

SAFETY DATA SHEET

Sn-117m Colloid

FILE NO.: SDS Exu001, v.1

SDS DATE: 3/19/2020

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Sn-117m Colloid
 SYNONYMS: Synovetin OA™
 PRODUCT CODES: N/A

MANUFACTURER: Exubrion Therapeutics, Inc.
 DIVISION:
 ADDRESS: 5203 Bristol Industrial Way, Buford, GA 30518

EMERGENCY PHONE: 877-444-7333
 CHEMTREC PHONE:
 OTHER CALLS:
 FAX PHONE:

CHEMICAL NAME: Hydrated tin(IV) oxide, Sn-117m enriched
 CHEMICAL FAMILY:
 CHEMICAL FORMULA: SnO₂•XH₂O

PRODUCT USE: Radiotherapeutic device
 PREPARED BY: IsoTherapeutics Group, LLC or Theragenics Corporation
 1004 S. Velasco St., Angleton, TX 77515 5203 Bristol Industrial Way, Buford, GA 30518

SECTION 1 NOTES:

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT:

CAS NO.	% WT	% VOL	SARA 313 REPORTABLE
7732-18-5 (Water)	92-94		No
7790-47-8 (SnI ₄)	0.4-0.8		No
57-13-6 (Urea)	2.5-3.0		No
7647-01-0 (HCl)	3.3-3.8		No
	<u>ppm</u>	<u>mg/m3</u>	

OSHA PEL-TWA: no data available
 OSHA PEL STEL : no data available
 OSHA PEL CEILING: no data available

ACGIH TLV-TWA: no data available
 ACGIH TLV STEL: no data available
 ACGIH TLV CEILING: no data available

SECTION 2 NOTES:

Urea and SnI₄ are consumed in the process. The product mixture contains hydrated tin(IV) oxide (α-stannic acid), Sn-117m enriched and various ammonium salts (chloride, iodide, and bicarbonate).

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: RADIOACTIVE MATERIAL. Promptly remove any contamination from the skin, eyes, or clothing. Radioactive drugs must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

ROUTES OF ENTRY: Absorption (skin and eyes); ingestion; inhalation; injection

POTENTIAL HEALTH EFFECTS

EYES: irritant; some radiation damage is possible

SKIN: irritant; some radiation damage is possible

INGESTION: slightly hazardous; GI injury due to radiation is possible

INHALATION: toxic to mucous membranes. In the unlikely event that the substance is inhaled, damage to airways due to radiation is also possible

INJECTION: subcutaneous injection will likely cause irritation, some possible radiation damage at the site of injection; intravenous injection

SAFETY DATA SHEET

FILE NO.: SDS Exu001, v.1

Sn-117m Colloid

SDS DATE: 3/19/2020

ACUTE HEALTH HAZARDS: Hazardous in case of inhalation. Radiation effects dependent on the amount of radioactive Sn-117m present.

CHRONIC HEALTH HAZARDS: The health risks associated with chronic radiation exposure (cancer, leukemia, etc.) are dependent on accumulated dose.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: no data available

CARCINOGENICITY

OSHA:

ACGIH:

NTP:

IARC:

OTHER:

SECTION 3 NOTES:

SECTION 4: FIRST AID MEASURES

EYES: If a splash occurs, wash eyes with water for at least 15 minutes or until no more radioactivity can be removed. Notify radiation safety personnel.

SKIN: If skin contact occurs, wash the affected area thoroughly with soap and water until no more radioactivity can be removed. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

INGESTION: Notify radiation safety personnel immediately. The amount of Sn-117m ingested should be assessed and documented. Consult a physician for proper therapy.

INHALATION: Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented.

INJECTION (inadvertent): Notify radiation safety personnel immediately. The amount of Sn-117m injected should be assessed and documented. Consult a physician for proper therapy.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: Wear proper protective equipment to avoid contact with the product.

SECTION 4 NOTES:

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: not determined
 (% BY VOLUME) **LOWER:** not determined

FLASH POINT: not determined. Not considered a fire or explosion hazard.

F:

C:

METHOD USED:

AUTOIGNITION TEMPERATURE: not determined

F:

C:

NFPA HAZARD CLASSIFICATION

HEALTH:

FLAMMABILITY:

REACTIVITY:

OTHER:

HMIS HAZARD CLASSIFICATION

HEALTH:

FLAMMABILITY:

REACTIVITY:

PROTECTION:

EXTINGUISHING MEDIA: Use any means suitable for extinguishing surrounding fire.

SPECIAL FIRE FIGHTING PROCEDURES: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Not considered a fire or explosion hazard.

HAZARDOUS DECOMPOSITION PRODUCTS: Sn-117m-containing particles

SAFETY DATA SHEET

Sn-117m Colloid

FILE NO.:SDS Exu001, v.1

SDS DATE: 3/19/2020

SECTION 5 NOTES:

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: If the product is received in a leaking condition or any loss or release of the radioactive contents occurs, notify your Radiation Safety Department and IsoTherapeutics Group 979-848-0800. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state or federal regulations.

