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USA

Coloplast Corp.
South Sixth St.
Minneapolis, MN 55402
Telephone: +1-800-533-0464
Fax: +1-612-337-7803
www.us.coloplast.com

CANADA

Coloplast Canada Corporation
3300 Ridgeway Drive, Unit 12
Mississauga, Ont. L5L 5Z9
Telephone: +1-800-533-0464
Fax: +1-877-820-8206
www.coloplast.ca

EUROPE

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Telephone: +45 49 11 11 11
Fax: +45 49 11 19 32
www.coloplast.com

SAFETY DATA SHEET:

Reference: This SDS is prepared in compliance with: Regulation (EC) No 1907/2006 with amendments.

**SECTION 1. ----- IDENTIFICATION OF THE SUBSTANCE/MIXTURE
AND OF THE COMPANY/UNDERTAKING -----**

Product identifier:

Product Name: Ostomy paste

Product Code: 2650 & 2651

Product Information: Ostomy Care

Relevant identified uses of the substance or mixture and uses advised against:
Medical device used for protecting and levelling skin around ostomies.

Details of the supplier of the safety data sheet:

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark
Telephone: +45 4911 1111
Fax: +45 4911 2260
Responsible person for the safety data sheet (e-mail): MSDS@coloplast.com

Emergency telephone number:

+45 4911 1111 (Within office hours. Local emergency number is given on the packaging)

SECTION 2. ----- HAZARDS IDENTIFICATION -----

This product is assessed in accordance with Directive 93/42/EEC on medical devices and Directive 1999/45/EC and Regulation (EC) no 1272/2008 on classification, labelling and packaging of substances and mixtures.

Classification of the substance or mixture:

Classification according to Directive 67/548/EEC None.
or 1999/45/EC and later amendments:

Classification according to Regulation (EC) No 1272/2008: Eye Irrit. 2;H319

Physical and Chemical hazards: None.

Hazards to Humans: Irritant paste; causes serious eye irritation.

Hazards to environment: None.

Label elements:**According to Regulation (EC) No 1272/2008:****Contains:** Butan-1-ol**Pictogram(s):****Signal word:**

Warning

Hazard statement(s):

H319: Causes serious eye irritation.

Precautionary statement(s):

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Other labelling:

None.

Other hazards:

No known.

PBT/vPvB: No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

SECTION 3. ----- COMPOSITION/INFORMATION ON INGREDIENTS -----**Mixtures:**

The main ingredients are: Guar gum and ethanol.

The following substances have to be declared according to legislation:

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (67/548/EEC)	Classification (EC 1272/2008)
15-25	64-17-5	200-578-8	603-002-00-5	None	Ethanol *	F;R11	Flam. Liq. 2;H225
3-6	67-63-0	200-661-7	603-117-00-0	None	Isopropyl alcohol *	F;R11 Xi;R36 R67	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336
< 3	71-36-3	200-751-8	603-004-00-6	None	Butan-1-ol *	R10 Xn;R22 Xi;R37/38-41 R67	Flam. Liq. 3;H226 Acute Tox. 4; H302 STOT SE 3;H335 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H336

* The substance is an organic solvent.

Wording of R-sentences and H-statements - see section 16.

SECTION 4. ----- FIRST AID MEASURES -----**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 directed 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. In case of discomfort: Seek medical advice.

Most important symptoms and effects, both acute and delayed:

At high concentrations: Headache, dizziness, fatigue, nausea, vomiting, stomach ache, diarrhoea and intoxication. Volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

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 -----

Extinguishing Media: Use water spray, carbon dioxide, dry chemical or foam.

Special hazards arising from the substance or mixture: Do not inhale smoke fumes.
In case of fire, the product may form hazardous decomposition products: Primarily oxides of carbon.

Advice for firefighters: Wear self contained breathing apparatus when generation of smoke is vigorous.

SECTION 6. ----- ACCIDENTAL RELEASE MEASURES -----

Personal precautions, protective equipment and emergency procedures: Not relevant. This product is intended to be in contact with the skin.

Environmental precautions: Not relevant.

Methods and materials for containment and cleaning up: Absorb with paper towel. Place in a suitable container for disposal. Further handling of spillage - see section 13.

Reference to other sections: See references above.

