

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>loflupane I-123 injection</b>
<b>Other means of identification</b>	
<b>Product code</b>	2010
<b>Synonyms</b>	loflupane I-123
<b>Recommended use</b>	Diagnostic radiopharmaceutical for intravenous use only.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Supplier</b>	
<b>Company name</b>	Curium US LLC
<b>Address</b>	2703 Wagner Place Maryland Heights, MO 63043 United States
<b>Telephone number</b>	Customer Service 888-744-1414
<b>E-mail</b>	NuclearMedicine@curiumpharma.com
<b>Emergency telephone number:</b>	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.  RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Hazard(s) not otherwise classified (HNOC)</b>	This a diagnostic radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to clinical personnel and patients. Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose training and experience has been approved by the appropriate government agency authorized to license the use of radionuclides.

## Supplemental information

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	94.71%
Ethanol	64-17-5	3.94%
Sodium acetate	127-09-3	0.78%
Acetic acid	64-19-7	0.57%
loflupane (I-127)	155797-99-2	0.01%
loflupane (I-123)	155798-07-5	<0.01%

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. The amount of I-123 in the thyroid gland and other tissues should be assessed and documented. A thyroid blocking agent may need to be administered at the discretion of a physician.

### Skin contact

Wash off immediately with soap and plenty of 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. The amount of I-123 in the thyroid gland and other tissues should be assessed and documented. A thyroid blocking agent may need to be administered at the discretion of a physician.

### Most important symptoms/effects, acute and delayed

Hypersensitivity and injection site reactions have been reported following administration. In clinical trials, the most common adverse reactions, headache, nausea, vertigo, dry mouth or dizziness occurred in < 1% of subjects.

### 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

Do not use water jet as an extinguisher, as this will spread the fire.

### Specific hazards arising from the chemical

Radioactive. During fire, gases hazardous to health may be formed such as: Carbon oxides. May produce airborne radioactive materials during a fire. Nitrogen Oxides (NOx). Volatilized I-123. Avoid all exposures!

### 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

In case of fire and/or explosion do not breathe fumes. Ensure and follow all guidance provided in handling fire involving radioactive materials. Move containers from fire area if you can do so without risk. Water runoff can cause environmental damage.

### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials. Decontaminate protective clothing and equipment before reuse or dispose of as radioactive waste.

## 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 license 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. 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

Stop the flow of material, if this is without risk. Collect in containers and seal securely. Following product recovery, flush area with water. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility in accordance with NRC or other applicable local, state or federal regulations. For waste disposal, see section 13 of the SDS. Shield waste containers as needed to maintain accessible dose rate ALARA and < 2 mR/hr.

### Environmental precautions

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

## 7. Handling and storage

### Precautions for safe handling

Follow all guidances provided by the US Nuclear Regulatory Commission in the US or equivalent authority in your country and your radiation safety personnel. Maintain radioactive exposures as low as reasonably achievable. Label as radioactive material. 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. Provide adequate ventilation. Avoid prolonged exposure. Pregnant or breastfeeding women should handle this product in keeping with ALARA principles and keeping exposure to the woman and the embryo/fetus below regulatory limits. Misuse or mishandling beyond its intended use may result in excess radiation exposure. Use transfer pipets, spill trays and absorbent coverings to confine radioactive contamination. Should be handled in closed systems, if possible. 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 license issued by the appropriate federal or state authority. Shield waste containers as needed to maintain accessible dose rate ALARA and < 2 mR/hr.

