



Safety Data Sheet

Issue date: 22 September 2022 Revision date: 13 February 2023 Supersedes version of: 22 September 2022 Version: 2.0

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

1.1. Product identifier

Product form : Mixture

Trade name : Dansac Nodor S
Product code : 080-01; 080-00

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 : Ostomy use

Odour agents neutralizing agent

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

Global corporate headquarters Hollister Incorporated

2000 Hollister Drive Libertyville, Illinois 60048

847-680-1000 www.Hollister.com

Manufacturer

Dansac A/S Lille Kongevej 304

Fredensborg 3480 Denmark

T: +45 48465000 www.dansac.com

1.4. Emergency telephone number

Emergency number : +45 48465000; +45 82 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]

Serious eye damage/eye irritation Not classified

Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411

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

Adverse physicochemical, human health and environmental effects

Toxic to aquatic life with long lasting effects.

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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]

Hazard pictograms (CLP)



Signal word (CLP)

Hazard statements (CLP) : H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.

P391 - Collect spillage.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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]
Zinc sulfate heptahydrate	CAS-No.: 7446-20-0 EC-No.: 231-793-3;616-097-3 EC Index-No.: 030-006-00-9	1 – 5	Acute Tox. 4 (Oral), H302 (ATE=1260 mg/kg bodyweight) Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Aluminium sulfate tetradecahydrate	CAS-No.: 16828-12-9 EC-No.: 605-512-3	1 – 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412

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 general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical

advice (show the label where possible).

First-aid measures after inhalation Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact Wash with water and soap as a precaution.

First-aid measures after eye contact Rinse eyes with water as a precaution. Seek medical attention if ill effect or irritation

develops.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Call a poison center or a doctor if you feel unwell.

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

: Not expected to present a significant hazard under anticipated conditions of normal use. Normal use of this product shall imply use in accordance with the instructions on the packaging. Single patient-multiple use: Sharing the product with multiple users creates risk of infection.

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

Treat symptomatically.

Symptoms/effects

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 : Presents no particular fire or explosion hazard. Thermal decomposition may produce :

Carbon oxides (CO, CO2). Metal oxides. Sulphur oxides.

Explosion hazard : No hazard identified.

Hazardous decomposition products in case of fire : Thermal decomposition can lead to the release of irritating gases and vapours.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering

the environment.

Protective equipment for firefighters : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Prevent entry to sewers and public waters.

6.1.1. For non-emergency personnel

Protective equipment : No special protection required. Emergency procedures : No special requirements.

6.1.2. For emergency responders

Protective equipment : No special protection required. Emergency procedures : No special requirements.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb spillage to prevent material damage. In case of large spillages: Contain any spills

with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for cleaning up : Collect spillage. Wipe up with absorbent material (for example cloth).

Other information : Dispose in a safe manner in accordance with local/national regulations.

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".

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Read instructions/label before use. Observe the label precautions. Not for internal use or

direct application to skin. Wash hands thoroughly after use. Keep away from infants and children. Single patient-multiple use: Sharing the product with multiple users creates risk of

infection.

Hygiene measures : Use good personal hygiene practices. Do not eat, drink or smoke when using this product.

Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep

away from infants and children.

Incompatible materials : Strong acids. Oxidising agents. Reducing agents.

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

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods

Monitoring methods 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:

Not required for normal conditions of use. Normal use of this product shall imply use in accordance with the instructions on the packaging.

8.2.2. Personal protection equipment

Personal protective equipment:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging.

8.2.2.1. Eye and face protection

Eye protection:

No special protection required

8.2.2.2. Skin protection

Hand protection:

No special protection required

8.2.2.3. Respiratory protection

Respiratory protection:

No special protection required

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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid Colour Colourless. Appearance Clear. Transparent. Odour Odourless. Odour threshold : Not available : Not available Melting point Freezing point : Not available : ≈ 100 °C (212 °F) **Boiling point** Flammability : Non flammable. **Explosive limits** Not available Lower explosion limit : Not available Upper explosion limit : Not available : Not available Flash point : Not available Auto-ignition temperature Decomposition temperature : Not available : 3-4 рΗ Viscosity, kinematic : Not available

Solubility : Soluble in water. Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available : Not available Vapour pressure at 50 °C : 1 g/cm³ Density : Not available Relative density : Not available Relative vapour density at 20 °C Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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10.4. Conditions to avoid

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

10.5. Incompatible materials

Strong acids. Oxidising agents. Reducing agents

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition may produce: Carbon oxides (CO, CO2). Metal oxides. Sulphur oxides.

SECTION 11: Toxicological information

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

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)

LD50 oral rat		
LDJU Ulai lat		

Dansac Nodor S

> 5000 mg/kg bodyweight

Zinc sulfate heptahydrate (7446-20-0)

LD50 oral rat 1260 mg/kg

Skin corrosion/irritation : Not classified (On basis of test data)

Serious eye damage/irritation : Not classified (On basis of test data)

pH: 3 - 4

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) 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)

Aluminium sulfate tetradecahydrate (16828-12-9)

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)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine

disrupting properties

No additional information available

11.2.2. Other information

Potential Adverse human health effects and

symptoms

: Single patient-multiple use: Sharing the product with multiple users creates risk of infection

Other information : Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life with long lasting effects.

Hazardous to the aquatic environment, short-term

: Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term

: Toxic to aquatic life with long lasting effects.

(chronic)

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12.2. Persistence and degradability

Dansac Nodor S

Persistence and degradability Not established.

