Safety Data Sheet

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This product is defined as an article as per the Occupational Safety and Health Administration's Hazard Communication Standard (29 CFR 1910.1200(b)(6)(v)). As defined in this Standard:

'Article' means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and which does not pose a physical hazard or health risk to employees.

When used under reasonable conditions and in accordance with the directions for use, the product should not present a health and safety hazard. However, use or processing of the product in a manner not in accordance with the directions for use may affect its performance and present potential health and safety hazards.

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This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier

Ioban™ 2 Antimicrobial Incise Drapes 6035, 6040, 6048, 6050, 6051, 6640EU, 6648EU, 6650EU, 6651EU

Product Identification Numbers

70-2006-7884-8 70-2007-4532-4 70-2007-4534-0 IW-4101-1644-4

1.2. Recommended use and restrictions on use

Recommended use

Used in surgical procedures to protect the patient's skin and to protect surgical staff from the patient's body fluids.

1.3. Supplier's details

Address: KCI Medical India Private Limited, S - 327, Greater Kailash - II, New Delhi, Delhi, 110048, India
Telephone: 1-855-423-6725
E Mail: psops_supportteam@solventum.com
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1.4. Emergency telephone number

CHEMTREC 1-800-424-9300 OR 1-703-527-3887, Contract number# 1015211

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture
This product is considered to be an article and is exempt from GHS classification.

2.2. Label elements
Signal Word
Not applicable.

Symbols
Not applicable

Pictograms
Not applicable

2.3. Other hazards
None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Wt
Polyethylene Film	9002-88-4	75 - 90
Paper	None	10 - 15
Antimicrobial iodophor adhesive	Trade Secret	4 - 6

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation
No need for first aid is anticipated. If symptoms develop, remove the affected person to fresh air. Get medical attention.

Skin contact
No need for first aid is anticipated.

Eye contact
If exposed, flush eyes with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms develop, get medical attention.

If swallowed
Do not induce vomiting. 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 ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture
None inherent in this product.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	During combustion.

5.3. Special protective actions for fire-fighters
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
Not applicable. Ventilate the area with fresh air. Observe precautions from other sections.

6.2. Environmental precautions
Not applicable.

6.3. Methods and material for containment and cleaning up
Not applicable.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions. For industrial/occupational use only. Not for consumer sale or use.

7.2. Conditions for safe storage including any incompatibilities
No special storage requirements. Not applicable.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits
No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

8.2. Exposure controls

8.2.1. Engineering controls
No engineering controls required.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Eye protection not required. 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:
Safety glasses with side shields.

Skin/hand protection
No protective gloves required.

Respiratory protection

Respiratory protection is not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Color	Gold, Orange
Odor	Moderate Iodine
Odour threshold	*Not applicable.*
pH	*Not applicable.*
Melting point/Freezing point: NA	*Not applicable.*
Boiling point/Initial boiling point/Boiling range	121.1 ºC
Flash point	121.1 ºC
Evaporation rate	*Not applicable.*
Flammability	Not applicable.
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Vapour pressure	*Not applicable.*
Relative Vapor Density	*Not applicable.*
Density	*Not applicable.*
Relative density	1
Water solubility	Nil
Solubility- non-water	*Not applicable.*
Partition coefficient: n-octanol/water	*No data available.*
Autoignition temperature	*Not applicable.*
Decomposition temperature	*Not applicable.*
Kinematic Viscosity	*Not applicable.*
Volatile organic compounds (VOC)	*Not applicable.*
Percent volatile	*Not applicable.*
VOC less H2O & exempt solvents	*Not applicable.*

Particle Characteristics	*Not applicable.*

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 polymerisation will not occur.

10.4 Conditions to avoid
None known.

10.5 Incompatible materials
None known.

10.6 Hazardous decomposition products

Substance	Condition
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

Under recommended usage conditions, hazardous decomposition products are not expected. Hazardous decomposition products may occur as a result of oxidation, heating, or reaction with another material.

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 labelling, 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
No health effects are expected.

Skin contact
No health effects are expected.

Eye contact
No health effects are expected.

Ingestion
No health effects are expected.

Additional information:
This product, when used under reasonable conditions and in accordance with the 3M directions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards

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
Polyethylene Film	Dermal		LD50 estimated to be > 5,000 mg/kg
Polyethylene Film	Ingestion	Rat	LD50 > 2,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Rabbit	Minimal irritation
Polyethylene Film	Professional judgement	No significant irritation

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

Sensitization:

Skin Sensitisation

Name	Species	Value
Overall product	Human	Not classified

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

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

Carcinogenicity

Name	Route	Species	Value
Polyethylene Film	Not specified.	Multiple animal species	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

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

Target Organ(s)

Specific Target Organ Toxicity - single exposure
For the component/components, either no data are currently available or the data are not sufficient for classification.

Specific Target Organ Toxicity - repeated exposure
For the component/components, either no data are currently available or the data are not sufficient for classification.

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

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

Acute aquatic hazard:
Not acutely toxic to aquatic life by GHS criteria.

Chronic aquatic hazard:
Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Polyethylene Film	9002-88-4	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Antimicrobial iodophor adhesive	Trade Secret	N/A	Data not available or insufficient for classification	N/A	N/A	N/A

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polyethylene Film	9002-88-4	Data not available-insufficient	N/A	N/A	N/A	N/A
Antimicrobial iodophor adhesive	Trade Secret	Data not available-insufficient	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polyethylene Film	9002-88-4	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Antimicrobial iodophor adhesive	Trade Secret	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil
Please contact manufacturer for more details

12.5 Other Adverse effects
No information available.

SECTION 13: Disposal considerations

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

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility.

SECTION 14: Transport Information

Not hazardous for transportation.

Air Transport (IATA)Regulations

UN No Not applicable
Proper Shipping Name Not applicable
Hazard Classs/Division Not applicable
Subsidiary Risk Not applicable
Packing Group: Not applicable

Marine Transport (IMDG)
UN No Not applicable
Proper Shipping Name Not applicable
Hazard Classs/Division Not applicable
Subsidiary Risk Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

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.

Applicable Environmental, Health and Safety Regulations
The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989
The Bio Medical Waste (Management & Handling) Rules, 1998
Hazardous Chemicals (Classification, Packaging and Labelling Draft Rules), 2011

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules
None.

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:
Product is classified as Non-Hazardous.

SECTION 16: Other information

NFPA Hazard Classification
Health: 0 **Flammability:** 1 **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.

Revision information:
Section 1: Product identification numbers information was added.
Section 7: Conditions safe storage information was modified.

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