

Coloplast Prep

23. November 2022
Version 3.0

Safety Data Sheet

Based on template version 7.0

Section 1

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

1.1 Product identifier

Product name: Coloplast Prep
Product code: 60925, 62041

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

Product information: Medical device.
The wipes are used for cleaning the skin area before application of ostomy care devices.

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

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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Europe

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

Coloplast Prep

2.1 Classification of the substance or mixture

Classification according to Regulation (EC)
No 1272/2008: Flam. Liq. 2; H225 Eye Dam. 1; H318
STOT SE 3; H336

Classification according to Directive 67/548/EEC or
1999/45/EC and later amendments: 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.

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

According to Regulation (EC) No 1272/2008:

Contains: propan-2-ol; butan-1-ol

Pictogram(s): Signal word:
 Danger



Hazard statement(s):
H225 Highly flammable liquid and vapour.
H318 Causes serious eye damage.
H336 May cause drowsiness or dizziness.

Precautionary statement(s):
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective eye protection/face protection.
P305+351+338+310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P403+235 Store in a well-ventilated place. Keep cool.

Other labelling:
None

2.3 Other hazards

The product does not contain any PBT or vPvB substances.

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Section 3

Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

The main ingredients are: propan-2-ol, butan-1-ol

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)
60 - 85	67-63-0	200-661-7	-	01- 2119457 558-25	propan-2-ol	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336
3-5	71-36-3	200-751-6	-	01- 2119484 630-38	butan-1-ol	Flam. Liq. 3;H226 Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H335 STOT SE 3;H336

Wording of H-statements - see section 16.

Section 4

First aid measures

4.1 Description of first aid measures

Inhalation: Move the affected person to fresh air. Keep at rest. If needed: Get medical attention.

Skin Contact:

This product is intended to be in contact with the skin when used as stated in the instructions for use. In case of skin problems: Seek medical advice.

Eye Contact:

Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion:

Rinse mouth and drink plenty of water. **Do not induce vomiting.** If vomiting occurs keep head down to avoid vomit in the lungs. In case of discomfort: Seek medical advice.

Burns:

This product is intended to be in contact with the skin when used as stated in the instructions for use. Flush with water until pain ceases. Remove clothes that are not burnt to the skin. If needed seek medical attention, continue to flush on the way.

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4.2 Most important symptoms and effects, both acute and delayed

Eye contact may result in deep caustic burns, pain, tearing and cramping of the eyelids. Risk of serious eye injury and loss of sight. The product releases organic solvent vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication.

4.3 Indication of any immediate medical attention and special treatment needed

Show this Safety Data Sheet to a physician or emergency ward.

Section 5

Firefighting measures

5.1 Extinguishing media

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

Use personal protective equipment - see section 8. Remove sources of ignition. Ventilate area of leak or spill.

6.2 Environmental precautions

Do not empty into drains - see section 12. Inform appropriate authorities in accordance with local regulations.

6.3 Methods and materials for containment and cleaning up

Absorb spilled liquid with paper towel. Place in a suitable container for disposal. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

6.4 Reference to other sections.

Please see the references above

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Section 7

Handling and storage

7.1 Precautions for safe handling

Running water and eyewash equipment should be available. Smoking and naked flames prohibited. 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, out of reach of children and away from food, animal feeding stuffs, medicines, etc. Do not expose to heat (e.g. sunlight). Keep in tightly closed original packaging. Store in a dry, cool, well-ventilated area. Do not store with the following: Oxidisers.

7.3 Specific end use(s)

See section 1.2.

Section 8

Exposure controls/personal protection

Legal basis: Commission Directive 2000/39/EC (Occupational Exposure Limits) as subsequently amended. Last amended by Commission Directive 2019/1831/EU. Directive 2004/37/EC (Exposure to carcinogens or mutagens at work) as subsequently amended. Last amended by Directive 2019/983/EU.

Measuring methods: Compliance with the stated occupational exposure limits may be checked by occupational hygiene measurements.

