



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex (0.7% available iodine) and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation 8630, 8635

Product Identification Numbers

70-2007-7456-3, 70-2007-7458-9, 70-2011-7323-7, 70-2011-7324-5
7100018326, 7100020799, 7100115636, 7100115635

1.2. Recommended use and restrictions on use

Recommended use

Skin prep for surgery

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	Medical Solutions Division
ADDRESS:	3M Center, St. Paul, MN 55144-1000, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number

1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

2.1. Hazard classification

Flammable Liquid: Category 2.
Serious Eye Damage/Irritation: Category 2A.
Specific Target Organ Toxicity (single exposure): Category 3.

2.2. Label elements

Signal word

Danger

Symbols

Flame | Exclamation mark |

Pictograms



Hazard Statements

Highly flammable liquid and vapor.

Causes serious eye irritation.
May cause drowsiness or dizziness.

Precautionary Statements

Prevention:

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Ground/bond container and receiving equipment.
Use only non-sparking tools.
Take precautionary measures against static discharge.
Keep container tightly closed.
Use explosion-proof electrical/ventilating/lighting equipment.
Avoid breathing dust/fume/gas/mist/vapors/spray.
Use only outdoors or in a well-ventilated area.
Wear protective gloves and eye/face protection.

Response:

IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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.
Call a POISON CENTER or doctor/physician if you feel unwell.
In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish.

Storage:

Store in a well-ventilated place. Keep cool.
Keep container tightly closed.
Store locked up.

Disposal:

Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Hazards not otherwise classified

Repeated exposure may cause skin dryness or cracking.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
Isopropyl Alcohol	67-63-0	70 - 80 Trade Secret *
Water	7732-18-5	10 - 20
Ethyl Alcohol	64-17-5	1 - 5 Trade Secret *
IODINE	7553-56-2	< 0.8 Trade Secret *
Iodine Povacrylex (0.7% available iodine)	Mixture	< 10 Trade Secret *

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:

Remove person to fresh air. If you feel unwell, get medical attention.

Skin Contact:

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye Contact:

Immediately flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. Get medical attention.

If Swallowed:

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

No critical symptoms or effects. See Section 11.1, information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media

In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish.

5.2. Special hazards arising from the substance or mixture

Closed containers exposed to heat from fire may build pressure and explode.

Hazardous Decomposition or By-Products

<u>Substance</u>	<u>Condition</u>
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

5.3. Special protective actions for fire-fighters

Water may not effectively extinguish fire; however, it should be used to keep fire-exposed containers and surfaces cool and prevent explosive rupture. Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Contain spill. Cover spill area with a fire extinguishing foam that is resistant to polar solvents. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible using non-sparking tools. Place in a metal container approved for transportation by appropriate authorities. Clean up residue with detergent and water. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

For industrial/occupational use only. Not for consumer sale or use. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. Take precautionary measures against static discharge. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.) Do not get in eyes. Wear low static or properly grounded shoes. To minimize the risk of ignition, determine applicable electrical classifications for the process using this product and select specific local exhaust ventilation equipment to avoid flammable vapor accumulation. Ground/bond container and receiving equipment if there is potential for static electricity accumulation during transfer.

7.2. Conditions for safe storage including any incompatibilities

Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store away from heat. Store away from acids. Store away from oxidizing agents.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	C.A.S. No.	Agency	Limit type	Additional Comments
Ethyl Alcohol	64-17-5	ACGIH	STEL:1000 ppm	A3: Confirmed animal carcin.
Ethyl Alcohol	64-17-5	OSHA	TWA:1900 mg/m3(1000 ppm)	
Isopropyl Alcohol	67-63-0	ACGIH	TWA:200 ppm;STEL:400 ppm	A4: Not class. as human carcin
Isopropyl Alcohol	67-63-0	OSHA	TWA:980 mg/m3(400 ppm)	
IODINE	7553-56-2	OSHA	CEIL:1 mg/m3(0.1 ppm)	
IODIDES, INHALABLE FRACTION	Mixture	ACGIH	TWA(inhalable fraction and vapor):0.01 ppm	A4: Not class. as human carcin

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

OSHA : United States Department of Labor - Occupational Safety and Health Administration

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

Use explosion-proof ventilation equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Indirect Vented Goggles

Skin/hand protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing.

