

# **CytoSheath** Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 14 Jun 2024 Version: Rev 0, 2024-06

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

### 1.1. Product identifier

Product form : Mixture, Liquid
Product name : CytoSheath
Product code : CYTO-1001

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

#### 1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Health Care

#### 1.2.2. Uses advised against

No additional information available

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

Cytomark, a division of Caltag Medsystems Whiteleaf Business Centre
11 Little Balmer
Buckingham, MK18 1TF - United Kingdom T +44 1280 827460
Support@cytomark.co.uk

### 1.4. Emergency telephone number

Emergency number : +44 (0)1280 827460

Office hours only.

### **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

### Adverse physicochemical, human health and environmental effects

No additional information avaliable

#### 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

### 2.3. Other hazards

No additional information available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

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### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

First-aid measures general: If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: If experiencing respiratory symptoms: Remove person to fresh air and keep comfortable for

breathing.

First-aid measures after skin contact: If skin irritation or rash occurs: Gently wash with plenty of soap and water.

First-aid measures after eye contact: Rinse eyes with water as a precaution. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion: If you feel unwell, seek medical advice.

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

Symptoms/effects: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation:
Symptoms/effects after skin contact:
Symptoms/effects after eye contact:
May cause respiratory irritation.
May cause slight irritation.
May cause slight irritation.

Symptoms/effects after ingestion: Ingestion may cause nausea, vomiting and diarrhoea.

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

Treat symptomatically.

### **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : The product is not flammable.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

Precautionary measures fire : Exercise caution when fighting any chemical fire.

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### **SECTION 6: Accidental release measures**

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

General measures : None under normal use.

#### 6.1.1. For non-emergency personnel

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure

controls/personal protection".

Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : Absorb spillage.

Methods for cleaning up : Absorb with liquid-binding material.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of solid materials or residues refer to section 13: "Disposal considerations".

#### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Always wash hands after handling the product.

Hygiene measures : Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Does not require any specific or particular technical measures.

Storage conditions : Keep only in the original container in a cool, dry place. Keep container tightly closed.

Incompatible products : No data available

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Incompatible materials : Sources of ignition. Direct sunlight.

### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### **Occupational Exposure Limits**

### **Biological Limit Values**

No biological exposure limits noted for the ingredient(s).

### **DNEL-Values**

Remarks: DNEL-Values

Sodium Chloride			
General population	Inhalation	Systemic, long-term; 443.28 mg/m3	Repeated dose toxicity
Workers	Inhalation	Systemic, long-term; 2068.62 mg/m3	Repeated dose toxicity
Workers	Inhalation	Systemic, short-term; 2068.62 mg/m3	Repeated dose toxicity
General population	Inhalation	Systemic, short-term; 443.28 mg/m3	Repeated dose toxicity
General population	Oral	Systemic, long-term; 126.65 mg/kg	Repeated dose toxicity
Workers	Dermal	Systemic, long-term; 295.52 mg/kg	Repeated dose toxicity
Workers	Dermal	Systemic, short-term; 295.52 mg/kg	Repeated dose toxicity
General population	Oral	Systemic, short-term; 126.65 mg/kg	Repeated dose toxicity
General population	Dermal	Systemic, short-term; 126.65 mg/kg	Repeated dose toxicity
General population	Dermal	Systemic, short-term; 126.65 mg/kg	Repeated dose toxicity

Disodium hydrogenorthophosphate			
Workers	Eyes	Local Effect	Repeated dose toxicity
Workers	Inhalatation	Systemic, long-term; 4.07 mg/m3	Repeated dose toxicity
General population	Inhalatation	Systemic, long-term; 3.04 mg/m3	Repeated dose toxicity
General population	Inhalatation	Systemic, long-term; 6.63 mg/m3	Repeated dose toxicity
Workers	Inhalatation	Systemic, long-term; 15.47 mg/m3	Repeated dose toxicity

2-phenoxyethanol			
General population	Inhalation	Local, long-term; 2.41 mg/m3	Repeated dose toxicity
General population	Eyes	Local effect;	Low hazard (no threshold derived)
Workers	Eyes	Local effect;	Low hazard (no threshold derived)
Workers	Inhalation	Local, long-term; 5.7 mg/m3	
Workers	Inhalation	Systemic, long-term; 5.7 mg/m3	
Workers	Dermal	Systemic, long-term; 20.83 mg/kg	Repeated dose toxicity
General population	Oral	Systemic, short-term; 9.23 mg/kg	Repeated dose toxicity
General population	Dermal	Systemic, long-term; 10.42 mg/kg	Repeated dose toxicity
General population	Oral	Systemic, long-term; 9.23 mg/kg	Repeated dose toxicity

Sodium fluoride			
General population	Inhalation	Systemic, long-term; 0.36 mg/kg	
General population	Eyes	Systemic, short-term; 0.36 mg/kg	
Workers	Eyes	Systemic, short-term; 2.5 mg/m3	Repeated dose toxicity
Workers	Inhalation	Systemic, long-term; 2.5 mg/m3	Repeated dose toxicity

Potassium chloride			
Workers	Inhalation	Systemic, long-term; 1064 mg/m3	Repeated dose toxicity
General population	Inhalation	Systemic, long-term; 273 mg/m3	Repeated dose toxicity
General population	Inhalation	Systemic, short-term; 1365 mg/m3	Repeated dose toxicity
Workers	Inhalation	Systemic, short-term; 5320 mg/m3	Repeated dose toxicity
General population	Oral	Systemic, short-term; 455 mg/kg	Repeated dose toxicity
General population	Dermal	Systemic, long-term; 182 mg/kg	Repeated dose toxicity

