

MATERIAL SAFETY DATA SHEET

Section 1 –Identification

Product Name: Unisex Catheter Kit

Product Size: unit

Product Numbers COVERED: GMKIUXXFR (*XX-REFERS TO SIZE*)

Manufacturer: Greystone Medical LLC

Address: 7433 Pine Creek Trail Suite #B

City: Waterford

State: MI

ZIP: 48327

Country: US

Phone Number: 248-919-8491

Section 2 - Hazards Identification

2.1 PVC Compound-Gloves	No significant hazards
2.2 Lubrication Jelly	
Eye Contact	May cause slight temporary eye irritation. Corneal injury is unlikely.
Skin Contact	Prolonged contact may cause slight skin irritation with local redness.
Skin Absorption	Prolonged skin contact is unlikely to result in absorption of harmful amounts. Prolonged/repeated exposure to damaged skin (as in burn patients) may result in absorption of toxic amounts.
Inhalation	At room temperature, exposure to vapor is minimal due to low volatility; single exposure is not likely to be hazardous. For respiratory irritation and narcotic effects: No relevant data found.
Ingestion	Very low toxicity if swallowed. Harmful effects not anticipated from swallowing small amounts.
Aspiration hazard	Based on physical properties, not likely to be an aspiration hazard.
2.3 Catheter Connector	
Hazard Description	Not Applicable
2.4 Catheter Tubing	
Hazard Description	Not harmful to human body as per GB9691-1988

**2.5 PVP Swab
 Health**

Cause allergic action, stimulation on skin and mucus, adverse action is rare. But external used on the pregnant, lactating women and infant will cause obvious iodine absorption, local irritation and burning sensation, they are common reactions The large area and long term application cause neutropenia, severe burns patients can cause metabolic acidosis, liver damage , contact dermatitis, hypothyroidism and iodine poisoning.
 Contact a POISON CONTROL CENTER if ingested.

Section 3 - Composition/Information on Ingredients
3.1 PVC Gloves

Component	CAS#	Amount
PVC	9002-86-2	48%-58%
DOTP	6422-86-2	25%-40%
JNJ	64742-47-8	25%-40%
CA-Zn	N/A	0.6%-1.2%
PU	N/A	2%-4.6%

3.2 Lubrication Jelly

Component	CAS #	Amount
Polyethylene glycol-300	25322-68-3	7-10 %
Polyethylene glycol-1450	25322-68-3	7-10 %
Water	7732-18-5	80-85%
Additives	-	<2

3.3 Catheter Connector

Component	CAS #	Amount
Thermoplastic Elastomer		100%

3.3 Catheter Tubing

Component	CAS #	Amount
Polyethylene	9002-88-4	97.7%

3.5 PVP Swab

Component	CAS #	Amount
Providone Iodine	25655-41-8	-

Section 4 - First Aid Measures-all materials

If inhaled	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	None known.
Protection of first-aiders	No special precautions are necessary for first aid responders.
Notes to physician	Treat symptomatically and supportively.

Section 5 - Fire Fighting Measures

Unusual fire and explosion	None
Appropriate Extinguishing Media	Water haze, Foam, Carbon Dioxide, Chemical Powder
Protective equipment	Wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Extinguishing media: Use agent most appropriate to extinguish
The products of the burning are dangerous.	The formation of hydrocarbons and aldehydes are possible in the initial stages of a fire (especially in between 400°C and 700°C).

Section 6 – Accidental Release Measures

Person-related safety precautions	No specific measures are necessary. See point 8
Measures for environmental protection:	No special measures required. See points 12 and 13.
Measures for cleaning/collecting: Large spills:	See point 13 Act as during a limited release. Recycle product or dispose properly.
Additional information:	Collect any spilled material. It could cause danger of slipping.

Section 7 - Handling and Storage

Handling	No special requirements necessary, if handled at room temperature.
Storage	Store in original container. Use product promptly after opening.

Avoid prolonged exposure to heat and air.
 Humidity control range cannot be more than 85% RH,
 temperature control in -5 °C to 43 °C

Section 8 - Exposure Controls/Personal Protection

Respiratory Protection	Follow the OSHA respirator regulations found in 29CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.
Skin Protection	Wear appropriate protective gloves to prevent skin exposure.
Eye/Face Protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Other Protective Equipment	Clothing: Wear appropriate protective clothing to prevent skin exposure.