Gloves made from the following material(s) are recommended: Butyl Rubber

Neoprene

Nitrile Rubber

Respiratory protection

An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:

Half facepiece or full facepiece air-purifying respirator suitable for organic vapors and particulates

For questions about suitability for a specific application, consult with your respirator manufacturer.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state

Liquid

Color

Brown

Specific Physical Form:

Resin solution (thin) in alcohol

Odor

Alcohol

Odor threshold

No Data Available

pH

No Data Available

Melting point

Not Applicable

Boiling Point

180.00 °F

Flash Point

55 - 65 °F [*Test Method:Closed Cup*]

Evaporation rate

Approximately 7.7 [*Ref Std:ETHER=1*]

Flammability (solid, gas)

Not Applicable

Flammable Limits(LEL)

2.00 % volume

Flammable Limits(UEL)

12.00 % volume

Vapor Pressure

33 mmHg [*@ 68 °F*] [*Details:MIT data*]

Vapor Density

2.00 [*Ref Std:AIR=1*]

Density

786 kg/m3

Specific Gravity

0.7851 [*Ref Std:WATER=1*]

Solubility in Water

Moderate

Solubility- non-water

No Data Available

Partition coefficient: n-octanol/ water

No Data Available

Autoignition temperature	No Data Available
Decomposition temperature	No Data Available
Viscosity	21 centistoke
Molecular weight	No Data Available
Volatile Organic Compounds	647.32 g/l
Percent volatile	85.00 - 95.00 %
VOC Less H2O & Exempt Solvents	760.86 g/l

SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non reactive under normal use conditions.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Heat

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

<u>Substance</u>	<u>Condition</u>
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:

Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

May cause additional health effects (see below).

Skin Contact:

Prolonged or repeated exposure may cause: Dermal Defatting: Signs/symptoms may include localized redness, itching,

drying and cracking of skin.

Eye Contact:

Severe Eye Irritation: Signs/symptoms may include significant redness, swelling, pain, tearing, cloudy appearance of the cornea, and impaired vision.

Ingestion:

Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

May cause additional health effects (see below).

Additional Health Effects:

Single exposure may cause target organ effects:

Central Nervous System (CNS) Depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness.

Additional Information:

This product contains ethanol. Alcoholic beverages and ethanol in alcoholic beverages have been classified by the International Agency for Research on Cancer as carcinogenic to humans. There are also data associating human consumption of alcoholic beverages with developmental toxicity and liver toxicity. Exposure to ethanol during the foreseeable use of this product is not expected to cause cancer, developmental toxicity, or liver toxicity.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Isopropyl Alcohol	Dermal	Rabbit	LD50 12,870 mg/kg
Isopropyl Alcohol	Inhalation-Vapor (4 hours)	Rat	LC50 72.6 mg/l
Isopropyl Alcohol	Ingestion	Rat	LD50 4,710 mg/kg
Ethyl Alcohol	Dermal	Rabbit	LD50 > 15,800 mg/kg
Ethyl Alcohol	Inhalation-Vapor (4 hours)	Rat	LC50 124.7 mg/l
Ethyl Alcohol	Ingestion	Rat	LD50 17,800 mg/kg
IODINE	Dermal		estimated to be 1,000 - 2,000 mg/kg
IODINE	Inhalation-Dust/Mist		estimated to be > 12.5 mg/l
IODINE	Inhalation-Vapor		estimated to be 10 - 20 mg/l
IODINE	Ingestion		estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Isopropyl Alcohol	Multiple animal species	No significant irritation
Ethyl Alcohol	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
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Isopropyl Alcohol	Rabbit	Severe irritant
Ethyl Alcohol	Rabbit	Severe irritant