SECTION 7. ----- HANDLING AND STORAGE -----

Precautions for safe handling:

Avoid breathing vapours. Provide adequate ventilation. Avoid contact with skin, eyes and clothing.
Wash contaminated skin with water and mild soap.

Conditions for safe storage, including any incompatibilities:

Store in well-closed original packaging in a cool and well-ventilated place.

Store securely, inaccessible to unauthorized persons, separate from food, foodstuff, medicaments etc.

Specific end use(s):

See section 1.

SECTION 8. ----- EXPOSURE CONTROLS/PERSONAL PROTECTION -----

Control parameters:

	Isopropyl alcohol (= 2-propanol):	Ethanol:	Butan-1-ol:
USA (ACGIH)	200 ppm (TWA) 400 ppm (STEL)	1000 ppm (TWA)	20 ppm (TWA)
Germany (MAK)	200 ppm = 500 mg/m ³	500 ppm = 960 mg/m ³	100 ppm = 310 mg/m ³
Denmark (AT)	200 ppm = 490 mg/m ³	1000 ppm = 1900 mg/m ³	50 ppm = 150 mg/m ³ H = May be absorbed through skin L = ceiling value, not to be exceeded
DNEL	No CSR	No CSR	No CSR
PNEC	No CSR	No CSR	No CSR

Exposure controls:

Appropriate engineering controls: Avoid inhalation of vapors. Provide adequate ventilation.

Personal protective equipment:

Inhalation:
Respiratory equipment is normally not required.

Skin:
Wear protective gloves of nitril (> 0.3 mm) in case of extensive contact/use. Break through time: app. 20 min.

Eyes:
Safety goggles are normally not required.

Environmental exposure controls: See section 6 and 13.

SECTION 9. ----- PHYSICAL AND CHEMICAL PROPERTIES -----**Information on basic physical and chemical properties:**

Appearance:	Paste
Odour:	Alcohol
Odour threshold:	Not determined
pH:	Not applicable
Melting point / freezing point (°C):	Not determined
Initial boiling point and boiling range (°C):	Not determined
Decomposition temperature (°C):	Not determined
Flash point (°C):	Not determined
Evaporation rate:	Not determined
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits (ppm):	Not determined
Vapour pressure (mmHg):	Not determined
Vapour density (air=1):	Not determined
Relative density (g/ml, 20°C):	Not determined
Solubility:	Not determined
Partition coefficient: n-octanol/water, Log K_{ow}:	Not applicable
Autoignition temperature (°C):	Not determined
Viscosity (mm²/s, 25°C):	Not determined
Explosive properties:	Not relevant
Oxidising properties:	Not relevant

Other Information:

None relevant.

SECTION 10. ----- STABILITY AND REACTIVITY -----

Reactivity:	No available data.
Chemical stability:	The product is stable under the advised storage conditions – see section 7.
Possibility of hazardous reactions:	No known.
Conditions to avoid:	No known.
Incompatible materials:	No known.
Hazardous decomposition products:	When heated to high temperatures (decomposition), toxic gasses are formed such as oxides of carbon.

SECTION 11. ----- TOXICOLOGICAL INFORMATION -----**Information on toxicological effects:**

Toxicological data:	Isopropyl alcohol:
	Eye irritation (rabbit, Draize test) [Merck]
	No acute toxicity (rodents), sensitization (guinea pig, Buehler test) or CMR effects (animal tests) [IUCALID]
	Ethanol:
	LD ₅₀ (rotte) = 1780 mg/kg [IUCALID]

No skin- or eye irritation (rabbit, OECD 404/405) [IUCLID]

No sensitization (guinea pig, GPMT) [IUCLID]

Butan-1-ol:

LD₅₀ (rotte) = 790 mg/kg [RTECS]

Moderate skin irritation (20 mg/24H, rabbit, Draize test) [RTECS]

Severe eye irritation (2 mg/24H, rabbit, Draize) [RTECS]

No other relevant available or applicable data.

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

Symptoms:

Inhalation: May cause irritation of the respiratory tract and at high concentrations headache, dizziness, fatigue, nausea, vomiting and intoxication.

Skin: May cause irritation and degreasing of skin with redness.

Eyes: May cause irritation with redness, pain and blurred vision.

