

## Sween 24



25. February 2015  
Version 2.0

## Safety Data Sheet

Based on template version 3.0

### Section 1

#### Identification of the substance/mixture and of the company/undertaking

##### 1.1 Product identifier

Product name: Sween 24  
Product code: 67090, 67091, 67092, 67094, and 67095

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

Product information: Medical device  
Skin protectant/ barrier

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

Manufacturer: Coloplast A/S  
Holtedam 1  
DK-3050 Humlebaek  
Denmark  
Telephone +45 49111111  
[msds@coloplast.com](mailto:msds@coloplast.com)

##### 1.4 Emergency telephone number:

(DK) +45 82 12 12 12  
(US) 1-800-222-1222  
(CA) 1-877-820-7008

### USA

Coloplast Corp.  
1601 West River Road N  
Minneapolis, MN 55411  
Telephone: +1-800-533-0464  
[www.us.coloplast.com](http://www.us.coloplast.com)

### Canada

Coloplast Canada Corporation  
3300 Ridgeway Drive, Unit 12  
Mississauga, Ont. L5L 5Z9  
Telephone: +1-877-820-7008  
[www.coloplast.ca](http://www.coloplast.ca)

### Europe

Coloplast A/S  
Holtedam 1  
DK-3050 Humlebaek  
Telephone: +45 49 11 11 11  
[www.coloplast.com](http://www.coloplast.com)

### Section 2

#### Hazards identification

This product is regulated as a medical device in the European Economic Area (EEA). In other regions it may be regulated as a medical device, a cosmetic or not regulated. The product is assessed and supplied with a safety data sheet in accordance with Regulation (EC) no 1272/2008. Labelling of the product is prepared in accordance with Directive 93/42/EEC on medical devices and local legislation.

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### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC)  
No 1272/2008: Not classified

Wording of H-statements – see section 16.

### 2.2. Label elements

The product is a medical device in EAA and therefore the labelling elements from the CLP regulations do not apply, according to Regulation (EC) No 1272/2008, Title I, Article 1, Section 5.

### 2.3 Other hazards

Assessment to determine PBT and vPvB has not been made

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## Section 3

### Composition/information on ingredients

#### 3.1 Substances

N/A

#### 3.2 Mixtures

The following substances have to be declared according to legislation:

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (EC 1272/2008)
0 - 5	81646-13-1	279-791-1	-	-	Docosyltri-me-thylammoni-um-methyl-sulphate	Skin Irrit. 2;H315 Eye Irrit. 2;H319 Aquatic Acute 1;H400
0 - 5	22832-87-7	245-256-6	-	-	Miconazole-nitrate	Acute Tox.4; H302
0 - 2	1314-13-2	215-222-5	-	-	Zinc oxide	Aquatic Acute 1;H400 Aquatic Chronic 1;H410

Wording of H-statements - see section 16.

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## Section 4

### First-AID measures

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### 4.1 Description of first aid measures

Inhalation: Seek fresh air.

Skin Contact: Remove contaminated clothing. Wash the skin with water.

Eye Contact: Flush with water (preferably using eye wash equipment) until irritation subsides. Seek medical advice if symptoms persist.

Ingestion: Wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of persistent discomfort.

Burns: Not relevant.

When obtaining medical advice, show the safety data sheet or label.

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

May cause slight irritation to the skin and eyes.

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

Treat symptoms. No special immediate treatment required.

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## Section 5

### Fire fighting measures

#### 5.1 Suitable extinguishing media

Extinguish with powder, foam, carbon dioxide or water mist. Use water or water mist to cool non-ignited stock. Do not use water stream, as it may spread the fire.

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

Can generate harmful flue gases containing carbon monoxide in the event of fire.

#### 5.3 Advice for firefighters

Move containers from danger area if it can be done without risk. Avoid inhalation of vapour and flue gases – seek fresh air. Wear Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves.

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## Section 6

### Accidental release measures

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

For non-emergency personnel: Stop leak if this can be done without risk.

For emergency responders: In addition to the above: Normal protective clothing equivalent to EN 469 is recommended.

#### 6.2 Environmental precautions

Prevent spillage from entering drains and/or surface water.

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### 6.3 Methods and materials for containment and cleaning up:

Contain and absorb spill with sand or other absorbent material and transfer to suitable waste containers. Wipe up minor spills with a cloth.

### 6.4 Reference to other sections

See section 13 for instructions on disposal.

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## Section 7

### Handling and storage

#### 7.1 Precautions for safe handling

Running water and eye wash equipment should be available. Wash hands before breaks, before using restroom facilities, and at the end of work.

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

Store safely and keep out of reach of children.

#### 7.3 Specific end use(s)

None.

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## Section 8

### Exposure controls/personal protection

#### 8.1 Control parameters

Legal basis: Commission Directive 2000/39/EC. Last amended by Commission Directive 2009/161/EU.

Contains no substances subject to reporting requirements.

#### 8.2 Exposure controls

Appropriate engineering controls:

Wear the personal protective equipment specified below.

Personal protective measures: Not required.

Environmental exposure controls: Ensure compliance with local regulations for emissions.

