

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

TegadermTM Transparent Film Dressing 1610, 1614, 1616, 1622, 1624, 1626, 1627, 1628, 1629, 1630, 1650, 1655

Product Identification Numbers

70-2007-4920-1 70-2007-4927-6 70-2007-4930-0 70-2007-4932-6 70-2018-0346-0

70-2018-0355-1

1.2. Recommended use and restrictions on use

Recommended use

I.V. secural and wound management.

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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thereon.

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	
Printed Silicone Coated Paper Liner	None	15 - 65	
Silicone Coated Paper Liner	Trade Secret	<= 40	
Acrylate Adhesive	Trade Secret	5 - 25	
Polyurethane Backing	Trade Secret	5 - 15	
Border Backing	None	<= 10	
Label Tape	None	<= 5	

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

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

<u>Substance</u> Carbon monoxide. Carbon dioxide.

Condition

During combustion. 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.

6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up

Not applicable. Place in a container approved for transportation by appropriate authorities, but do not seal the container for 48 hours to avoid pressure build-up.

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. Keep out of reach of children.

7.2. Conditions for safe storage including any incompatibilities

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

Not applicable.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Eye protection not required.

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	Colorless
Odor	Slight Acrylic
Odour threshold	Not applicable.
рН	Not applicable.
Melting point/Freezing point: NA	No data available.
Boiling point/Initial boiling point/Boiling range	Not applicable.
Flash point	Not applicable.
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	Not applicable.
Water solubility	Nil
Solubility- non-water	Not applicable.
Partition coefficient: n-octanol/water	No data available.
Autoignition temperature	No data available.
Decomposition temperature	Not applicable.
Kinematic Viscosity	Not applicable.
Volatile organic compounds (VOC)	No data available.
Percent volatile	No data available.
VOC less H2O & exempt solvents	No data available.

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

Physical Blockage: Signs/symptoms may include cramping, abdominal pain, and constipation.

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

Tieute Tokieny							
Name	Route	Species	Value				
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg				
Border Backing	Dermal		LD50 estimated to be > 5,000 mg/kg				

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Border Backing Ingesti	stion Rat	LD50 > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Overall product	Human	No significant irritation
Border Backing	In vitro	No significant irritation
	data	

Serious Eye Damage/Irritation

Name		Species	Value
Border Ba	king	Human	No significant irritation

Sensitization:

Skin Sensitisation

Name	Species	Value
Border Backing	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

Name	Route	Value
Border Backing	In Vitro	Not mutagenic

Carcinogenicity

For the component/components, either no data are currently available or 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

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Border Backing	Ingestion	heart skin endocrine system bone, teeth, nails, and/or hair hematopoietic system liver immune system muscles nervous system eyes kidney and/or bladder respiratory system	Not classified	Rat	NOAEL Not available	13 weeks

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
Acrylate Adhesive	Trade Secret	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Border Backing	None	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Label Tape	None	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
Acrylate Adhesive	Trade Secret	Data not available- insufficient	N/A	N/A	N/A	N/A
Border Backing	None	Data not available- insufficient	N/A	N/A	N/A	N/A
Label Tape	None	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
Acrylate Adhesive	Trade Secret	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Border Backing	None	Data not available or insufficient for	N/A	N/A	N/A	N/A

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		classification				
Label Tape	None	Data not available	N/A	N/A	N/A	N/A
		or insufficient for				
		classification				

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.

Prior to disposal, consult all applicable authorities and regulations to insure proper classification. 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 NameNot applicableHazard Classs/DivisionNot applicableSubsidiary RiskNot 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 manufacturer 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

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:

The product is classified as Non-hazardous as per MSIHC Rules, 1989.

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: Address information was modified.

Company Telephone information was modified.

Section 1: E-mail address information was modified.

Section 1: Emergency telephone information was modified.

Section 1: Product identification numbers information was added.

Section 1: Product name information was modified.

Section 02: GHS Classification Statements information was added.

Section 02: GHS Pictogram Not Applicable information was added.

Section 02: GHS Signal Word - Not applicable information was added.

Section 02: GHS Symbol Text - Not applicable information was added.

Label: GHS Classification information was deleted.

Label: Graphic information was deleted.

Section 2: Ingredient table information was modified.

Section 4: First aid for eye contact information information was modified.

Section 4: First aid for inhalation information information was modified.

Section 04: Information on toxicological effects information was deleted.

Section 5: Fire - Advice for fire fighters information information was modified.

Section 6: Accidental release clean-up information information was modified.

Section 7: Precautions safe handling information information was modified.

Section 8: Personal Protection - Respiratory Information information was modified.

Section 09: Color information was added.

Section 9: Flammability (solid, gas) information information was deleted.

Section 09: Flammability information information was added.

Section 09: Kinematic Viscosity information information was added.

Section 09: Odor information was added.

Sections 3 and 9: Odour, colour, grade information information was deleted.

Section 09: Particle Characteristics N/A information was added.

Section 09: Percent Volatile information was added.

Section 9: Property description for optional properties information was deleted.

Section 09: Vapor Density Value information was added.

Section 9: Vapour density value information was deleted.

Section 9: Viscosity information information was deleted.

Section 09: VOC Less H2O & Exempt Solvents information was added.

Section 09: Volatile Organic Compounds information was added.

Section 11: Acute Toxicity table information was modified.

Section 11: Germ Cell Mutagenicity Table information was modified.

Section 11: Health Effects - Eve information information was modified.

Section 11: Health Effects - Skin information information was modified.

Section 11: Serious Eye Damage/Irritation Table information was modified.

Section 11: Skin Corrosion/Irritation Table information was modified.

Section 11: Skin Sensitization Table information was modified.

Section 11: Target Organs - Repeated Table information was modified.

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- Section 12: Chronic aquatic hazard information information was added.
- Section 12: Component ecotoxicity information information was modified.
- Section 12: Persistence and Degradability information information was modified.
- Section 12:Bioccumulative potential information information was modified.
- Section 13: Standard Phrase Category Waste GHS information was modified.
- Section 15: Applicable Environmental, Health and Safety Regulations information was modified.
- Section 15: MSIHC Part I of Schedule I ingredients information was added.
- Section 15: Regulations Inventories information was modified.
- Sectio 16: UK disclaimer information was deleted.
- Section 16: Web address information was modified.

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