

Triad

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: Triad
Product code: 1964, 1967

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

Product information: Medical device
Paste used in connection with wound dressing

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

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

Canada

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

Europe

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Telephone: +45 49 11 11 11
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:

Aquatic Chronic 2;H411

Wording of H-statements – see section 16.

Most serious harmful effects:

The product is a medical device and therefore not covered by the classification and labelling rules that apply to chemical products. Irritating to eyes. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Vapours may cause drowsiness and dizziness.

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 below illustrated pictograms, signal words and hazard statements are therefore only listed in the present MSDS and not present on the product labelling.

According to Regulation (EC) No 1272/2008:

Pictogram(s):

Signal word:



Hazard statement(s):

H411: Toxic to aquatic life with long lasting effects.

Precautionary statement(s):

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2.3 Other hazards

Assessment to determine PBT and vPvB has not been made.

Section 3

Composition/information on ingredients

3.2 Mixtures

Triad

The main ingredients are:

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (EC 1272/2008)
10-30	1314-13-2	215-222-5	-	-	Zinc oxide	Aquatic Acute 1;H400 Aquatic Chronic 1;H410

Wording of H-statements - see section 16.

Section 4 First-AID measures

4.1 Description of first aid measures

Inhalation: Seek fresh air. Seek medical advice in case of persistent discomfort.

Skin Contact: Remove contaminated clothing. Wash skin with soap and water. Seek medical advice in case of persistent discomfort.

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

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

The product is not directly flammable. Choose extinguishing agents based on the surrounding fire. Do not use water stream, as it may spread the fire.

5.2 Special hazards arising from the substance or mixture

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The product is not directly flammable. Avoid inhalation of vapour and fumes – seek fresh air.

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.#CX 05.03.003# 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:

6.2 Environmental precautions

Prevent spillage from entering drains and/or surface water. Normal protective clothing equivalent to EN 469 is recommended.

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.#CX 06.04.002# See section 13 for instructions on disposal

Section 7

Handling and storage

7.1 Precautions for safe handling

Running water and eye wash equipment must 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.

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.

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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

State:	Paste
Colour:	White
Odour:	Weak.
Odour threshold:	No data
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):	>100 °C
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 (25°C):	No data
Solubility:	No data
Partition coefficient: n-octanol/water, Log K _{ow} :	No data
Auto-ignition 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

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None known.

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.
Other toxicological effects:	None known.

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

Section 12 Ecological information

12.1 Toxicity

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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.

Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

EWC code: Depends on line of business and use, for instance 16 05 08* discarded organic chemicals consisting of or containing dangerous substances.

Absorbent/cloth contaminated with the product: EWC code: 15 02 02 absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

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.: 3077
14.2 UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)
14.3 Transport hazard class(es): 9

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14.4 Packing group:	III
14.5 Environmental hazards:	The product must be labelled as an environmental hazard (symbol: fish and tree) in packaging sizes of more than 5 kg/l.
14.6 Special precautions for user:	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not applicable

ADR - Classification:	
- Classification code:	M7
- ADR limited Quantities:	5 kg
- Hazard label:	9

IMDG - Classification:	
- IMDG limited Quantities:	5 kg
- Hazard label:	9
EMS:	F-A, S-F

IATA - Classification:	
- Hazard label:	9

Transportation on road in other countries than ADR-countries:

US: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

Canada: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide) /MATIÈRE DANGEREUSE DU POINT DE VUE DE L'ENVIRONNEMENT, SOLIDE, N.S.A. (oxyde de zinc)

Brazil: MATÉRIA PERIGOSA DO PONTO DE VISTA DO AMBIENTE, SÓLIDA, N.S.A. (óxido de zinco)

Australia: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

New Zealand: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

Hongkong / China: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

Section 15

Regulatory information

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

Council Directive 96/82/EC (Seveso), Dangerous for the environment: Column 2: 200 t, Column 3: 500 t.

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

Section 16

Other information

H-statements mentioned in section 2 and 3:

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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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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