12.3. Bioaccumulative potential

Dansac Nodor S

Bioaccumulative potential Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID	
14.1. UN number or ID n	14.1. UN number or ID number				
UN 3082	UN 3082	UN 3082	UN 3082	UN 3082	
14.2. UN proper shippin	g name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	Environmentally hazardous substance, liquid, n.o.s.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	
Transport document descr	iption				
UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc sulfate heptahydrate), 9, III, (-)	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc sulfate heptahydrate), 9, III, MARINE POLLUTANT	UN 3082 Environmentally hazardous substance, liquid, n.o.s. (Zinc sulfate heptahydrate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc sulfate heptahydrate), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc sulfate heptahydrate), 9, III	
14.3. Transport hazard class(es)					
9	9	9	9	9	

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ADR	IMDG	IATA	ADN	RID	
14.4. Packing group	14.4. Packing group				
III	III	III	III	III	
14.5. Environmental hazards					
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes	Dangerous for the environment: Yes	Dangerous for the environment: Yes	
Consult the associated transport regulations for available and applicable exceptions or exemptions.					

14.6. Special precautions for user

Overland transport

Classification code (ADR) : M6

Special provisions (ADR) : 274, 335, 375, 601

Limited quantities (ADR) : 5I Excepted quantities (ADR) : E1

Packing instructions (ADR) : P001, IBC03, LP01, R001

Special packing provisions (ADR) : PP1
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T4
Portable tank and bulk container special provisions : TP1, TP29

(ADR)

Tank code (ADR) : LGBV
Vehicle for tank carriage : AT
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Special provisions for carriage - Loading, unloading : CV13

and handling (ADR)

Hazard identification number (Kemler No.) : 90

Orange plates :

90 3082

Tunnel restriction code (ADR)

Transport by sea

Special provisions (IMDG) : 274, 335, 969

: 5 L Limited quantities (IMDG) Excepted quantities (IMDG) : E1 Packing instructions (IMDG) : LP01, P001 Special packing provisions (IMDG) : PP1 IBC packing instructions (IMDG) IBC03 Tank instructions (IMDG) T4 TP1, TP29 Tank special provisions (IMDG) EmS-No. (Fire) F-A EmS-No. (Spillage) : S-F Stowage category (IMDG) Α

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y964
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 964
PCA max net quantity (IATA) : 450L

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CAO packing instructions (IATA) : 964
CAO max net quantity (IATA) : 450L

Special provisions (IATA) : A97, A158, A197, A215

ERG code (IATA) : 9L

Inland waterway transport

Classification code (ADN) : M6

Special provisions (ADN) : 274, 335, 375, 601

Limited quantities (ADN) : 5 L

Excepted quantities (ADN) : E1

Carriage permitted (ADN) : T

Equipment required (ADN) : PP

Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : M6

Special provisions (RID) : 274, 335, 375, 601

Limited quantities (RID) : 5L Excepted quantities (RID) : E1

Packing instructions (RID) : P001, IBC03, LP01, R001

Special packing provisions (RID) : PP1
Mixed packing provisions (RID) : MP19
Portable tank and bulk container instructions (RID) : T4
Portable tank and bulk container special provisions : TP1, TP29

(RID)

Tank codes for RID tanks (RID) : LGBV

Transport category (RID) : 3

Special provisions for carriage – Packages (RID) : W12

Special provisions for carriage - Loading, unloading : CW13, CW31

and handling (RID)

Colis express (express parcels) (RID) : CE8
Hazard identification number (RID) : 90

14.7. Maritime transport in bulk according to IMO instruments

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.

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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

Germany

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).

Observe restrictions according Act on the Protection of Young People in Employment

(JArbSchG).

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

WGK remark : Most stringent classification due to insufficient data.

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen

SZW-lijst van mutagene stoffen SZW-lijst van reprotoxische stoffen – Borstvoeding

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen - Ontwikkeling

: None of the components are listed: None of the components are listed

: None of the components are listed

: None of the components are listed

: None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
2	Hazard identification	Modified	

Abbreviations and acronyms:		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
ATE	Acute Toxicity Estimate	
BCF	Bioconcentration factor	
BLV	Biological limit value	
BOD	Biochemical oxygen demand (BOD)	
COD	Chemical oxygen demand (COD)	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC-No.	European Community number	
EC50	Effective concentration for 50 percent of test population (median effective concentration)	
EN	European Standard	
IARC	International Agency for Research on Cancer	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	

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Abbreviations and acronyms:		
LC50	Lethal concentration for 50 percent of test population (median lethal concentration)	
LD50	Lethal dose for 50 percent of test population (median lethal dose)	
LOAEL	Lowest Observed Adverse Effect Level	
NOAEC	No-Observed Adverse Effect Concentration	
NOAEL	No-Observed Adverse Effect Level	
NOEC	No-Observed Effect Concentration	
OECD	Organisation for Economic Co-operation and Development	
OEL	Occupational Exposure Limit	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
RID	Regulation concerning the International Carriage of Dangerous Goods by Railways	
SDS	Safety Data Sheet	
STP	Sewage treatment plant	
ThOD	Theoretical oxygen demand (ThOD)	
TLM	Median Tolerance Limit	
VOC	Volatile Organic Compounds	
CAS-No.	Chemical Abstract Service number	
N.O.S.	Not Otherwise Specified	
vPvB	Very Persistent and Very Bioaccumulative	
ED	Endocrine disrupting properties	

Sources of Key data

: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (et sequens).

Other information

: None.

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 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H302	Harmful if swallowed.	
H315	Causes skin irritation.	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	
H335	May cause respiratory irritation.	
H400	Very toxic to aquatic life.	
H410	Very toxic to aquatic life with long lasting effects.	

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Full text of H- and EUH-statements:		
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		
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 On basis of test data classified		
Aquatic Chronic 2	H411	Calculation method

Safety Data Sheet (SDS), EU

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).