Ingestion: May cause irritation of the gastrointestinal tract with nausea, stomach ache, vomiting, diarrhoea and symptoms as mentioned under "inhalation".

Chronic effects: Long term or repeated skin contact may degrease the skin and cause red, dry, cracked and thickened skin. Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

SECTION 12. ----- ECOLOGICAL INFORMATION -----

Toxicity: Ethanol has low toxicity in aquatic organisms:
 LC₅₀ (Pimephales promelas, 96h) = 15300 mg/l [IUCLID]
 EC₅₀ (Daphnia magna, 48h) = 9268 - 14221 mg/l [IUCLID]

Isopropyl alcohol:

LC₅₀ (Rasbora heteromorpha, 96h) = 4200 mg/l [IUCLID]

EC₅₀ (Daphnia magna, 48h) = 13299 mg/l [IUCLID]

EC₅₀ (Scenedesmus subspicatus, 72h) > 1000 mg/l [IUCLID]

Persistence and degradability: Ethanol is readily biodegradable.
 Isopropyl alcohol is readily biodegradable according to OECD test 301 E.

Bioaccumulative potential: Ethanol and Isopropyl alcohol:
 Log K_{ow} < 1 - No significant bioaccumulative effect.

Mobility in soil: Ethanol and Isopropyl alcohol:
 K_{oc} < 10 - Very high mobility in soil.

Results of PBT and vPvB assessment: No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

Other adverse effects: No known.

SECTION 13. ----- DISPOSAL CONSIDERATIONS -----

Waste treatment methods:

The recommended disposal technology is incineration at any approved facility. The disposal should always be in compliance with National, Federal, State and local regulations. The project should not be discharged into the environment.

US: If this product as supplied becomes a waste, it does not meet the criteria for hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261. Under normal private use the product may be disposed of together with other household waste per RCRA 40 CFR 261.4.B1.

European Union: According to The European Waste Catalogue (EWC), in accordance with EC Directive 75/442/EEC, the following Waste Code can be used: 18 01 06 Chemicals containing hazardous substances. However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used. It is the responsibility of the holder of the waste to determine the actual classification. Waste from private household may be disposed of together with other household waste.

SECTION 14. ----- TRANSPORT INFORMATION -----

UN-no.: 1325
UN proper shipping name: FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols)
Transport hazard class(es): 4.1
Packing group: III
Environmental hazards: None.
Special precautions for user: None.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not relevant.

ADR - Classification: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III
- Classification code: F1
- ADR limited Quantities: LQ: 5KG
- Hazard label:



IMDG - Classification: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III
- Classification code: -
- IMDG limited Quantities: 5 KG
- Hazard label:



IATA - Classification: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III
- Hazard label:



Transport by road in other countries than ADR-countries:

US: 49 CFR: 1170 UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III. LQ=5kg

Canada: TDG: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III. LQ=5kg

Brazil: ANTT. 420 2004/2/12 with amendments: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III. LQ=5kg

Australia: ADG7: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III. LQ=5kg

Turkey: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III. LQ=5kg

New Zealand: NZS 5433: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (alcohols), 4.1, III. LQ=5kg

Hongkong/China: As ADR

SECTION 15. ----- REGULATORY INFORMATION -----**Safety, health and environmental regulations/legislation specific for the substance or mixture:**

Must not be used by persons under 18 years of age.

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC).

Chemical Safety Assessment:

No CSR.

SECTION 16. ----- OTHER INFORMATION -----**R-sentences and H-statements mentioned in section 2 and 3:**

- R 10: Flammable.
R 11: Highly flammable.
R 22: Harmful if swallowed.
R 36: Irritating to eyes.
R 37/38: Irritating to respiratory system and skin.
R 41: Risk of serious damage to eyes.
R 67: Vapours may cause drowsiness and dizziness.
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:

- At. = Arbejdstilsynet
CMR = Carcinogenicity, mutagenicity and reproductive toxicity
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
GPMT = Guinea Pig Maximization Test
EC₅₀ = Effect Concentration 50 %
LC₅₀ = Lethal Concentration 50 %
LD₅₀ = Lethal Dose 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

RTECS = Register of Toxic Effects of Chemical Substances

Merck (Safety data sheet)

Changes since the previous edition:

Not relevant.

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