Iodixanol Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 05/14/2021 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Iodixanol Injection, USP

1.2. Intended Use of the Product

Iodixanol injection is a radiographic contrast agent indicated for intra-arterial and intravenous procedures.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
http://www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA / water	(CAS-No.) 7732-18-5	52 - 58	Not classified
1,3-Benzenedicarboxamide, 5,5'-[(2-hydroxy-1,3-propanediyl)bis(acetylimino)] bis[N,N'-bis(2,3-dihydroxypropyl)-2,4,6-triiodo-	Iodixanol / OptiPrep / Visipaque / (.+-.)-5,5'-[(2-Hydroxypropane-1,3-diyl)bis(acetylimino)]-2,2',4,4',6,6'-hexaiodo-N,N',N'',N'''-tetrakis(2,3-dihydroxypropyl)diisophthalamide / 5-(Acetyl-(3-(acetyl-(3,5-bis(2,3-dihydroxypropylcarbamoyl)-2,4,6-triiodophenyl)amino)-2-hydroxypropyl)amino)-N,N'-bis(2,3-dihydroxypropyl)-2,4,6-triiodobenzene-1,3-dicarboxamide; 5,5'-((2-	(CAS-No.) 92339-11-2	41.8569 – 47.626	Not classified

	Hydroxytrimethylene)bis(acetylimino))bis(N,N'-bis(2,3-dihydroxypr / 5-{N-[3-(N-{3,5-bis[(2,3-dihydroxypropyl)carbamoyl]-2,4,6-triiodophenyl}acetamido)-2-hydroxypropyl]acetamido}-1-N,3-N-bis(2,3-dihydroxypropyl)-2,4,6-triiodobenzene-1,3-dicarboxamide			
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Salt / SEA SALT / Sodium salt of hydrochloric acid / sodium chloride	(CAS-No.) 7647-14-5	0.0811 – 0.1423	Not classified
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / hydrochloric acid	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	2-Amino-2-(hydroxymethyl)-1,3-propanediol / 2-Amino-2-(hydroxymethyl)propane-1,3-diol / 2-Amino-2-methylol-1,3-propanediol / Aminotrimethylolmethane / Aminotris(hydroxymethyl)methane / Methylamine, 1,1,1-tris(hydroxymethyl)- / Trimethylolaminomethane / Tris / Tris buffer / Tris(hydroxymethyl)methanamine / Tris(hydroxymethyl)methylamine / Tris, free base / Tris-amino / Trisamine / Trometamol / Tromethamine / Tris(hydroxymethyl)aminomethane / 2-Amino-2-hydroxymethyl-1,3-propanediol / TROMETHAMINE / Tri(hydroxymethyl)aminomethane / tromethamine	(CAS-No.) 77-86-1	0.087 – 0.0913	Comb. Dust
Edetate Calcium Disodium		(CAS-No.) 6766-87-6	0.008 – 0.0084	Not classified
Calcium chloride (CaCl2), dihydrate	Calcium chloride dihydrate / Calcium chloride, dihydrate / Calcium chloride	(CAS-No.) 10035-04-8	0.0032 – 0.0056	Acute Tox. 4 (Oral), H302 Eye Irrit. 2A, H319

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation. May cause an allergic reaction in sensitive individuals.

Skin Contact: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO_2), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO_2). Metal oxides. Hydrogen Iodide. Nitrogen oxides.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropiately to minimize risk of accidents. . High pressure injection under the skin may have serious consequences and may require urgent treatment.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].Iodixanol injection, USP may be stored in a contrast media warmer for up to one month at 37°C (98.6°F).

Storage Area: Do not freeze.

7.3. Specific End Use(s)

Iodixanol injection is a radiographic contrast agent indicated for intra-arterial and intravenous procedures.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL (Ceiling)	7 mg/m³
USA OSHA	OSHA PEL C [ppm]	5 ppm
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m³
USA NIOSH	NIOSH REL C [ppm]	5 ppm
USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL C	3 mg/m³
Alberta	OEL Ceiling [ppm]	2 ppm
British Columbia	OEL Ceiling [ppm]	2 ppm
Manitoba	OEL Ceiling [ppm]	2 ppm
New Brunswick	OEL C	7.5 mg/m³
New Brunswick	OEL Ceiling [ppm]	5 ppm
Newfoundland & Labrador	OEL Ceiling [ppm]	2 ppm
Nova Scotia	OEL Ceiling [ppm]	2 ppm
Nunavut	OEL Ceiling [ppm]	2 ppm
Northwest Territories	OEL Ceiling [ppm]	2 ppm
Ontario	OEL Ceiling [ppm]	2 ppm
Prince Edward Island	OEL Ceiling [ppm]	2 ppm
Québec	Plafond (OEL Ceiling) [ppm]	2 ppm
Saskatchewan	OEL Ceiling [ppm]	2 ppm
Yukon	OEL C	7 mg/m³
Yukon	OEL Ceiling [ppm]	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Appearance	:	Colorless to pale yellow solution
Odor	:	Not available
Odor Threshold	:	Not available
pH	:	6.8 – 7.7 at 22 °C (71.6 °F)
Evaporation Rate	:	Not available
Melting Point	:	Not available
Freezing Point	:	Not available
Boiling Point	:	Not available
Flash Point	:	Not available
Auto-ignition Temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not applicable
Lower Flammable Limit	:	Not available
Upper Flammable Limit	:	Not available
Vapor Pressure	:	Not available
Relative Vapor Density at 20°C	:	Not available
Relative Density	:	Not available
Density	:	20 °C (68 °F), 320 mg/mL: 1.369 g/mL and 270 mg/mL: 1.314 g/mL 37 °C (98.6 °F), 320 mg/mL: 1.356 g/mL and 270 mg/mL: 1.303 g/mL
Specific Gravity	:	Not available
Solubility	:	Not available
Partition Coefficient: N-Octanol/Water	:	Not available
Viscosity	:	20 °C (68 °F), 320 mg/mL: 26.6 cP and 270 mg/mL: 12.7 cP 37 °C (98.6 °F), 320 mg/mL: 11.8 cP and 270 mg/mL: 6.3 cP

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

pH: 6.8 – 7.7 at 22 °C (71.6 °F)

Eye Damage/Irritation: Not classified

pH: 6.8 – 7.7 at 22 °C (71.6 °F)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg
Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m³ (Exposure time: 1 h)
Calcium chloride (CaCl2), dihydrate (10035-04-8)	
LD50 Oral Rat	1000 mg/kg
1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
LD50 Oral Rat	5900 mg/kg
LD50 Dermal Rat	> 5000 mg/kg
Edetate Calcium Disodium (6766-87-6)	
LD50 Oral Rat	10 g/kg
Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

12.2. Persistence and Degradability

Iodixanol Injection, USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Iodixanol Injection, USP

Bioaccumulative Potential	Not established.

Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
BCF Fish 1	3 (Estimated using a regression-derived equation)

12.4. Mobility in Soil Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

Sodium chloride (7647-14-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

Hydrochloric acid (7647-01-0)
Listed on the Canadian DSL (Domestic Substances List)

Sodium chloride (7647-14-5)
Listed on the Canadian DSL (Domestic Substances List)

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 05/14/2021

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

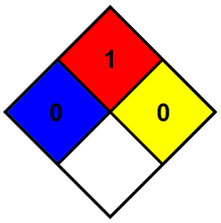
GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 1 Slight Hazard

Physical : 0 Minimal Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)