8.1 Control parameters

8.2 Exposure controls

Engineering measures: Wear the personal protective equipment specified below.

Personal protective measures:

Personal protective equipment, eye/face protection:

Wear safety goggles if there is a risk of eye splash. Eye protection must conform to EN 166.

Personal protective equipment, hand protection:

By handling of the product: Plastic or rubber gloves recommended.

Personal protective equipment, respiratory protection: Not required.

Exposure hazard: 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

Physical state:	Non-woven wipes wetted with liquid
Colour:	Light yellow
Odour:	Characteristic / Alcohol
pH:	7 (propan-2-ol)
Melting point / freezing point (°C):	-89.5 (propan-2-ol)
Boiling point or initial boiling point and boiling range (°C):	82 (propan-2-ol)
Flammability:	Highly flammable
Lower and upper explosion limit (°C):	2-12 (propan-2-ol)
Flash point (°C):	12 (propan-2-ol) (closed cup)
Auto-ignition temperature (°C):	399 (propan-2-ol)
Decomposition temperature (°C):	Not determined
Kinematic viscosity (mm ² /s):	Not determined
Solubility:	Miscible with water (liquid in wipes)
Partition coefficient: n-octanol/water (log value):	-0.35 (propan-2-ol)
Vapour pressure (hPa, 0°C):	4.4 (propan-2-ol)
Density and/or relative density (g/cm ³):	0.7585 (propan-2-ol)
Relative vapour density (g/cm ³ , 20°C):	2.08 (propan-2-ol) (Air=1)
Particle characteristics:	Not determined

9.2 Other information

None

Section 10

Stability and reactivity

10.1 Reactivity

Reacts with the following: Oxidizers.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Vapours may form explosive mixtures with air.

10.4 Conditions to avoid

Avoid heating and contact with ignition sources.

10.5 Incompatible materials

Oxidizers.

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 hazard classes as defined in Regulation (EC) No. 1272/2008

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

Symptoms related to the physical, chemical and toxicological characteristics:

Acute toxicity – oral:	Ingestion may cause discomfort. The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 67-63-0: LD ₅₀ (rat) = 5840 mg/kg CAS 71-36-3: LD ₅₀ (rat) = 790 mg/kg
Acute toxicity - dermal:	The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 67-63-0: LD ₅₀ (rabbit) = 12800 mg/kg CAS 71-36-3: LD ₅₀ (rabbit) = 3400 mg/kg
Acute toxicity - inhalation:	The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 67-63-0: LC ₅₀ (4h, vapour) (rat) > 10000 ppm (OECD 403) CAS 71-36-3: LC ₅₀ (4h, vapour) (rat) > 24 mg/l
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:	Eye contact may result in deep caustic burns, pain, tearing and cramping of the eyelids. Risk of serious eye injury and loss of sight.
Respiratory sensitisation or skin sensitisation:	The product does not have to be classified. Test data are not available.
Germ cell 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 releases organic solvent vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication.
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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Inhalation:	Inhalation of aerosols may cause irritation of the respiratory tract.
Skin:	Prolonged contact may cause slight irritation.
Eyes:	May cause irritation with redness.
Ingestion:	In general, not relevant
Chronic effects:	Not known

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

None known

11.2.2 Other information

None

Section 12

Ecological information

12.1 Toxicity

The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met.

CAS 67-63-0:

Fish: EC₅₀ (Pimephales promelas, 96h) = 10000 mg/l

Crustacea: EC₅₀ (Daphnia magna, 24h) = >10000 mg/l

CAS 71-36-3:

Fish: EC₅₀ (Oncorhynchus mykiss, 24h) = 921 mg/l

12.2 Persistence and degradability

CAS 71-36-3:

Biodegradation: 98 %

Exposure time: 19 d

Method: OECD Test Guideline 301E

Result: Readily biodegradable.

