

SAFETY DATA SHEET



1. Identification

| | |
|---|---|
| Product identifier | INDIUM In 111 CHLORIDE STERILE SOLUTION |
| Other means of identification | |
| SDS number | INDSS |
| Synonyms | In 111 Chloride |
| Recommended use | The content of this kit as sold is radioactive. Indium In 111 Chloride Sterile Solution is indicated for radiolabeling ProstaScint™ preparations used for in vivo diagnostic imaging procedures. It is also indicated for radiolabeling Zevalin™ preparations used for Radioimmunotherapy procedures. |
| 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 | |
| Emergency telephone number: | 24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300 |

2. Hazard(s) identification

| | |
|--|--|
| Physical hazards | Not classified. |
| Health hazards | Not classified. |
| OSHA defined hazards | Not classified. |
| Label elements | |
| Hazard symbol | None. |
| Signal word | None. |
| Hazard statement | RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL. |
| Precautionary statement | |
| Prevention | Obtain special instructions before use. Do not breathe mist/vapors. Wash thoroughly after handling. Observe good industrial hygiene practices. |
| Response | Wash hands after handling. |
| 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. |

As per 29 CFR 1910.1200(b)(6)(xi), ionizing and nonionizing radiation are outside the scope and application of the Hazard Communication Standard, although the radioactive material should be considered the principle hazard of the material. This material should only be handled by trained individuals in conformance with the requirements of applicable regulations. Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. 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.

3. Composition/information on ingredients

Mixtures

| Chemical name | CAS number | % |
|------------------------|------------|------|
| Water | 7732-18-5 | > 99 |
| Hydrochloric acid | 7647-01-0 | < 1 |
| INDIUM CHLORIDE IN-111 | 50800-85-6 | < 1 |

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

4. First-aid measures

Inhalation

Call a POISON CENTER or doctor/physician. Notify radiation safety personnel immediately. Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Evaluate and document the amount of material inhaled and seek medical attention for radiation intake.

Skin contact

Wash off with soap and water. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.

Ingestion

Notify radiation safety personnel immediately. Rinse mouth. The amount of material ingested should be assessed and documented.

Most important symptoms/effects, acute and delayed

Radiation-related adverse reactions are a function of the dose level received by the patient.

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

IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

During fire, hazardous combustion products are released that may include: Radioactive. Indium oxides. Hydrogen Chloride (HCl).

Special protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire fighting equipment/instructions

Move containers from fire area if you can do so without risk. 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. Follow all guidances provided by NRC or equivalent authority. In the case of a leak/release of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. If on site, follow the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate the area, allowing sufficient time for several air exchanges. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. Maintain radioactive exposures as low as reasonably achievable. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs. Do not breathe mist or vapor. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Should be handled in closed systems, if possible. Use personal protective equipment as required. Wear appropriate personal protective equipment. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store at controlled room temperature at 20–25 °C (68–77°F). Store away from incompatible materials (see Section 10 of the SDS).

Storage 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.

8. Exposure controls/personal protection

Occupational exposure limits

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

| Components | Type | Value |
|-----------------------------------|---------|---------------------|
| Hydrochloric acid (CAS 7647-01-0) | Ceiling | 7 mg/m ³ |
| | | 5 ppm |

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|---|---------|-----------------------|
| Hydrochloric acid (CAS 7647-01-0) | Ceiling | 2 ppm |
| INDIUM CHLORIDE IN-111 (CAS 50800-85-6) | TWA | 0.1 mg/m ³ |

US. NIOSH: Pocket Guide to Chemical Hazards

| Components | Type | Value |
|---|---------|-----------------------|
| Hydrochloric acid (CAS 7647-01-0) | Ceiling | 7 mg/m ³ |
| | | 5 ppm |
| INDIUM CHLORIDE IN-111 (CAS 50800-85-6) | TWA | 0.1 mg/m ³ |

Biological limit values

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

Exposure guidelines

The Occupational Derived Air Concentration Level for Indium-111 in the halide form is 3E-6 µCi/ml.

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.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

| | |
|---------------------------------------|---|
| Skin protection | |
| Other | Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended. |
| Respiratory protection | No personal respiratory protective equipment normally required. 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. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |
| General hygiene considerations | When using, do not eat, drink or smoke. 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. |

9. Physical and chemical properties

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|---|---|
| Appearance | Clear, colorless liquid in a 10 mL vial (Indium 111). |
| Physical state | Liquid. |
| Form | Liquid. |
| Color | Colorless. |
| Odor | Odorless. |
| Odor threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | 32 °F (0 °C) |
| Initial boiling point and boiling range | 212 °F (100 °C) |
| Flash point | Not available. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not applicable. |
| 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 | 1 |
| Solubility(ies) | |
| Solubility (water) | Soluble. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | Specific Activity: > 50 mCi/μg Indium at time of calibration. |
| Concentration | 10.0 mCi/mL minimum on the calibration date and time. |
| Explosive properties | Not explosive. |
| Half-Life | 67.32 hours (Radioactive) |
| Oxidizing properties | Not oxidizing. |
| Radioactivity | 5 mCi at the time of calibration (Indium 111) |

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. Indium In-111 decays by electron capture to cadmium Cd-111 (stable) with a physical half-life of 67.32 hours. |

| | |
|---|--|
| Possibility of hazardous reactions | Will not occur. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | May emit radioactive fumes containing In-111 when heated to decomposition. |

11. Toxicological information

Information on likely routes of exposure

| | |
|---------------------|---|
| Inhalation | Exposure to radioactive materials may produce adverse effects. |
| Skin contact | Exposure to radioactive materials may produce adverse effects. May be irritating to the skin. |
| Eye contact | Direct contact with eyes may cause temporary irritation. Exposure to radioactive materials may produce adverse effects. |
| Ingestion | Exposure to radioactive materials may produce adverse effects. May cause asymptomatic physiological uptake by thyroid gland or other tissues. |

Symptoms related to the physical, chemical and toxicological characteristics Radiation-related adverse reactions are a function of the dose level received by the patient.

