

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name or designation of the mixture	Kytocel
Registration number	-
Synonyms	None.
Issue date	01-October-2018
Version number	02
Revision date	29-November-2018
Supersedes date	01-October-2018

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Wound dressing.
Uses advised against	None known.

### 1.3. Details of the supplier of the safety data sheet

Company name	Aspen Medical Europe Ltd.
Address	Clinitron House, Ashby Park, Ashby-de-la-Zouch, Leicestershire, LE65 1JG
Telephone	01530 411000 0800 032 3399
E-mail	customers@aspenmedicaleurope.com

Non-EU Manufacturer	Aspen Surgical Products, Inc
Address	6945 Southbelt Dr. SE Caledonia, MI 49316, US
E-mail	customerservice@aspensurgical.com
Telephone	616-698-7100
Emergency phone number	3E Hotline - 24-Hour Emergency 1-855-350-3591

1.4. Emergency telephone number	+44 (0)1530 562216
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## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The article has been assessed for physical, health and environmental hazards and the following classification applies.

#### Classification according to Regulation (EC) No 1272/2008 as amended

As being an article the product does not require label in accordance with CLP Regulation (EC) No. 1272/2008 and this safety data sheet (SDS) is provided on the voluntary basis for information purpose only.

Hazard summary	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.
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### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms	None.
Signal word	None.
Hazard statements	The product is an article and therefore the classification requirements do not apply.

#### Precautionary statements

Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information	None.
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**2.3. Other hazards** This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

The components are not hazardous or are below required disclosure limits.

**Composition comments** This product is an article.  
The product is a non-woven pad or rope dressing composed of acylated chitosan fibres.

## SECTION 4: First aid measures

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 4.1. Description of first aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact** Remove from skin. Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye contact** Flush thoroughly with water. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

**4.2. Most important symptoms and effects, both acute and delayed** Exposure may cause temporary irritation, redness, or discomfort. May cause irritation through mechanical abrasion. Discomfort may occur upon inhalation of fibres. Occasional idiosyncratic dermatological reactions.

**4.3. Indication of any immediate medical attention and special treatment needed** Treat symptomatically.

## SECTION 5: Firefighting measures

**General fire hazards** No unusual fire or explosion hazards noted.

### 5.1. Extinguishing media

**Suitable extinguishing media** Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed such as: Carbon dioxide. Nitrogen Oxides.

### 5.3. Advice for firefighters

**Special protective equipment for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Special fire fighting procedures** Move material from fire area if you can do so without risk.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Avoid inhaling fine particulates. Avoid contact with eyes.

**For emergency responders** Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.

**6.2. Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** The product is immiscible with water. Stop the flow of material, if this is without risk. Shovel the material into waste container for disposal. Following product recovery, flush area with water.

**6.4. Reference to other sections** For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling** Observe good industrial hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities** Store in original packaging. Store at room temperature. To maintain product quality, do not store in heat or direct sunlight.

**7.3. Specific end use(s)** Wound dressing.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Recommended monitoring procedures</b>	Follow standard monitoring procedures.
<b>Derived no effect levels (DNELs)</b>	Not available.
<b>Predicted no effect concentrations (PNECs)</b>	Not available.
<b>Exposure guidelines</b>	Occupational Exposure Limits are not relevant to the current physical form of the product.
<b>8.2. Exposure controls</b>	
<b>Appropriate engineering controls</b>	General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>General information</b>	No protection is ordinarily required under normal conditions of use.
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
- Hand protection	Not normally needed.
- Other	No special requirements under ordinary conditions of use.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Check with respiratory protective equipment suppliers.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
<b>Environmental exposure controls</b>	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Pad or Rope.
<b>Colour</b>	Cream to pale yellow.

**Odour** None.

**Odour threshold** Not available.

**pH** Not applicable.

**Melting point/freezing point** Not applicable.

**Initial boiling point and boiling range** Not applicable.

**Flash point** Not applicable.

**Evaporation rate** Not applicable.

**Flammability (solid, gas)** Will burn if involved in a fire.

#### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Vapour pressure** Not applicable.