12.3 Bioaccumulative potential

CAS 67-63-0:

log Pow: 0.05

CAS 71-36-3:

log Pow: 0.88

BCF: 0.38

12.4 Mobility in soil

The product contains at least one substance with high soil mobility.

12.5 Results of PBT and vPvB assessment

The product does not contain any PBT or vPvB substances.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

No additional adverse effects to add.

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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

Do not discharge large quantities of concentrated spills and residue into drains. Uncleansed packaging is to be disposed of via the local waste-removal scheme. Empty, cleansed packaging should be disposed of for recycling. If this product as supplied becomes a waste, it meets the criteria of a hazardous waste (Dir. 2008/98/EU). Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

Category of waste:

Wiping cloths with organic solvents: EWC code: 15 02 02 Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

Section 14

Transport information

14.1 UN number or ID number:	3175
14.2 UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)
14.3 Transport hazard class(es):	4.1
14.4 Packing group:	II
14.5 Environmental hazards:	No
14.6 Special precautions for user:	None
14.7 Maritime transport in bulk according to IMO instruments:	Not relevant

ADR - Classification:

- Classification code:	F1
- ADR limited Quantities:	1 kg
- Hazard label:	4

Special provisions applicable to certain articles or substance: 216, 274, 601.

IMDG - Classification:

- Classification code:	F-A, S-I
- IMDG limited Quantities:	1 kg
- Hazard label:	4

Special provisions applicable to certain articles or substance: 216, 274

IATA - Classification:

Hazard Label:	4
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Transportation on road in other countries than ADR-countries:

US: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Canada: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)/ SOLIDES CONTENANT DU LIQUIDE INFLAMMABLE, N.S.A. (ISOPROPANOL)

Brazil: UN3175 SÓLIDOS CONTENDO LÍQUIDO INFLAMÁVEL, N.S.A. (ISOPROPANOL)

Australia: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

New Zealand: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Hongkong / China: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Section 15

Regulatory information

Covered by:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Council Directive (EC) on the protection of young people at work.

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

Special provisions:

Directive 2012/18/EU (Seveso), P5c FLAMMABLE LIQUIDS: Column 2: 5000 t, Column 3: 50000 t.

Special care should be applied for employees under the age of 18. Young people under the age of 18 may not carry out any work causing harmful exposure to this product.

15.2 Chemical Safety Assessment:

Chemical safety assessment has been performed for following substances:

CAS 67-63-0: Propan-2-ol

CAS 71-36-3: Butan-1-ol

Section 16

Other information

H-statements mentioned in section 2 and 3:

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

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Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC₅₀ = Effect Concentration 50 %
GPMT = Guinea Pig Maximization Test
LC₅₀ = Lethal Concentration 50 %
MAK = Maximale ArbeitsplatzKonzentrationen
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative

Literature references:

IUCLID = International Uniform Chemical Database Information

Legislation reference:

This SDS is prepared to comply with EC regulation no. 1907/2006 (REACH)
and Commission Regulation (EU) 2020/878

Changes since the previous edition:

Not relevant.

THE ABOVE INFORMATION HAS BEEN COMPILED FROM SOURCES BELIEVED TO BE RELIABLE AND IS ACCURATE TO THE BEST OF OUR KNOWLEDGE. HOWEVER, COLOPLAST CORP. CANNOT GIVE ANY GUARANTEES REGARDING INFORMATION FROM OTHER SOURCES AND EXPRESSLY DOES NOT MAKE ANY WARRANTIES, NOR ASSUMES ANY LIABILITY, FOR ITS USE.

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THIS PAGE SHOULD BE REMOVED BEFORE DISTRIBUTION/DISPLAY OF THE SDS TO CUSTOMERS OUTSIDE OF COLOPLAST

Change log

Version no.	Issue Date (Month Year)	Short description of and reason for change
1.0	-	Document established.
2.0	March 2015	Update of document.
2.0	October 2022	Update of the document based on the current classification of the mixture. Update to the new template (v. 7) The number of version remains 2.0, to align it with the Veeva version of the document.
3.0	November 2022	Document established based on template 7.0 Enumerated as ver. 3.0 to align it with the Veeva version of the document.

