Coloplast

Sea-Clens®

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Version 2.0

Safety Data Sheet

Based on template version 3.0

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Section 1
Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Sea-Clens
Product code: 61061, 61063

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

Product information: Medical device.
No-rinse wound cleanser.

1.3 Details of the supplier of the safety data sheet:

Manufacturer: Coloplast A/S
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Denmark
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1.4 Emergency telephone number:

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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.

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:
The product shall not be classified as hazardous according to EU classification and labelling rules.

Wording of H-statements – see section 16.

Most serious harmful effects:
May cause slight irritation to the skin and eyes.
Persons with a known allergy to 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl) urea (DIAZOLIDINYL UREA) may exhibit an allergic response to the product.

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.

The product shall not be classified as hazardous according to EU classification and labelling rules.

Contains 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl) urea (DIAZOLIDINYL UREA). May produce an allergic reaction.
Safety data sheet available on request.

According to Regulation (EC) No 1272/2008:

Pictogram(s):	Signal word:
-	-

Hazard statement(s):
-

Precautionary statement(s):
-

Supplemental information:
Contains 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl) urea (DIAZOLIDINYL UREA). May produce an allergic reaction.
Safety data sheet available on request.

2.3 Other hazards
Assessment to determine PBT and vPvB has not been made.

Section 3
Composition/information on ingredients

3.1 Substances
N/A

3.2 Mixtures

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (EC 1272/2008)
<1	78491-02-8	278-928-2	-	-	1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea	Skin Sens. 1;H317

Wording of H-statements - see section 16.

Section 4
First-AID measures

4.1 Description of first aid measures

Inhalation: Seek fresh air.

Skin Contact: Remove contaminated clothing. Wash 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

Other information: 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. The product contains small amounts of 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl) urea (DIAZOLIDINYL UREA). Persons with a known allergy may exhibit an allergic response to the product.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms. No special immediate treatment required.

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.
Unsuitable extinguishing media:
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.

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.

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 8 for type of protective equipment.
See section 13 for instructions on disposal.

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. Store at temperatures below 40 °C.

7.3 Specific end use(s)
None.

Section 8
Exposure controls/personal protection
8.1 Control parameters
Commission Directive 2000/39/EC (Occupational Exposure Limits). 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 equipment, eye/face protection: Not required.

Personal protective equipment, skin protection: Not required.

Personal protective equipment, respiratory protection: Not required.

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

Section 9
Physical and chemical properties
9.1 Information on basic physical and chemical properties

Appearance:	Liquid.
Odour:	-
pH:	-
Melting point / freezing point (°C):	Approx. 0 °C
Initial boiling point and boiling range (°C):	Approx. 100 °C
Decomposition temperature (°C):	-
Flash point (°C):	-
Evaporation rate:	-
Flammability (solid, gas):	-
Upper/lower flammability or explosive limits (vol-%):	-
Vapour pressure (hPa, 20°C):	-
Vapour density (air=1):	-
Relative density (g/ml, 25°C):	Approx. 1
Solubility:	Solubility in water: Completely miscible
Partition coefficient: n-octanol/water, Log K_{ow}:	-
Autoignition temperature (°C):	-
Viscosity (mPa*s, 25°C):	-
Explosive properties:	-
Oxidising properties:	-

9.2 Other information:
None.

Section 10
Stability and reactivity

10.1 Reactivity
Reacts with the following: Alkaline metals.
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
Alkaline metals.
10.6 Hazardous decomposition products
Carbon monoxide and carbon dioxide.

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 - demal:	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 contains small amounts of 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl) urea (DIAZOLIDINYL UREA). Persons with a known allergy may exhibit an allergic response to the product. 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.
Other toxicological effects:	None known.

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

The recommended disposal technology at any approved facility. The disposal should always be in compliance with national, federal, state and local regulations. The product should not be discharged to the environment.

European union
Avoid discharge to drain or surface water. Contact the local authorities.

EWC code: Depends on line of business and use, for instance 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:
- Classification code: Not relevant
- ADR limited Quantities: Not relevant
- Hazard label: Not relevant

Special provisions applicable to certain articles or substance: Not relevant

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

EMS: Not relevant

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification:
- Hazard label: 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

Section 15
Regulatory information

Covered by: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

Special provisions:
None

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

Section 16
Other information

H-statements mentioned in section 2 and 3:

H317 May cause an allergic skin reaction.

Abbreviations:
PBT = Persistent, Bioaccumulative and Toxic
vPvB = Very Persistent and Very Bioaccumulative
STOT = Specific Target Organ Toxicity

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.

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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