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Potassium chloride			
General population	Oral	Systemic, long-term; 91 mg/kg	Repeated dose toxicity
Workers	Dermal	Systemic, long-term; 303 mg/kg	Repeated dose toxicity
Workers	Dermal	Systemic, short-term; 910 mg/kg	Repeated dose toxicity
General population	Dermal	Systemic, short-term; 910 mg/kg	Repeated dose toxicity

Potassium dihydrogenorthophosphate			
Workers	Eyes	Local effect;	Repeated dose toxicity
General population	Eyes	Local effect;	Repeated dose toxicity
Workers	Inhalation	Systemic, long-term; 14.82 mg/m3	Repeated dose toxicity
General population	Inhalation	Systemic, long-term; 6.35 mg/m3	Repeated dose toxicity

### **PNEC-Values**

Remarks: PNEC-Values

Sodium chloride		
Soil	4.86 mg/kg	
Aquatic (freshwater)	5 mg/l	
Sewage treatment plant	500 mg/l	

Disodium hydrogenorthophosphate		
Sewage treatment plant	50 mg/l	
Aquatic (freshwater)	0.05 mg/l	
Aquatic (marine water)	0.005 mg/l	

2-phenoxyethanol	
Soil	1.31 mg/kg
Aquatic (marine water)	0.094 mg/l
Sediment (freshwater)	7.237 mg/kg
Sediment (marine water)	0.724 mg/kg
Aquatic (freshwater)	0.943 mg/l
Sewage treatment plant	36 mg/l

sodium fluoride	
Sewage treatment plant	51 mg/l
Aquatic (freshwater)	0.9 mg/l
Soil	11 mg/kg

Potassium chloride	
Aquatic (marine water)	0.1 mg/l
Sewage treatment plant	10 mg/l
Aquatic (freshwater)	0.1 mg/l

### 8.2. Exposure controls

Appropriate engineering controls: Ensure adequate ventilation.

Personal protective equipment: Avoid all unnecessary exposure.

Hand protection: Wear chemically resistant protective gloves. Standard EN 374 - Protective gloves against chemicals.

Eye protection: Chemical goggles or safety glasses. Standard EN 166 - Personal eye-protection - specifications

Skin and body protection: Wear a lab coat or similar protective clothing

Respiratory protection: 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

Other information: Do not eat, drink or smoke during use.

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### **SECTION 9: Physical and chemical properties**

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

Physical state: LiquidColour: ColourlessOdour: odourless.

No data available Odour threshold рΗ 7.34 - 7.50 Relative evaporation rate (butylacetate=1) : No data available Melting point No data available Freezing point No data available Boiling point : No data available Flash point : No data available Auto-ignition temperature No data available No data available Decomposition temperature : Non flammable. Flammability (solid, gas) Vapour pressure No data available Relative vapour density at 20 °C No data available

Solubility : Soluble

Log Pow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

### 9.2. Other information

#### **VOC Content:**

Relative density

EU. Directive 2010/75/EU on Industrial Emissions (IPPC), Annex II, L 334/17: 1.92 g/l ~0.19 % (calculated)

No data available

EC Directive 2004/42: 1.92 g/l ~0.19 % (calculated)

### **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal use.

#### 10.4. Conditions to avoid

Avoid exposure to high temperatures or direct sunlight.

### 10.5. Incompatible materials

Metals. Water reactive material

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### **SECTION 11: Toxicological information**

### 11.1. Information on toxicological effects

### Acute toxicity:

Not classified

### Skin corrosion/irritation:

Not classified

### Additional information:

Based on available data, the classification criteria are not met

### Serious eye damage/irritation:

Not classified

### Additional information:

Based on available data, the classification criteria are not met

### Respiratory or skin sensitisation:

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Not classified

Additional information:

Based on available data, the classification criteria are not met

Germ cell mutagenicity:

Not classified

Based on available data, the classification criteria are not met

Carcinogenicity:

Not classified

Additional information:

Based on available data, the classification criteria are not met

Reproductive toxicity:

Not classified

Additional information:

Based on available data, the classification criteria are not met

STOT-single exposure:

Not classified

Additional information:

Based on available data, the classification criteria are not met

STOT-repeated exposure:

Not classified

Additional information:

Based on available data, the classification criteria are not met

Aspiration hazard:

Not classified

Additional information:

Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms:

Based on available data, the classification criteria are not met.

### **SECTION 12: Ecological information**

#### 12.1. Toxicity

### Acute aquatic toxicity:

Not classified

Chronic aquatic toxicity:

Not classified

### 12.2. Persistence and degradability

Persistence and degradability: No data avaliable.

### 12.3. Bioaccumulative potential

No data avaliable.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment.

#### **SECTION 13: Disposal considerations**

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of

contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment.

### **SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID		
14.1. UN number						
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		
14.2. UN proper shipping name						
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		
14.3. Transport hazard class(es)						
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		

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ADR	IMDG	IATA	ADN	RID			
14.4. Packing group							
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable			
14.5. Environmental hazards							
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable			
No supplementary information available							

#### 14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### **SECTION 15: Regulatory information**

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

### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substance

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### **SECTION 16: Other information**

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE

COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending

Regulation (EC) No 1907/2006.

Other information : None.

### SDS EU (REACH Annex II) -

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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