Document Approvals
Approved Date: 2022-12-14

Approval Task Verdict: Approve	PLALWIN Aleksandra Witkowska-Nowak, Biosafety & Chemical Compliance Specialist (plalwin@coloplast.com) Technical / Specialist 14-Dec-2022 13:44:20 GMT+0000
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Conveen Prep Wipe

22. November 2021
Version 2.0

Safety Data Sheet

Based on template version 6.0

Section 1

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

1.1 Product identifier

Product name: Conveen Prep Wipe
Product code: 62042

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

Product information: Medical device.
The product provides a visible barrier film of protection when applied to the skin prior to application of a Continence Care appliance.

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

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

USA

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Europe

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Conveen Prep Wipe

product is prepared in accordance with European Union Medical Device Regulation (EU) 2017/745.

2.1 Classification of the substance or mixture

Classification according to Regulation (EC)
No 1272/2008: Flam. Liq. 2;H225 Eye Dam. 1;H318
STOT SE 3;H336

Wording of H-statements – see section 16

Most serious harmful effects:
Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. The product releases vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication.

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 necessarily present on the product labelling.

According to Regulation (EC) No 1272/2008:

Contains:
propan-2-ol; butan-1-ol

Pictogram(s): Signal word:
 Danger



Hazard statement(s):

H225 Highly flammable liquid and vapour.
H318 Causes serious eye damage.
H336 May cause drowsiness or dizziness.

Precautionary statement(s):

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective eye protection/face protection.

Conveen Prep Wipe

P305+351+338+310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

P403+235 Store in a well-ventilated place. Keep cool.

Supplemental information:

-

2.3 Other hazards

The product does not contain any PBT or vPvB substances.

Section 3

Composition/information on ingredients

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)
60 - 85	67-63-0	200-661-7	-	01- 2119457558-25	propan-2-ol	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336
3-5	71-36-3	200-751-6	-	01- 2119484630-38	butan-1-ol	Flam. Liq. 3;H226 Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H335 STOT SE 3;H336

Wording of EUH-/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 soap and water.

Eye Contact: Open eye wide, remove any contact lenses and flush immediately with water (preferably using eye wash equipment). Seek medical advice immediately. Continue flushing until medical attention is obtained.

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

Burns: Flush with water until pain ceases. Remove clothing that is not stuck to the skin - seek medical advice/transport to hospital. If possible, continue flushing until medical attention is obtained.

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

4.2 Most important symptoms and effects, both acute and delayed

Eye contact may result in deep caustic burns, pain, tearing and cramping of the eyelids. Risk of serious eye injury and loss of sight. The product releases organic solvent vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms. No special immediate treatment required.

Section 5

Firefighting measures

5.1 Extinguishing media

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: Stay upwind/keep distance from source. Stop leak if this can be done without risk. Provide adequate ventilation. Smoking and naked flames prohibited. Take precautionary measures against static discharges. Use spark-free tools and explosion proof equipment. Wear gloves. Wear safety goggles.

For emergency responders: In addition to the above: Protective suit equivalent to EN 368, type 3, is recommended.

6.2 Environmental precautions

Sweep up/collect spills for possible reuse or transfer to suitable waste. Do not discharge large quantities of concentrated spills and residue into drains.

Conveen Prep Wipe

6.3 Methods and material for containment and cleaning up:

Sweep up/collect spills for possible reuse or transfer to suitable waste containers.

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 eyewash equipment should be available. Smoking and naked flames prohibited. 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, out of reach of children and away from food, animal feeding stuffs, medicines, etc. Do not expose to heat (e.g. sunlight). Keep in tightly closed original packaging. Store in a dry, cool, well-ventilated area. Do not store with the following: Oxidisers.

7.3 Specific end use(s)

See section 1.2.

Section 8

Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits: Contains no substances subject to reporting requirements.