### Conditions for safe storage, including any incompatibilities

Store between 15°C - 30°C (60°F - 86°F). Keep away from heat. Store locked up. Store in original tightly closed container. Do not freeze. 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
Acetic acid (CAS 64-19-7)	PEL	25 mg/m <sup>3</sup>
		10 ppm
Ethanol (CAS 64-17-5)	PEL	1900 mg/m <sup>3</sup>
		1000 ppm

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Acetic acid (CAS 64-19-7)	STEL	15 ppm
	TWA	10 ppm
Ethanol (CAS 64-17-5)	STEL	1000 ppm

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Acetic acid (CAS 64-19-7)	STEL	37 mg/m <sup>3</sup>
		15 ppm
	TWA	25 mg/m <sup>3</sup>
		10 ppm

**US. NIOSH: Pocket Guide to Chemical Hazards**

<b>Components</b>	<b>Type</b>	<b>Value</b>
Ethanol (CAS 64-17-5)	TWA	1900 mg/m <sup>3</sup> 1000 ppm
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).	
<b>Exposure guidelines</b>	Airborne Exposure Limit (I-123): NRC Occupational Concentration Limit: (3 x 10 <sup>-6</sup> µCi/ml)	
<b>Appropriate engineering controls</b>	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.	
<b>Individual protection measures, such as personal protective equipment</b>		
<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).	
<b>Skin protection</b>		
<b>Hand protection</b>	Wear appropriate chemical resistant gloves. The use of nitrile-latex gloves is recommended. Double gloving is recommended.	
<b>Skin protection</b>		
<b>Other</b>	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.	
<b>Respiratory protection</b>	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. Consult with your facility's Radiation Safety Personnel or Health Physics staff for use of appropriate respiratory equipment.	
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.	
<b>General hygiene considerations</b>	Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. No smoking, eating or drinking should be allowed in any area where radioactive materials are handled or stored. 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.	
<b>9. Physical and chemical properties</b>		
<b>Appearance</b>	Clear liquid.	
<b>Physical state</b>	Liquid.	
<b>Form</b>	Liquid.	
<b>Color</b>	Clear liquid.	
<b>Odor</b>	Faint. Alcoholic odor.	
<b>Odor threshold</b>	Not available.	
<b>pH</b>	Not available.	
<b>Melting point/freezing point</b>	28.4 °F (-2 °C)	
<b>Initial boiling point and boiling range</b>	205 °F (96.11 °C)	
<b>Flash point</b>	Not available.	
<b>Evaporation rate</b>	Not available.	
<b>Flammability (solid, gas)</b>	Not applicable.	
<b>Upper/lower flammability or explosive limits</b>		
<b>Explosive limit - lower (%)</b>	Not available.	
<b>Explosive limit - upper (%)</b>	Not available.	
<b>Vapor pressure</b>	Not available.	
<b>Vapor density</b>	Not available.	
<b>Relative density</b>	Not available.	
<b>Solubility(ies)</b>		
<b>Solubility (water)</b>	Soluble in water.	
<b>Partition coefficient (n-octanol/water)</b>	Not available.	
<b>Auto-ignition temperature</b>	Not available.	

<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Half-Life</b>	13.2 hours
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.

Aqueous radioactive solutions are subject to radiolysis, the breaking apart of water molecules in solution. This occurs as a natural result of some of the higher radiation energies interacting with the solution water molecules. As a result, solutions may become concentrated over time.

<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
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<b>Conditions to avoid</b>	Contact with incompatible materials.
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<b>Incompatible materials</b>	Strong oxidizing agents.
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<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.
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## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Small fraction of Iodine-123 may volatilize which may result asymptomatic physiological uptake by thyroid gland or other tissues. Prolonged inhalation may be harmful.
<b>Skin contact</b>	May cause skin sensitization and irritation in hypersensitive individuals.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure. May cause symptomatic physiological uptake by thyroid gland or other tissues.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Hypersensitivity and injection site reactions have been reported following administration. In clinical trials, the most common adverse reactions, headache, nausea, vertigo, dry mouth or dizziness occurred in < 1% of subjects.
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### Information on toxicological effects

<b>Acute toxicity</b>	May result in slight to total thyroid dysfunction.
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Components	Species	Test Results
Acetic acid (CAS 64-19-7)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	1060 mg/kg
<b>Inhalation</b>		
<i>Vapor</i>		
LC50	Rat	11.4 mg/l, 4 Hours
Ethanol (CAS 64-17-5)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	20000 ppm, 10 Hours
<b>Oral</b>		
LD50	Rat	6.2 g/kg
Sodium acetate (CAS 127-09-3)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	2700 mg/kg

