



Safety Data Sheet

Copyright, 2020, 3M Canada Company. All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

Document group:	11-1594-8	Version number:	17.01
Issue Date:	2020/10/13	Supersedes Date:	2020/04/08

This Safety Data Sheet has been prepared in accordance with the Canadian Hazardous Products Regulations.

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

70-2011-7323-7 70-2011-7324-5 UU-0092-4108-2 UU-0092-4109-0

1.2. Recommended use and restrictions on use

Intended Use

Skin prep for surgery

Restrictions on use

Not applicable

1.3. Supplier's details

Company: 3M Canada Company
Division: Medical Solutions Division
Address: 1840 Oxford Street East, Post Office Box 5757, London, Ontario N6A 4T1
Telephone: (800) 364-3577
Website: www.3M.ca

1.4. Emergency telephone number

Medical Emergency Telephone: 1-800-3M HELPS / 1-800-364-3577; Transportation Emergency Telephone (CANUTEC): (613) 996-6666

SECTION 2: Hazard identification

This product is exempt from hazard classification according to Canadian Hazardous Products Regulations for the following reason(s):

Cosmetic, device, drug or food as defined in section 2 of the Food and Drugs Act;

2.1. Classification of the substance or mixture

Flammable Liquid: Category 2.

Serious Eye Damage/Irritation: Category 2A.

Specific Target Organ Toxicity (single exposure): Category 3.

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

2.2. Label elements

Signal word

Danger

Symbols

Flame | Exclamation mark |

Pictograms



Hazard statements

Highly flammable liquid and vapour.

Causes serious eye irritation. May cause drowsiness or dizziness.

Precautionary statements

Prevention:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground and bond container and receiving equipment. Use non-sparking tools. Take action to prevent static discharges. Keep container tightly closed. Use explosion-proof electrical/ventilating/lighting equipment. Avoid breathing dust/fume/gas/mist/vapours/spray. Use only outdoors or in a well-ventilated area. Wear protective gloves and eye/face protection. Wash exposed skin thoroughly after handling.

Response:

IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. 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 centre 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. Store locked up.

Disposal:

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

2.3. Other hazards

Repeated exposure may cause skin dryness or cracking.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	C.A.S. No.	% by Wt	Common Name
Isopropyl Alcohol	67-63-0	70 - 80 Trade Secret *	2-Propanol
Water	7732-18-5	10 - 20	Water
Ethyl Alcohol	64-17-5	1 - 5 Trade Secret *	Ethanol
Iodine	7553-56-2	< 0.8 Trade Secret *	Iodine
Iodine Povacrylex (0.7% available iodine)	Mixture	< 10 Trade Secret *	Not Applicable

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

*The actual concentration of this ingredient 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

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.

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 vapours, 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

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

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 or professional 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/vapours/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	
Isopropyl Alcohol	67-63-0	ACGIH	TWA:200 ppm;STEL:400 ppm	
IODIDES, INHALABLE FRACTION	Mixture	ACGIH	TWA(inhalable fraction and vapor):0.01 ppm	

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

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/vapours/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:

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

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 vapours 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

Physical state	Liquid
Specific Physical Form:	Resin solution (thin) in alcohol
Colour	Brown
Odour	Alcohol
Odour threshold	<i>No Data Available</i>
pH	<i>No Data Available</i>
Melting point/Freezing point	<i>Not Applicable</i>
Boiling point	82.2 °C
Flash Point	12.8 °C - 18.3 °C [Test Method: Closed Cup]
Evaporation rate	Approximately 7.7 [Ref Std: ETHER=1]
Flammability (solid, gas)	Not Applicable
Flammable Limits(LEL)	2 % volume
Flammable Limits(UEL)	12 % volume
Vapour Pressure	4,399.6 Pa [@ 20 °C] [Details: MITS data]
Viscosity/Kinematic Viscosity Viscosity/Kinematic Viscosity	2 [Ref Std: AIR=1]
Density	786 kg/m3
Relative density	0.7851 [Ref Std: WATER=1]
Water solubility	Moderate
Solubility- non-water	<i>No Data Available</i>
Partition coefficient: n-octanol/ water	<i>No Data Available</i>
Autoignition temperature	<i>No Data Available</i>
Decomposition temperature	<i>No Data Available</i>
Viscosity/Kinematic Viscosity	21 mm2/sec
Volatile Organic Compounds	647.32 g/l
Percent volatile	85 - 95 %
VOC Less H2O & Exempt Solvents	760.86 g/l
Molecular weight	<i>No Data Available</i>

Nanoparticles

This material does not contain nanoparticles.

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.

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

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
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.

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

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
Ethyl Alcohol	Inhalation	central nervous system depression	May cause drowsiness or dizziness	Human	LOAEL 2.6 mg/l	30 minutes
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	Ingestion	central nervous system depression	May cause drowsiness or dizziness	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	Not classified	Rat	NOAEL 12.3	24 months

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

		bladder			mg/l	
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

No data available.

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.

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. Safety, health and environmental regulations/legislation specific for the substance or mixture

Global inventory status

Contact 3M for more information.

SECTION 16: Other information

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

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

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.

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.

Document group:	11-1594-8	Version number:	17.01
Issue Date:	2020/10/13	Supercedes Date:	2020/04/08

The information in this Safety Data Sheet (SDS) is believed to be correct as of the date issued. The manufacturer MAKES NO WARRANTIES, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY IMPLIED WARRANTY OR CONDITION ARISING OUT OF A COURSE OF PERFORMANCE, COURSE OF DEALING, CUSTOM OR USAGE OF TRADE. User is responsible for determining whether the product is fit for a particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and application of a product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the product to determine whether it is fit for a particular purpose and suitable for user's method of use or application.

3M Canada SDSs are available at www.3M.ca