**Vapour density** Not applicable.

**Relative density** Not available.

**Solubility(ies)** Insoluble in water, but can form gels when absorbing water.

**Partition coefficient (n-octanol/water)** Not applicable.

**Auto-ignition temperature** Not available.

<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not applicable.
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.
<b>9.2. Other information</b>	
<b>Oxidation reduction potential</b>	Not applicable.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Direct sources of heat.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	Thermal decomposition or combustion may produce: Carbon dioxide (CO <sub>2</sub> ). Carbon monoxide (CO). Nitrogen oxides (NO <sub>x</sub> ).

## SECTION 11: Toxicological information

**General information** Under normal conditions of intended use, this material does not pose a risk to health.

### Information on likely routes of exposure

<b>Inhalation</b>	Discomfort may occur upon inhalation of fibres.
<b>Skin contact</b>	Occasional idiosyncratic dermatological reactions.
<b>Eye contact</b>	May cause irritation through mechanical abrasion.
<b>Ingestion</b>	Ingestion may cause irritation and stomach discomfort.

**Symptoms** Exposure may cause temporary irritation, redness, or discomfort. May cause irritation through mechanical abrasion. Discomfort may occur upon inhalation of fibres. Occasional idiosyncratic dermatological reactions.

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	Not expected to be acutely toxic.
<b>Skin corrosion/irritation</b>	Occasional idiosyncratic dermatological reactions.
<b>Serious eye damage/eye irritation</b>	May cause irritation through mechanical abrasion.
<b>Respiratory sensitisation</b>	Based on available data, the classification criteria are not met.
<b>Skin sensitisation</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity - single exposure</b>	Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Mixture versus substance information</b>	No information available.
<b>Other information</b>	Not available.

## SECTION 12: Ecological information

<b>12.1. Toxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>12.2. Persistence and degradability</b>	No data is available on the degradability of any ingredients in the mixture.
<b>12.3. Bioaccumulative potential</b>	No data available for this product.
<b>Partition coefficient n-octanol/water (log K<sub>ow</sub>)</b>	Not applicable.
<b>Bioconcentration factor (BCF)</b>	Not available.
<b>12.4. Mobility in soil</b>	No data available for this product.

- 12.5. Results of PBT and vPvB assessment** This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII.
- 12.6. Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

- Residual waste** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
- Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
- EU waste code** The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
- Disposal methods/information** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
- Special precautions** Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

### ADR

14.1. - 14.6.: Not regulated as dangerous goods.

### RID

14.1. - 14.6.: Not regulated as dangerous goods.

### ADN

14.1. - 14.6.: Not regulated as dangerous goods.

### IATA

14.1. - 14.6.: Not regulated as dangerous goods.

### IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## SECTION 15: Regulatory information

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

#### EU regulations

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended**

Not listed.

**Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended**

Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA**

Not listed.

#### Authorisations

**Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended**

Not listed.

#### Restrictions on use

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

**Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.**

Not listed.

**Other EU regulations**

**Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended**

Not listed.

**Other regulations**

According to REACH Regulation (EC) No 1907/2006, the product is considered as an article. The creation of a safety data sheet in accordance with Article 31 of the Regulation (EC) No 1907/2006 is not legally required for articles.

This product is an article in accordance with CLP Regulation (EC) No 1272/2008. This safety data sheet (SDS) is provided on the voluntary basis for information purpose only.

**National regulations**

Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.

**15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out.

**SECTION 16: Other information**

**List of abbreviations**

None.

**References**

GESTIS Substance Database  
HSDB® - Hazardous Substances Data Bank  
ECHA C&L Inventory database  
Supplier's SDS

**Information on evaluation method leading to the classification of mixture**

Not applicable.

**Full text of any H-statements not written out in full under Sections 2 to 15**

None.

**Training information**

Not assigned.

**Disclaimer**

Aspen Surgical Products, Inc cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.