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### Section 9

#### Physical and chemical properties

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

Appearance:	Sween 24: Creme Critic Aid Clear and Critic Aid Clear AF: Ointment
Colour:	Sween 24: White Critic Aid Clear and Critic Aid Clear AF: Off-white
Odour:	Weak
pH (concentrate)	No data
pH (solution for use):	No data
Melting point / freezing point (°C):	No data
Initial boiling point and boiling range (°C):	No data
Decomposition temperature (°C):	No data
Flash point (°C):	No data
Evaporation rate:	No data
Flammability (solid, gas):	No data
Upper/lower flammability or explosive limits (vol-%):	No data
Vapour pressure (hPa, 20°C):	No data
Vapour density (air=1):	No data
Relative density (g/ml, 25°C):	No data
Solubility:	No data
Partition coefficient: n-octanol/water, Log K <sub>ow</sub> :	No data
Autoignition temperature (°C):	No data
Viscosity (mPa*s, 25°C):	No data
Explosive properties:	No data
Oxidising properties:	No data

##### 9.2 Other information:

None.

### Section 10

#### Stability and reactivity

##### 10.1 Reactivity

Not reactive.

##### 10.2 Chemical stability

The product is stable when used in accordance with the supplier's directions

##### 10.3 Possibility of hazardous reactions

None known.

##### 10.4 Conditions to avoid

None known

##### 10.5 Incompatible materials

None known.

##### 10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

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### Section 11

#### Toxicological information

This product is a medical device and has been assessed in accordance with Directive 93/42/EEC on medical devices.

#### 11.1 Information on toxicological effects

Toxicological data:  
None.

Information on likely routes of exposure: Inhalation, skin and ingestion

Symptoms:

Acute toxicity – oral:	Ingestion may cause discomfort. The product does not have to be classified. Test data are not available.
Acute toxicity - dermal:	The product does not have to be classified. Test data are not available.
Acute toxicity - inhalation:	The product does not have to be classified. Test data are not available.
Skin corrosion/irritation:	May cause slight irritation. The product does not have to be classified. Test data are not available.
Serious eye damage/eye irritation:	Temporary irritation. The product does not have to be classified. Test data are not available.
Sensitisation:	The product does not have to be classified. Test data are not available.
Mutagenicity:	The product does not have to be classified. Test data are not available.
Carcinogenic properties:	The product does not have to be classified. Test data are not available.
Reproductive toxicity:	The product does not have to be classified. Test data are not available.
Single STOT exposure:	The product does not have to be classified. Test data are not available.
Repeated STOT exposure:	The product does not have to be classified. Test data are not available.
Aspiration hazard:	The product does not have to be classified. Test data are not available.

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### Section 12

#### Ecological information

##### 12.1 Toxicity

The product does not have to be classified. Test data are not available.

##### 12.2 Persistence and degradability

Test data are not available.

##### 12.3 Bioaccumulative potential

Test data are not available.

##### 12.4 Mobility in soil

Test data are not available

##### 12.5 Results of PBT and vPvB assessment

No assessment has been made

##### 12.6 Other adverse effects

None known.

### Section 13

#### Disposal considerations

##### 13.1 Waste treatment methods

##### European Union

Avoid discharge to drain or surface water.

Contact the local authorities.

EWC code: 16 05 09 discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

Absorbent/cloth contaminated with the product:

EWC code: 15 02 03 Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02.

Uncleansed packaging is to be disposed of via the local waste-removal scheme. Empty, cleansed packaging should be disposed of for recycling.

### Section 14

#### Transport information

14.1 UN-no.:	Not relevant
14.2 UN proper shipping name:	Not relevant
14.3 Transport hazard class(es):	Not relevant
14.4 Packing group:	Not relevant
14.5 Environmental hazards:	Not relevant
14.6 Special precautions for user:	Not relevant
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not relevant

ADR - Classification:	Not relevant
- Classification code:	Not relevant
- ADR limited Quantities:	Not relevant"
- Hazard label:	Not relevant
Special provisions applicable to certain articles or substance:	Not relevant

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IMDG - Classification: Not relevant  
- Classification code: Not relevant  
- IMDG limited Quantities: Not relevant  
- Hazard label: Not relevant

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification: Not relevant

### Transportation on road in other countries than ADR-countries:

US: Not relevant  
Canada: Not relevant  
Brazil: Not relevant  
Australia: Not relevant  
New Zealand: Not relevant  
Hongkong / China: Not relevant

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## Section 15 Regulatory information

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

None

### 15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

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## Section 16 Other information

H-statements mentioned in section 2 and 3:

H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

Abbreviations:

PBT = Persistent, Bioaccumulative and Toxic  
vPvB = Very Persistent and Very Bioaccumulative

Classification method:

Calculation based on the hazards of the known components.

Changes since the previous edition:

Not relevant.

Training:

No special training is required, but a thorough knowledge of this safety data sheet should be a prerequisite condition.



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### Other information:

This safety data sheet has been prepared for and applies to this product only. It is based on our current knowledge and the information that the supplier was able to provide about the product at the time of preparation. The safety data sheet complies with applicable law on preparation of safety data sheets in accordance with 1907/2006/EC (REACH) as subsequently changed.

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