<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.
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<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Due to partial or complete lack of data the classification is not possible.
<b>Skin sensitization</b>	May cause allergic skin disorders in sensitive individuals.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Risk of cancer cannot be excluded with prolonged exposure. Radioactive forms of iodine will act as an endocrine disruptor at sufficient dosages.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	
Ethanol (CAS 64-17-5)	1 Carcinogenic to humans.
<b>NTP Report on Carcinogens</b>	
Not listed.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)</b>	
Not listed.	
<b>Reproductive toxicity</b>	Pregnancy: No human or animal data. Any radiopharmaceutical, may cause fetal harm. Use only if clearly needed. Nursing Mothers: A decision should be made whether to interrupt nursing after administration or not to administer DaTscan, taking into consideration the importance of the drug to the mother.
<b>Specific target organ toxicity - single exposure</b>	May result in slight to total thyroid dysfunction. Radioactive forms of iodine will act as an endocrine disruptor at sufficient dosages.
<b>Specific target organ toxicity - repeated exposure</b>	May result in slight to total thyroid dysfunction. Radioactive forms of iodine will act as an endocrine disruptor at sufficient dosages.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Chronic effects</b>	Data on biological effects of ionizing radiation are based on exposures much higher than those permitted occupationally. No effects are expected from exposures received as a result of normal use.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
Acetic acid (CAS 64-19-7)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 65 mg/l, 48 hours
Ethanol (CAS 64-17-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia obtusa) 10100 - 11200 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas) 13480 mg/l, 96 hours

**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)

Acetic acid (CAS 64-19-7)	-0.17
Ethanol (CAS 64-17-5)	-0.31

**Mobility in soil** No data available.

**Other adverse effects** No data available.

## 13. Disposal considerations

**Disposal instructions** 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. Provide for safe disposal of radioactive waste by following institutional Waste Handling & Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff may not pour measurable quantities of radioactive material down the drain.

<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose 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).
<b>Contaminated packaging</b>	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

<b>UN number</b>	UN2912
<b>UN proper shipping name</b>	Radioactive material, low specific activity (LSA-I)
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	7
<b>Packing group</b>	Not available.
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.
<b>Special provisions</b>	A56, T5, TP4, W7
<b>Packaging exceptions</b>	421, 422, 428
<b>Packaging non bulk</b>	427
<b>Packaging bulk</b>	427

### IATA

<b>UN number</b>	UN2912
<b>UN proper shipping name</b>	Radioactive material, low specific activity (LSA-I)
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	7
<b>Packing group</b>	Not available.
<b>Environmental hazards</b>	No.
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.

### IMDG

<b>UN number</b>	UN2912
<b>UN proper shipping name</b>	Radioactive material, low specific activity (LSA-I)
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	7
<b>Packing group</b>	Not available.
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No.
<b>EmS</b>	Not available.
<b>Special precautions for user</b>	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 established.

## 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)**

Acetic acid (CAS 64-19-7)

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** No**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.**FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace**

Acetic acid (CAS 64-19-7)

High priority

Ethanol (CAS 64-17-5)

Low priority

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

Acetic acid (CAS 64-19-7)

Ethanol (CAS 64-17-5)

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

Acetic acid (CAS 64-19-7)

Ethanol (CAS 64-17-5)

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

Acetic acid (CAS 64-19-7)

Ethanol (CAS 64-17-5)

**US. Rhode Island RTK**

Acetic acid (CAS 64-19-7)

Ethanol (CAS 64-17-5)

**California Proposition 65**This product contains a substance (radioactive material) known to the State of California to cause reproductive toxicity. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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



<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply 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

<b>Issue date</b>	09-August-2021
<b>Revision date</b>	-
<b>Version #</b>	01
<b>Disclaimer</b>	Curium US LLC cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.