Legal basis: Commission Directive 2000/39/EC (Occupational Exposure Limits) as subsequently amended. Last amended by Commission Directive 2019/1831/EU. Directive 2004/37/EC (Exposure to carcinogens or mutagens at work) as subsequently amended. Last amended by Directive 2019/983/EU.

Measuring methods: Compliance with the stated occupational exposure limits may be checked by occupational hygiene measurements.

8.2 Exposure controls

Appropriate engineering controls: Wear the personal protective equipment specified below.

Personal protective equipment, eye/face protection:

Wear safety goggles if there is a risk of eye splash. Eye protection must conform to EN 166.

Personal protective equipment, hand protection:

By handling of the product: Plastic or rubber gloves recommended.

Personal protective equipment, respiratory protection: Not required.

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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

Physical state:	Non-woven wipes
Colour:	wetted with liquid
Odour:	Light yellow
pH:	Characteristic / Alcohol
Melting point / freezing point (°C):	7 (propan-2-ol)
Boiling point or initial boiling point and boiling range (°C):	-89.5 (propan-2-ol)
Flammability:	82 (propan-2-ol)
Lower and upper explosion limit (vol%):	Highly flammable
Flash point (°C):	2-12 (propan-2-ol)
	12 (propan-2-ol)
Auto-ignition temperature (°C):	(closed cup)
Decomposition temperature (°C):	399 (propan-2-ol)
Kinematic viscosity (mm ² /s):	Not determined
Solubility:	Not determined
	Miscible with water
Partition coefficient: n-octanol/water (log value):	(liquid in wipes)
Vapour pressure (kPa, 20°C):	-0.35 (propan-2-ol)
Density and/or relative density (g/cm ³):	4.4 (propan-2-ol)
Relative vapour density (g/cm ³ , 20°C):	0.7585 (propan-2-ol)
	2.08 (propan-2-ol)
Evaporation rate:	(Air=1)
	2.9 (propan-2-ol)
Particle characteristics:	(n-butyl acetate = 1)
	Not determined

9.2 Other information:

None.

Section 10

Stability and reactivity

10.1 Reactivity

Reacts with the following: Oxidizers.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Vapours may form explosive mixtures with air.

10.4 Conditions to avoid

Avoid heating and contact with ignition sources.

10.5 Incompatible materials

Oxidizers.

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 European Union Medical Device Regulation (EU) 2017/745.

11.1 Information on hazard classes as defined in Regulation (EC) No. 1272/2008

Acute toxicity – oral:	Ingestion may cause discomfort. The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 67-63-0: LD ₅₀ (rat) = 5840 mg/kg CAS 71-36-3: LD ₅₀ (rat) = 790 mg/kg
Acute toxicity - dermal:	The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 67-63-0: LD ₅₀ (rabbit) = 12800 mg/kg CAS 71-36-3: LD ₅₀ (rabbit) = 3400 mg/kg
Acute toxicity - inhalation:	The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 67-63-0: LC ₅₀ (4h, vapour) (rat) > 10000 ppm (OECD 403) CAS 71-36-3: LC ₅₀ (4h, vapour) (rat) > 24 mg/l
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:	Eye contact may result in deep caustic burns, pain, tearing and cramping of the eyelids. Risk of serious eye injury and loss of sight.
Respiratory sensitisation or skin sensitisation:	The product does not have to be classified. Test data are not available.
Germ cell 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 releases organic solvent vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication.
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.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

None known.

11.2.2 Other information

None.

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Section 12

Ecological information

12.1 Toxicity

The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met.

CAS 67-63-0:

Fish: EC₅₀ (Pimephales promelas, 96h) = 10000 mg/l

Crustacea: EC₅₀ (Daphnia magna, 24h) = >10000 mg/l

CAS 71-36-3:

Fish: EC₅₀ (Oncorhynchus mykiss, 24h) = 921 mg/l

12.2 Persistence and degradability

CAS 71-36-3:

Biodegradation: 98 %

Exposure time: 19 d

Method: OECD Test Guideline 301E

Result: Readily biodegradable.

