

Dansac skin crème

Safety Data Sheet

Issue date: 13 February 2023 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name : Dansac skin crème
Product code : 085-00, 085-50

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Help prevent dry and irritated skin underneath ostomy skin barriers by moisturizing and soothing the skin. For external use only.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Hollister ULC
Foxford Road
Rehins, Ballina
County Mayo, Ireland F26 F3X5
Tel: +353 96 60600
Email: baehsinfo@Hollister.com
Manufacturer web: www.hollister.com

Manufacturer

Dansac A/S
Lille Kongevej 304
Fredensborg 3480 Denmark
T: +45 48465000
www.dansac.com

Global corporate headquarters
Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048
847-680-1000
www.Hollister.com

Hollister Limited
Rectory Court
42 Broad Street
Wokingham, Berkshire RG40 1AB, England

1.4. Emergency telephone number

Emergency number : +45 48465000; +45 82 12 12 12 (Denmark Poison Control (Giftlinjen))

SECTION 2: Hazards identification

This product is regulated as a medical device in European Economic Area (EEA) and therefore, is exempt for the requirement to provide a CLP/REACH compliant SDS as it is medical device per Medical Device Regulation (MDR) (2017/745). 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 Medical Device Regulation (MDR) (2017/745) on medical devices and local legislation.

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

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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 SDS and not necessarily present on the product labelling.

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
White mineral oil, petroleum	CAS-No.: 8042-47-5 EC-No.: 232-455-8	1 – 5	Asp. Tox. 1, H304
Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)-	CAS-No.: 39236-46-9 EC-No.: 254-372-6	0.1 – 1	Skin Sens. 1B, H317
Steroids, soya hydroxy, ethoxylated	CAS-No.: 68648-64-6 EC-No.: 614-690-1	0.1 – 1	Aquatic Chronic 3, H412
PROPYLPARABEN	CAS-No.: 94-13-3 EC-No.: 202-307-7	0.1 – 1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
METHYLPARABEN	CAS-No.: 99-76-3 EC-No.: 202-785-7	0.1 – 1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412
2-Propenoic acid, homopolymer	CAS-No.: 9003-01-4 EC-No.: 618-347-7	0.1 – 1	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use. Remove person to fresh air and keep comfortable for breathing. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use. Rinse with plenty of water. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Not expected to present a significant eye contact hazard under anticipated conditions of normal use. Rinse with plenty of water. If eye irritation persists: Get medical advice and attention.

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First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use. In all cases of doubt, or when symptoms persist, seek medical attention.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact : May cause slight temporary irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : The product is not flammable.
Explosion hazard : None in normal use conditions.

5.3. Advice for firefighters

Firefighting instructions : Fight fire with normal precautions from a reasonable distance.
Protective equipment for firefighters : Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No additional risk management measures required.

6.1.1. For non-emergency personnel

Emergency procedures : No additional risk management measures required.

6.1.2. For emergency responders

Emergency procedures : No additional risk management measures required.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (for example cloth).
Other information : For disposal of residues refer to section 13 : "Disposal considerations".

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : No special handling advices are necessary.
Hygiene measures : Use good personal hygiene practices. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep cool.
Incompatible materials : None known.

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7.3. Specific end use(s)

For further information see section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Triethanolamine (102-71-6)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Triethanolamine
ACGIH OEL TWA	5 mg/m ³
Remark (ACGIH)	TLV® Basis: Eye & skin irr
Regulatory reference	ACGIH 2022
Stearic acid (57-11-4)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Stearic acid
ACGIH OEL TWA	10 mg/m ³ (I - Inhalable particulate matter) 3 mg/m ³ (R - Respirable particulate matter)
Remark (ACGIH)	TLV® Basis: LRT irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2022

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

None in normal use conditions.

8.2.2. Personal protection equipment

Personal protective equipment:

Not required for normal conditions of use.

8.2.2.1. Eye and face protection

Eye protection:

If there is a risk of eye contact: Use suitable eye protection

8.2.2.2. Skin protection

No additional information available

8.2.2.3. Respiratory protection

No additional information available

8.2.2.4. Thermal hazards

No additional information available

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8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: whitish.
Colour	: Cream.
Odour	: Slight.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 99 °C (> 210 ° F)
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral)	: Not classified (On basis of test data)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

Dansac skin crème	
LD50 oral rat	> 5000 mg/kg

White mineral oil, petroleum (8042-47-5)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rabbit	> 5000 mg/kg

Urea, N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)]- (39236-46-9)	
LD50 oral rat	11300 mg/kg

2-Propenoic acid, homopolymer (9003-01-4)	
LD50 oral rat	2500 mg/kg
LD50 dermal rabbit	> 2000 mg/kg

Skin corrosion/irritation	: Not classified (On basis of test data)
Serious eye damage/irritation	: Not classified (On basis of test data)
Respiratory or skin sensitisation	: Not classified. (On basis of test data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)

2-Propenoic acid, homopolymer (9003-01-4)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)

PROPYLPARABEN (94-13-3)	
STOT-single exposure	May cause respiratory irritation.

METHYLPARABEN (99-76-3)	
STOT-single exposure	May cause respiratory irritation.

2-Propenoic acid, homopolymer (9003-01-4)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: This material has not been tested for environmental effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

White mineral oil, petroleum (8042-47-5)	
LC50 - Fish [1]	> 10000 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)

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2-Propenoic acid, homopolymer (9003-01-4)

LC50 - Fish [1]

580 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

White mineral oil, petroleum (8042-47-5)

Partition coefficient n-octanol/water (Log Pow)

> 6

2-Propenoic acid, homopolymer (9003-01-4)

Partition coefficient n-octanol/water (Log Pow)

0.27 (at 20 °C (at pH \geq 3.59- \leq 3.63))

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of in accordance with relevant local regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

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Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no REACH substances with Annex XVII restrictions

REACH Annex XIV (Authorisation List)

Contains no REACH Annex XIV substances

REACH Candidate List (SVHC)

Contains no substance on the REACH candidate list

PIC Regulation (Prior Informed Consent)

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

POP Regulation (Persistent Organic Pollutants)

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Ozone Regulation (1005/2009)

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Explosives Precursors Regulation (2019/1148)

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on drug precursors)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Sources of Key data : Company information.

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Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Asp. Tox. 1	Aspiration hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Eye Dam./Irrit. Not classified		On basis of test data
Skin Sens. Not classified		On basis of test data

Safety Data Sheet (SDS)

The information contained in this Safety Data Sheet (SDS) is offered as a guide to the use and handling of this material. All safety aspects of all Hollister products are thoroughly evaluated prior to commercialization. This SDS has been prepared in good faith by technically knowledgeable personnel. Hollister Incorporated shall not be held liable for any damages, losses or injuries of any nature which may result from the use of or reliance upon any information contained in this SDS. Each individual should make a determination as to the suitability of the information for his or her particular purpose(s).