SAFETY DATA SHEET

1. Identification

Product identifier **SODIUM IODIDE I-123 DIAGNOSTIC CAPSULES**

Other means of identification

SDS number N/A9

Synonyms I-123 Diagnostic Capsules * I-123 Capsules

Recommended use The content of this kit as sold is radioactive. Administration of Sodium Iodide I-123 is indicated as a diagnostic procedure to be used in evaluating thyroid function and/or morphology.

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

Reproductive toxicity	Effects on or via lactation
Specific target organ toxicity, single exposure	Category 1 (Thyroid)

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement May cause harm to breast-fed children. Causes damage to organs (Thyroid).

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 dust. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling.

Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation. Radioactive drugs must be handled by qualified personnel only. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Observe good industrial hygiene practices.

Response Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented. The amount of material ingested should be assessed and documented. Wash hands after handling. If exposed or concerned: Get medical advice/attention.

Storage Store locked up. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive content. 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

The contents of the capsule are radioactive. Adequate shielding of the preparation must be maintained at all times.

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	%
Sodium Iodide I-123	41927-88-2	< 0.001
Sodium thiosulfate	7772-98-7	< 0.001
Sucrose	57-50-1	~ 100

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

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 I-123 in the thyroid gland should be assessed and documented. A thyroid blocking agent may be warranted and administered under the direction of a physician.

Most important symptoms/effects, acute and delayed

Dust may be irritating to eyes and respiratory tract.

Side effects: Serious adverse reactions may include chest pain, tachycardia, rash and hives. Other adverse reactions, although rare, include nausea, vomiting and itching skin.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

Females of childbearing age and pediatric patients should not be studied unless the benefits anticipated from the performance of the test outweigh the possible risk of exposure to the amount of ionizing radiation associated with the test.

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

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, hazardous combustion products are released that may include: Radioactive. Carbon oxides (COx). Iodine. Sodium oxides.

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. In case of fire do not breathe fumes.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not breathe dust. 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. Avoid inhalation of dust from the spilled material. 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. Minimize dust generation and accumulation. 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. Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Do not breathe dust. Avoid contact during pregnancy/while nursing. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices. All shippers and consignees, as well as handlers of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority. 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.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Keep containers tightly closed. Store in a well-ventilated place. Store at controlled room temperature at 20–25 ºC (68-77ºF). Store away from incompatible materials (see Section 10 of the SDS). 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.

8. Exposure controls/personal protection

Occupational exposure limits

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

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing.

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.
Respiratory protection	No personal respiratory protective equipment normally required. 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	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

Appearance	Red & white or green & white gelatin capsule.
Physical state	Solid.
Form	Capsules.
Color	Red & white or green & white gelatin capsule.
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 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	1
Solubility(ies)	
Solubility (water)	Dissolves in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	Specific Activity: 1,933 mCi/µg of Iodine on the date and time of calibration.
Explosive properties	Not explosive.
Half-Life	13.2 hours (Radioactive)
Oxidizing properties	Not oxidizing.
Radioactivity	100 & 200 µCi/capsule on the calibration date and time.

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. In the presence of moist air, a very small fraction of the Sodium Iodide I-123 may break down and emit radioactive fumes containing I-123.

Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Avoid dust formation. Moisture. Heat, flames and sparks. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon dioxide. Carbon monoxide. May emit radioactive fumes containing I-123 when heated to decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	In the presence of moist air, a very small fraction of the Sodium Iodide I-123 may break down and emit radioactive fumes containing I-123. Inhalation of dusts may cause respiratory irritation.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Dust may irritate the eyes.
Ingestion	May cause asymptomatic physiological uptake by thyroid gland or other tissues.
Symptoms related to the physical, chemical and toxicological characteristics	Dust may be irritating to eyes and respiratory tract. Side effects: Serious adverse reactions may include chest pain, tachycardia, rash and hives. Other adverse reactions, although rare, include nausea, vomiting and itching skin.

Information on toxicological effects

Acute toxicity	May cause asymptomatic physiological uptake by thyroid gland or other tissues.
Skin corrosion/irritation	Not classified.
Serious eye damage/eye irritation	Dust may irritate the eyes.

Respiratory or skin sensitization

Respiratory sensitization	Not available.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	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 genetic and teratogenic effects.
Carcinogenicity	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 genetic and teratogenic effects.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity	May cause harm to breastfed babies. Since I-123 is excreted in human milk, formulafeeding should be substituted for breast-feeding if the agent must be administered to the mother during lactation.
Specific target organ toxicity - single exposure	Causes damage to organs (Thyroid).
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	Females of childbearing age and pediatric patients should not be studied unless the benefits anticipated from the performance of the test outweigh the possible risk of exposure to the amount of ionizing radiation associated with the test.

12. Ecological information

Ecotoxicity	There are no data on the ecotoxicity of this product.
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Sucrose (CAS 57-50-1)	-3.7

Mobility in soil No data available.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions Sodium Iodide I-123 Diagnostic Capsules 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. 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 Not applicable.

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)

Not listed.

SARA 304 Emergency release notification

Not regulated.

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

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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

Sucrose (CAS 57-50-1)

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

Not listed.

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

Sucrose (CAS 57-50-1)

US. Rhode Island RTK

Sucrose (CAS 57-50-1)

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.

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

Country(s) or region	Inventory name	On inventory (yes/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

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Revision date -

Version # 01

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