SECTION 6 NOTES:

SECTION 7: HANDLING AND STORAGE

HANDLING AND STORAGE: Store at 15°C to 30°C. Handling time should be kept to a minimum and appropriate shielding should be used. Handling devices such as syringe shields and tongs should be used. Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide (Sn-117m).

OTHER PRECAUTIONS:

SECTION 7 NOTES:

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: shields and shielded containers appropriate for low-energy gamma emissions

VENTILATION : Properly sealed containers are not expected to require any special ventilation.

RESPIRATORY PROTECTION: Not expected to require personal respirator usage.

EYE PROTECTION:safety glasses or goggles

SKIN PROTECTION: Disposable plastic, latex, or rubber gloves; labcoat.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: (see ENGINEERING CONTROLS)

WORK HYGIENIC PRACTICES: No smoking, eating, or drinking should be allowed in any area where radioactive materials are handled or stored. Dispose of radioactively contaminated clothing and PPE according to regulatory requirements.

EXPOSURE GUIDELINES: no data available

SECTION 8 NOTES:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: cream/yellow/pale orange suspension

ODOR: none

PHYSICAL STATE: solid/liquid suspension

pH AS SUPPLIED: 6.5-9.0

pH (Other):

BOILING POINT: not determined

F:

C:

MELTING POINT: not determined

F:

C:

SAFETY DATA SHEET

Sn-117m Colloid

FILE NO.: SDS Exu001, v.1

SDS DATE: 3/19/2020

FREEZING POINT: not determined

F:

C:

VAPOR PRESSURE (mmHg): not determined

@

F:

C:

VAPOR DENSITY (AIR = 1): not determined

@

F:

C:

SPECIFIC GRAVITY (H2O = 1): not determined

@

F:

C:

EVAPORATION RATE: not determined

BASIS (=1):

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (con't)

SOLUBILITY IN WATER: The solids are insoluble. The vehicle is aqueous (miscible with water.)

PERCENT SOLIDS BY WEIGHT: ~0.5

PERCENT VOLATILE: 0
BY WT/ BY VOL @

F:

C:

VOLATILE ORGANIC COMPOUNDS (VOC):

WITH WATER: 0 LBS/GAL
WITHOUT WATER: 0 LBS/GAL

MOLECULAR WEIGHT: Amount of hydration variable. Molecular weight of anhydrous SnO₂ = 150.7

VISCOSITY: not determined

@

F:

C:

SECTION 9 NOTES:

SECTION 10: STABILITY AND REACTIVITY

STABLE

UNSTABLE

STABILITY: Stable under ordinary conditions of use and storage.

CONDITIONS TO AVOID (STABILITY):

INCOMPATIBILITY (MATERIAL TO AVOID): anything incompatible with water (alkali metals, etc.)

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Sn-117m-containing particles, ammonia

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES:

SECTION 11: TOXICOLOGICAL INFORMATION

SAFETY DATA SHEET

FILE NO.: SDS Exu001, v.1

Sn-117m Colloid

SDS DATE: 3/19/2020

TOXICOLOGICAL INFORMATION: It is widely accepted by the scientific community that exposure to sufficient quantities of ionizing radiation can potentially cause harmful biological effects which include cancer, leukemia, and other effects.

SECTION 11 NOTES:

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: Insoluble Sn-117m colloids must not be discharged into sanitary sewage systems. Excreta from humal or animal patients treated with diagnostic or therapeutic doses of Sn-117m colloids may be discharged into sanitary sewage systems.

SECTION 12 NOTES:

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Sn-117m colloids are Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations.

RCRA HAZARD CLASS: unknown

SECTION 13: DISPOSAL CONSIDERATIONS (con't)

SECTION 13 NOTES:

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: Radioactive Material, Type A Package
HAZARD CLASS: 7
ID NUMBER: UN2915
PACKING GROUP:
LABEL STATEMENT:

WATER TRANSPORTATION

PROPER SHIPPING NAME:
HAZARD CLASS:
ID NUMBER:
PACKING GROUP:
LABEL STATEMENTS:

AIR TRANSPORTATION

PROPER SHIPPING NAME: Radioactive Material, Type A Package
HAZARD CLASS: 7
ID NUMBER: UN2915
PACKING GROUP:
LABEL STATEMENTS:

OTHER AGENCIES:

SECTION 14 NOTES:

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): not currently regulated

SAFETY DATA SHEET

Sn-117m Colloid

FILE NO.:SDS Exu001, v.1

SDS DATE: 3/19/2020

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): not currently regulated

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

311/312 HAZARD CATEGORIES: acute/chronic

313 REPORTABLE INGREDIENTS: none

STATE REGULATIONS: not currently regulated

INTERNATIONAL REGULATIONS: not currently regulated

SECTION 15 NOTES:

SECTION 16: OTHER INFORMATION

OTHER INFORMATION:

PREPARATION INFORMATION:

DISCLAIMER: Employers should use this information only as a supplement to other information gathered by them, and make independent judgment of the suitability of this information to ensure proper use, and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.