Skin Sensitization

Name	Species	Value
Isopropyl Alcohol	Guinea pig	Not classified
Ethyl Alcohol	Human	Not classified

Respiratory Sensitization

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
Isopropyl Alcohol	In Vitro	Not mutagenic
Isopropyl Alcohol	In vivo	Not mutagenic
Ethyl Alcohol	In Vitro	Some positive data exist, but the data are not sufficient for classification
Ethyl Alcohol	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Isopropyl Alcohol	Inhalation	Rat	Some positive data exist, but the data are not sufficient for classification
Ethyl Alcohol	Ingestion	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration
Isopropyl Alcohol	Ingestion	Not classified for development	Rat	NOAEL 400 mg/kg/day	during organogenesis
Isopropyl Alcohol	Inhalation	Not classified for development	Rat	LOAEL 9 mg/l	during gestation
Ethyl Alcohol	Inhalation	Not classified for development	Rat	NOAEL 38 mg/l	during gestation
Ethyl Alcohol	Ingestion	Not classified for development	Rat	NOAEL 5,200 mg/kg/day	prematuring & during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
Isopropyl Alcohol	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	
Isopropyl Alcohol	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	
Isopropyl Alcohol	Inhalation	auditory system	Not classified	Guinea pig	NOAEL 13.4 mg/l	24 hours
Isopropyl Alcohol	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Human	NOAEL Not available	poisoning and/or abuse

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex (0.7% available iodine) and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation 8630, 8635 12/06/21

Ethyl Alcohol	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	Human	LOAEL 9.4 mg/l	not available
Ethyl Alcohol	Inhalation	central nervous system depression	Not classified	Human and animal	NOAEL not available	
Ethyl Alcohol	Ingestion	central nervous system depression	Not classified	Multiple animal species	NOAEL not available	
Ethyl Alcohol	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 3,000 mg/kg	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
Isopropyl Alcohol	Inhalation	kidney and/or bladder	Not classified	Rat	NOAEL 12.3 mg/l	24 months
Isopropyl Alcohol	Inhalation	nervous system	Not classified	Rat	NOAEL 12 mg/l	13 weeks
Isopropyl Alcohol	Ingestion	kidney and/or bladder	Not classified	Rat	NOAEL 400 mg/kg/day	12 weeks
Ethyl Alcohol	Inhalation	liver	Some positive data exist, but the data are not sufficient for classification	Rabbit	LOAEL 124 mg/l	365 days
Ethyl Alcohol	Inhalation	hematopoietic system immune system	Not classified	Rat	NOAEL 25 mg/l	14 days
Ethyl Alcohol	Ingestion	liver	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 8,000 mg/kg/day	4 months
Ethyl Alcohol	Ingestion	kidney and/or bladder	Not classified	Dog	NOAEL 3,000 mg/kg/day	7 days

Aspiration Hazard

For the component/components, either no data are currently available or the data are not sufficient for classification.

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

Ecotoxicological information

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

Chemical fate information

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

SECTION 13: Disposal considerations

13.1. Disposal methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Incinerate in a permitted waste incineration facility. As a disposal alternative, utilize an acceptable permitted waste disposal facility. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated

& disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

EPA Hazardous Waste Number (RCRA): D001 (Ignitable)

SECTION 14: Transport Information

For Transport Information, please visit <http://3M.com/Transportinfo> or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact 3M for more information.

EPCRA 311/312 Hazard Classifications:

Physical Hazards

Flammable (gases, aerosols, liquids, or solids)

Health Hazards

Hazard Not Otherwise Classified (HNOC)

Serious eye damage or eye irritation

Specific target organ toxicity (single or repeated exposure)

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification

Health: 2 Flammability: 3 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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