Section 9 - Physical/Chemical Properties

9.1 PVC Compound-Gloves

pH	N/A
Boiling Point	N/A
Freezing Point	N/A
Specific Gravity	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (AIR = 1)	N/A
Evaporation Rate (Butyl Acetate = 1)	N/A
Solubility in Water	N/A
Appearance and Odor	N/A

9.2 Lubrication Jelly

pH	5.5
Boiling Point	N/A
Freezing Point	N/A
Specific Gravity	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (AIR = 1)	N/A
Evaporation Rate (Butyl Acetate = 1)	N/A
Solubility in Water	Soluble
Appearance and Odor	Viscous gel / colorless / no odor

9.3 Catheter Connector

pH	N/A
Boiling Point	N/A
Freezing Point	N/A
Specific Gravity	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (AIR = 1)	N/A
Evaporation Rate (Butyl Acetate = 1)	N/A
Solubility in Water	N/A
Appearance and Odor	Solid / none

9.4 Catheter Tubing

pH	N/A
Boiling Point	N/A
Freezing Point	N/A
Specific Gravity	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (AIR = 1)	N/A
Evaporation Rate (Butyl Acetate = 1)	N/A
Solubility in Water	InSoluble, swelling in xylene
Appearance and Odor	Solid / none

9.5 PVP Swab

pH	N/A
Boiling Point	N/A
Freezing Point	N/A
Specific Gravity	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (AIR = 1)	N/A
Evaporation Rate (Butyl Acetate = 1)	N/A
Solubility in Water	Soluble
Appearance and Odor	Yellowish-brown amorphous hygroscopic powder or liquid / slight odor

Section 10 - Stability and Reactivity Data

Reactivity	No dangerous reaction known under conditions of normal use.
Chemical stability	Thermally stable at typical use temperatures.
Possibility of hazardous reactions	Polymerization will not occur.
Conditions to Avoid:	Exposure to elevated temperatures can cause product to decompose. Generation of gas during decomposition can cause pressure in closed systems. Fire and sunlight.
Incompatible Materials	Avoid contact with: Strong acids. Strong bases. Strong oxidizers.
Hazardous decomposition products	Decomposition products depend upon temperature, air supply

and the presence of other materials. Decomposition products can include and are not limited to: Aldehydes. Alcohols. Ethers. Carbon dioxide. Carboxylic acids.

Section 11 - Toxicological Information

Potential Health Effects	N/A
Inhalation	N/A
Eye	N/A
Skin	N/A
Ingestion	N/A
Target Organs	N/A
Primary Routes of Exposure	N/A
Potential Effects of Chronic Exposure	N/A
Carcinogenicity	N/A
Irritation/Sensitization	N/A
Teratogenicity	N/A
Mutagenicity	N/A
Reproductive Toxicity	N/A
Other	The concentrations used clinically (0.1 to 20%) are toxic for granulocytes and monocytes. Povidone-iodine was cytotoxic to SH-SY5Y (neuronal) and RSC96 (Schwann) cells. Povidone-Iodine preparation was ototoxic in guinea pigs.

Section 12 – Ecological Information

Ecotoxicity	N/A
Biodegradability	This product oxides of nitrogen, irritating and toxic fumes and gases, iodine.
Bioaccumulation	N/A
Mobility	Lubrication product only is water soluble and is expected to remain primarily in water
Other Adverse Effects	N/A

Section 13 - Disposal Considerations

DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. AS YOUR SUPPLIER, WE HAVE NO CONTROL OVER THE MANAGEMENT PRACTICES OR MANUFACTURING PROCESSES OF PARTIES HANDLING OR USING THIS MATERIAL. THE INFORMATION PRESENTED HERE PERTAINS ONLY TO THE PRODUCT AS SHIPPED IN ITS INTENDED CONDITION AS DESCRIBED IN MSDS SECTION: Composition Information. FOR

UNUSED & UNCONTAMINATED PRODUCT, the preferred options include sending to a licensed, permitted: Incinerator or other

Section 14 – Transport Information

DOT Non-Bulk	Not regulated
DOT Bulk	Not regulated
IMDG	Not regulated
ICAO/IATA	Not regulated

Section 15 – Regulatory Information

OSHA Hazard Communication Standard:

This product is not a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Sections 311 and 312 :

Immediate (Acute) Health Hazard	No
Delayed (Chronic) Health Hazard	No
Fire Hazard No Reactive Hazard	No
Sudden Release of Pressure Hazard	No

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Section 313 :

To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.

Section 16: Other Information

Greystone Medical LLC. is a registered Medical Devices manufacturer as designated by the FDA.

Disclaimer: This product is exempt from Safety Data Sheet regulations as the product is for consumer use. (Provided with this information by the compiling agencies):

This information contained in this SDS is offered as a guide to the handling of this specific material. The information contained in this Safety Data Sheet (SDS) is offered as a guide to the use and handling of this material. It has been prepared in good faith by technically knowledgeable Personnel and it believed to be correct as of the effective date listed. All safety aspects of all Greystone Medical's products are thoroughly evaluated prior to commercialization Greystone Medical shall not be held liable for any damages, losses or injuries of any nature which may result from the use of or reliance upon any information contained in this SDS. Each individual should make a determination as to the suitability of the information for his or her particular purpose(s). Greystone Medical, LLC and the United States of America in no manner whatsoever, expressly or implied, warrants this information to be accurate and disclaims all liability for its use. Any person utilizing this document should seek competent



7433 Pine Creek Trail Suite #B, Waterford, MI, 48327
www.Greystone-Medical.com

professional advice to verify and assume responsibility for the suitability of this information to their particular situation.