Information on toxicological effects

Acute toxicity May cause asymptomatic physiological uptake by thyroid gland or other tissues.

| Components | Species | Test Results |
|-----------------------------------|---------|-------------------|
| Hydrochloric acid (CAS 7647-01-0) | | |
| Acute | | |
| Dermal | | |
| LD50 | Rabbit | > 5100 mg/kg |
| Inhalation | | |
| <i>Gas</i> | | |
| LC50 | Rat | 4.2 mg/l, 1 hours |
| Oral | | |
| LD50 | Rat | 238 - 277 mg/kg |

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

| | |
|----------------------------------|----------------|
| Respiratory sensitization | Not available. |
| Skin sensitization | Not available. |

Germ cell mutagenicity

Gamma radiation is a potential mutagen to human. The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Carcinogenicity

Gamma radiation is carcinogenic to humans. The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally. Risk of cancer cannot be excluded with prolonged exposure.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrochloric acid (CAS 7647-01-0) 3 Not classifiable as to carcinogenicity to humans.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Chronic effects The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Further information No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females.

12. Ecological information

Ecotoxicity This product has no known eco-toxicological effects.

| Product | Species | Test Results |
|---|---------|---|
| INDIUM In 111 CHLORIDE STERILE SOLUTION (CAS Mixture) | | |
| Aquatic | | |
| Fish | LC50 | 28481.9707 mg/l, 96 hours |
| Components | | |
| Hydrochloric acid (CAS 7647-01-0) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| Crustacea | EC50 | Daphnia magna 0.492 mg/l, 48 Hours |
| Fish | LC50 | Oncorhynchus mykiss 7.45 mg/l, 96 Hours |

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 An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal considerations

Disposal instructions Indium In 111 Chloride Sterile Solution is 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. If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, consult local, state and federal regulations for proper disposal.

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.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

DOT

| | |
|-------------------------------------|---|
| UN number | UN2915 |
| UN proper shipping name | Radioactive material, Type A package |
| Transport hazard class(es) | |
| Class | 7 |
| Subsidiary risk | 8 |
| Label(s) | 7 |
| Packing group | Not available. |
| Special precautions for user | Read safety instructions, SDS and emergency procedures before handling. |
| Special provisions | A56, W7, W8 |
| Packaging exceptions | None |
| Packaging non bulk | 415, 418, 419 |
| Packaging bulk | 415, 418, 419 |

IATA

| | |
|-----------------------------------|--------------------------------------|
| UN number | UN2915 |
| UN proper shipping name | Radioactive material, Type A package |
| Transport hazard class(es) | |
| Class | 7 |
| Subsidiary risk | 8 |
| Label(s) | 7 |

Packing group Not available.
Environmental hazards No.
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN2915
UN proper shipping name Radioactive material, Type A package
Transport hazard class(es)
 Class 7
 Subsidiary risk 8
 Label(s) 7
Packing group Not available.
Environmental hazards
 Marine pollutant No.
EmS Not available.
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

US federal regulations Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Hydrochloric acid (CAS 7647-01-0) Listed.

SARA 304 Emergency release notification

HYDROGEN CHLORIDE (CAS 7647-01-0) 5000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

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

| Chemical name | CAS number | Reportable quantity (pounds) | Threshold planning quantity (pounds) | Threshold planning quantity, lower value (pounds) | Threshold planning quantity, upper value (pounds) |
|-------------------|------------|------------------------------|--------------------------------------|---|---|
| Hydrochloric acid | 7647-01-0 | 5000 | 500 | | |

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

| Chemical name | CAS number | % by wt. |
|-------------------|------------|----------|
| Hydrochloric acid | 7647-01-0 | < 1 |

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Hydrochloric acid (CAS 7647-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Hydrochloric acid (CAS 7647-01-0)

Safe Drinking Water Act (SDWA) Not regulated.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number

Hydrochloric acid (CAS 7647-01-0) 6545

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Hydrochloric acid (CAS 7647-01-0) 20 %WV

DEA Exempt Chemical Mixtures Code Number

Hydrochloric acid (CAS 7647-01-0) 6545

US state regulations**US. Massachusetts RTK - Substance List**

Hydrochloric acid (CAS 7647-01-0)

US. New Jersey Worker and Community Right-to-Know Act

Hydrochloric acid (CAS 7647-01-0)

US. Pennsylvania Worker and Community Right-to-Know Law

Hydrochloric acid (CAS 7647-01-0)

US. Rhode Island RTK

Hydrochloric acid (CAS 7647-01-0)

INDIUM CHLORIDE IN-111 (CAS 50800-85-6)

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (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))

Hydrochloric acid (CAS 7647-01-0)

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| 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) | No |
| 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** 06-December-2018**Revision date** -**Version #** 01

List of abbreviations
 EC50: Effective Concentration, 50%.
 LD50: Lethal Dose, 50%.
 LC50: Lethal Concentration, 50%.
 IATA: International Air Transport Association.
 IMDG Code: International Maritime Dangerous Goods Code.
 DOT: Department of Transportation (49 CFR 172.101).
 TWA: Time Weighted Average Value.
 GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

References

US. IARC Monographs on Occupational Exposures to Chemical Agents
NLM: Hazardous Substances Data Base
National Toxicology Program (NTP) Report on Carcinogens
HSDB® - Hazardous Substances Data Bank
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
NRC: Nuclear Regulatory Commission,

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