12.3 Bioaccumulative potential

CAS 67-63-0:

log Pow: 0.05

CAS 71-36-3:

log Pow: 0.88

BCF: 0.38

CAS 71-36-3:

12.4 Mobility in soil

The product contains at least one substance with high soil mobility.

12.5 Results of PBT and vPvB assessment

The product does not contain any PBT or vPvB substances.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

None known.

Section 13

Disposal considerations

13.1 Waste treatment methods

The recommended disposal technology at any approved facility. Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

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Do not discharge large quantities of concentrated spills and residue into drains. Uncleansed packaging is to be disposed of via the local waste-removal scheme. Empty, cleansed packaging should be disposed of for recycling. If this product as supplied becomes a waste, it meets the criteria of a hazardous waste (Dir. 2008/98/EU). Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

Category of waste:

Wiping cloths with organic solvents: EWC code: 15 02 02 Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

Section 14

Transport information

14.1 UN number or ID number:	3175
14.2 UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)
14.3 Transport hazard class(es):	4.1
14.4 Packing group:	II
14.5 Environmental hazards:	No
14.6 Special precautions for user:	None
14.7 Maritime transport in bulk according to IMO instruments:	Not relevant

ADR - Classification:

- Classification code:	F1
- ADR limited Quantities:	1 kg
- Hazard label:	4

Special provisions applicable to certain articles or substance: 216, 274, 601.

IMDG - Classification:

- IMDG limited Quantities:	1 kg
- Hazard label:	4
EMS:	F-A, S-I

Special provisions applicable to certain articles or substance: 216, 274.

IATA - Classification:

- Hazard label:	4
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Transportation on road in other countries than ADR-countries:

US: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Canada: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)/ SOLIDES CONTENANT DU LIQUIDE INFLAMMABLE, N.S.A. (ISOPROPANOL)

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Brazil: UN3175 SÓLIDOS CONTENDO LÍQUIDO INFLAMÁVEL, N.S.A. (ISOPROPANOL)

Australia: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

New Zealand: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Hongkong / China: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Section 15

Regulatory information

Covered by:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Council Directive (EC) on the protection of young people at work.

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

Special provisions:

Directive 2012/18/EU (Seveso), P5c FLAMMABLE LIQUIDS: Column 2: 5000 t, Column 3: 50000 t.

Special care should be applied for employees under the age of 18. Young people under the age of 18 may not carry out any work causing harmful exposure to this product.

15.2 Chemical Safety Assessment:

Chemical safety assessment has been performed for following substances:

CAS 67-63-0: Propan-2-ol

CAS 71-36-3: Butan-1-ol

Section 16

Other information

H-/EUH-statements mentioned in section 2 and 3:

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

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.

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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.

THE ABOVE INFORMATION HAS BEEN COMPILED FROM SOURCES BELIEVED TO BE RELIABLE AND IS ACCURATE TO THE BEST OF OUR KNOWLEDGE. HOWEVER, COLOPLAST CORP. CANNOT GIVE ANY GUARANTEES REGARDING INFORMATION FROM OTHER SOURCES AND EXPRESSLY DOES NOT MAKE ANY WARRANTIES, NOR ASSUMES ANY LIABILITY, FOR ITS USE.

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OF THE SDS TO CUSTOMERS OUTSIDE OF COLOPLAST**

Change log

Version no.	Issue Date (Month Year)	Short description of and reason for change
1.0	March 2012	Document established based on template version 4.0
2.0	November 2021	Update of template (version 6.0) Update of product classification based on the latest compositional information, as well as substances classification.

Document Approvals
Approved Date: 2022-10-25

Approval Task Verdict: Approve	PLALWIN Aleksandra Witkowska-Nowak, Biosafety & Chemical Compliance Specialist (plalwin@coloplast.com) Technical / Specialist 25-Oct-2022 06:41:50 GMT+0000
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