SAFETY DATA SHEET

1. Identification

Product identifier **Octreoscan™ Kit for the Preparation of Indium In 111 Pentetreotide**

Other means of identification

SDS number OCKIP

Synonyms Indium In-111 labeled Pentetreotide

Recommended use The content of this kit as sold is radioactive.

Octreoscan™ is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radiopharmaceutical. Indium In 111 pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

It is used as a diagnostic radiopharmaceutical.

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

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.

RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL.

Precautionary statement

Prevention Avoid breathing dust. Wear protective gloves/eye protection/face protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash 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

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	%
Inositol	87-89-8	57.8
Sodium citrate dihydrate	6132-04-3	28.4
Gentisic Acid	490-79-9	11.6
Citric acid (hydrated form)	5949-29-1	2.1
Ferric chloride	7705-08-0	< 1
Hydrochloric acid	7647-01-0	< 1
INDIUM CHLORIDE IN-111	50800-85-6	< 1
Pentetreotide	138661-02-6	0.06

Composition comments

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

The kit is consisting of two components:
1) A 10-mL Octreoscan Reaction Vial which contains a lyophilized mixture of: (i) 10 µg pentetreotide [N-(diethylenetriamine-N,N,N',N"- tetraacetic acid-N"-acetyl)-D-phenylalanyl-L-hemicystyl-Lphenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicystyl-Lthreoninol cyclic (2 to 7) disulfide], (also known as octreotide DTPA), (ii) 2.0 mg gentisic acid [2, 5-dihydroxybenzoic acid], (iii) 4.9 mg trisodium citrate, anhydrous, (iv) 0.37 mg citric acid, anhydrous, and (v) 10.0 mg inositol.

2) A 10-mL vial of Indium In 111 Chloride Sterile Solution, which contains: 1.1 mL or 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/ mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

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

Remove contaminated clothing immediately and wash skin with soap and water. Always blot dry. Do not abrade skin. Get medical attention if irritation develops and persists. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists. 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	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin. Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is sub therapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/ discomfort, loose stools, and vomiting. Hypertension and hyper- and hypogly cemia have also been reported with the use of octreotide.
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. Wash contaminated clothing before reuse.

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, gases hazardous to health may be formed. When heated to decomposition, lyophilized material may emit carbon dioxide and carbon monoxide; solution may emit radioactive fumes containing In-111.
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. 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. 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 in the US or equivalent authority in your country 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 dust/fume/gas/mist/vapors/spray. 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. 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.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Keep container tightly closed. Protect from light. The drug should be stored at 2°C to 8°C both prior to and following reconstitution with Indium Chloride In-111 and discarded after six (6) hours from the time of preparation. 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/m3
		5 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	7 mg/m3
		5 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

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. Provide eyewash station.

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.

Skin protection

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

Respiratory protection No personal respiratory protective equipment normally required.

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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance Lyophilized white pellet in a 10 mL vial.
Clear, colorless liquid in a 10 mL vial (Indium 111).

Physical state Liquid.

Form Pellets. Solution.

Color Lyophilized white pellet in a 10 mL vial.
Clear, colorless liquid in a 10 mL vial (Indium 111).

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)	Somewhat soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Concentration	3.0 mCi/mL minimum on the claibration date and time (Indium 111).
Half-Life	67.32 hours (Radioactive)
Radioactivity	3.3 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.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Light. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Reducing agents.
Hazardous decomposition products	When heated to decomposition, lyophilized material may emit carbon dioxide and carbon monoxide; solution may emit radioactive fumes containing In-111.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected. No respiratory symptoms. Indium Chloride does not easily become airborne.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	May cause asymptomatic physiological uptake by specific target organs or tissues.

Symptoms related to the physical, chemical and toxicological characteristics

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin.

Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is sub therapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/ discomfort, loose stools, and vomiting. Hypertension and hyper- and hypogly cemia have also been reported with the use of octreotide.

Information on toxicological effects

Acute toxicity May cause asymptomatic physiological uptake by specific target organs or tissues.

Components	Species	Test Results
Ferric chloride (CAS 7705-08-0)		
Acute		
Oral		
LD50	Rat	1 g/kg
Hydrochloric acid (CAS 7647-01-0)		
Acute		
Dermal		
LD50	Rabbit	> 5100 mg/kg
Inhalation		
Gas		
LC50	Rat	4.2 mg/l, 1 hours
Oral		
LD50	Rat	238 - 277 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity PENTETREOTIDE was evaluated for mutagenic potential in an in vitro mouse lymphoma forward mutation assay and an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

Carcinogenicity Studies have not been performed with indium In-111 pentetreotide to evaluate carcinogenic potential or effects on fertility. 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 Animal reproduction studies have not been conducted with indium In-111 pentetreotide. It is not known whether indium In-111 pentetreotide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium In-111 pentetreotide should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium In-111 pentetreotide is administered to a nursing woman.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure May cause damage to organs (immune system, blood) through prolonged or repeated exposure. Due to inconclusive data the classification criteria are not met.

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.

12. Ecological information

Ecotoxicity There are no data on the ecotoxicity of this product.

Components		Species	Test Results
Ferric chloride (CAS 7705-08-0)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	9.6 mg/l, 48 Hours
Fish	LC50	Bluegill (Lepomis macrochirus)	20.26 mg/l, 96 Hours
Hydrochloric acid (CAS 7647-01-0)			
Aquatic			
Acute			
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 Octreoscan reconstituted with Indium Chloride In-111 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 -

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	-
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	-
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)

Ferric chloride (CAS 7705-08-0)	Listed.
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.

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 Yes

Classified hazard categories Skin corrosion or irritation
Serious eye damage or eye irritation

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) Contains component(s) regulated under the Safe Drinking Water Act.

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

Ferric chloride (CAS 7705-08-0)
Hydrochloric acid (CAS 7647-01-0)

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

Ferric chloride (CAS 7705-08-0)
Hydrochloric acid (CAS 7647-01-0)

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

Ferric chloride (CAS 7705-08-0)
Hydrochloric acid (CAS 7647-01-0)

US. Rhode Island RTK

Ferric chloride (CAS 7705-08-0)
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 04-February-2019
Version # 02

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