.

Decomposition

Decomposition will not occur if handled and stored properly.

Polymerization

Polymerization will not occur.

TOXICOLOGICAL INFORMATION

Animal Data

Information on the adverse effects of this material in animal studies by the inhalation, dermal, oral, or ocular route(s) of exposure is not available.

No toxicity data are available for PULMOLITE, however, some protein-containing materials, such as Human Serum Albumin, have historically caused sensitization in animals.

Available toxicity information for stannous chloride, dihydrate is summarized as follows:

Intravenous Data
LDLo: 20 mg/kg (dog)
LD50: 7.8 mg/kg (rat)

Reproductive Toxicity

Developmental fetal effects and reproductive effects were noted at very high doses which were toxic to the mother (3 gm/kg).

Mutagenicity

"In vitro" testing showed some evidence of DNA damage in hamster ovaries and in human leukocytes.

LD50 is the median dose at which lethality occurred in 50% of the animals tested following exposure by injection.

LDLo is the lowest dose at which lethality was noted following exposure by injection.

DISPOSAL CONSIDERATIONS

Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

If reconstituted with Technetium Tc-99m, notify your Site Radiation Safety Officer and follow spill control and waste management procedures for radioactive materials spills in the Technelite MSDS.

TRANSPORTATION INFORMATION

Shipping Information

The known properties of this material, as packaged, do not constitute a hazard as defined by the U.S. Department of Transportation.

OTHER INFORMATION

NFPA, NPCA-HMIS

NFPA Rating

Health:	1
Flammability:	0
Reactivity:	0

NPCA-HMIS Rating

Health:	1
Flammability:	0
Reactivity:	0

References

DuPont Merck Pharmaceutical MSDS #DMP03512 dated 7/20/98.

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

End of MSDS