


SAFETY DATA SHEET

1. Identification

Product identifier	Pulmotech™ MAA (Kit for the Preparation of Technetium Tc 99m Albumin Aggregated Injection)
Other means of identification	None.
Recommended use	The content of this kit as sold is non-radioactive. Pulmotech MAA (kit for the preparation of technetium Tc 99m albumin aggregated injection) is provided as a lyophilized powder. Pulmotech MAA when prepared with sodium pertechnetate Tc 99m injection, provides Technetium Tc 99m Albumin Aggregated Injection which is suitable for intravenous or intraperitoneal administration. Technetium Tc 99m Albumin Aggregated Injection is a radioactive diagnostic agent indicated for lung scintigraphy as an adjunct in the evaluation of pulmonary perfusion in adults and pediatric patients and scintigraphy of peritoneovenous shunt as an aid in the evaluation of its patency in adults.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Supplier	
Company name	Curium US LLC
Address	2703 Wagner Place Maryland Heights, MO 63043 United States
Telephone number	Customer Service 888-744-1414
E-mail	NuclearMedicine@curiumpharma.com
Emergency telephone number:	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3
OSHA defined hazards	Not classified.	
Label elements		

Signal word	Warning
Hazard statement	May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Avoid breathing dust. Wear protective gloves. Contaminated work clothing must not be allowed out of the workplace. Avoid release to the environment.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sodium chloride	7647-14-5	48.6
Sodium acetate	127-09-3	2.2
Minimum Tin (Stannous Chloride)	10025-69-1	0.5
Human albumin serum albumin (HSA)/ Aggregated albumin	70024-90-7	37.8/10.8

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Dusts may irritate the respiratory tract, skin and eyes. May cause an allergic skin reaction. Dermatitis. Rash.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, hazardous combustion products are released that may include: Carbon oxides (CO _x). Hydrogen Chloride (HCl). Metal oxides.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire do not breathe fumes. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Minimize dust generation and accumulation. Avoid the generation of dusts during clean-up. Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent product from entering drains. Stop the flow of material, if this is without risk. Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Minimum Tin (Stannous Chloride) (CAS 10025-69-1)	PEL	2 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Minimum Tin (Stannous Chloride) (CAS 10025-69-1)	TWA	2 mg/m ³	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Minimum Tin (Stannous Chloride) (CAS 10025-69-1)	TWA	2 mg/m ³

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Skin protection

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection

If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Solid.
Form 15 mL glass vial.
Color White.

Odor Odorless.

Odor threshold	Not available.
pH	5 - 7
Melting point/freezing point	32 °F (0 °C)
Initial boiling point and boiling range	413.6 °F (212 °C)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Dust or powder may irritate the skin. May cause an allergic skin reaction.
Eye contact	Dust may irritate the eyes.
Ingestion	May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Dusts may irritate the respiratory tract, skin and eyes. May cause an allergic skin reaction. Dermatitis. Rash.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
Minimum Tin (Stannous Chloride) (CAS 10025-69-1)		
Acute		
Oral		
LD50	Mouse	1200 mg/kg
	Rabbit	10 g/kg
	Rat	700 mg/kg
Other		
LD100	Dog	159 mg/kg
	Mouse	66 mg/kg
LD50	Rat	52 mg/kg
Sodium acetate (CAS 127-09-3)		
Acute		
Oral		
LD50	Rat	2700 mg/kg
Sodium chloride (CAS 7647-14-5)		
Acute		
Dermal		
LD50	Rabbit	> 10000 mg/kg
Oral		
LD50	Rat	3000 mg/kg
Skin corrosion/irritation	Dust can cause skin irritation.	
Serious eye damage/eye irritation	Dust may irritate the eyes.	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	May cause an allergic skin reaction.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
NTP Report on Carcinogens		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not an aspiration hazard.	
Chronic effects	Prolonged inhalation may be harmful.	

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Components	Species	Test Results
Minimum Tin (Stannous Chloride) (CAS 10025-69-1)		
Aquatic		
Crustacea	EC50	Water flea (Daphnia magna)
		55 mg/l, 48 hours

Components	Species	Test Results	
Sodium chloride (CAS 7647-14-5)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	402.6 mg/l, 48 Hours
Fish	LC50	Bluegill (Lepomis macrochirus)	1294.6 mg/l, 96 hours
<i>Chronic</i>			
Crustacea	EC50	Daphnia magna	14800 mg/l, 21 days
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.		
Bioaccumulative potential	No data available.		
Mobility in soil	No data available.		
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.	
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.	
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.	
SARA 304 Emergency release notification	Not regulated.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	Not listed.	
Toxic Substances Control Act (TSCA)	One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".	
Superfund Amendments and Reauthorization Act of 1986 (SARA)		
SARA 302 Extremely hazardous substance	Not listed.	

SARA 311/312 Hazardous chemical Yes
Classified hazard categories Respiratory or skin sensitization
SARA 313 (TRI reporting)
 Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
 Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
 Not regulated.
Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List
 Minimum Tin (Stannous Chloride) (CAS 10025-69-1)
US. New Jersey Worker and Community Right-to-Know Act
 Minimum Tin (Stannous Chloride) (CAS 10025-69-1)
US. Pennsylvania Worker and Community Right-to-Know Law
 Not listed.
US. Rhode Island RTK
 Not regulated.
California Proposition 65
 California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.
US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))
 Minimum Tin (Stannous Chloride) (CAS 10025-69-1)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
 A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-April-2020
Revision date -
Version # 01

HMIS® ratings

Health: 2
Flammability: 0
Physical hazard: 0
Personal protection: F

NFPA ratings**List of abbreviations**

LD50: Lethal Dose, 50%.
EC50: Effective Concentration 50%.
PEL: Permissible Exposure Limit.
TWA: Time Weighted Average Value.
DOT: Department of Transportation (49 CFR 172.101).
IMDG Code: International Maritime Dangerous Goods Code.
IATA: International Air Transport Association.

Disclaimer

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