

# Cetostearyl alcohol emulsifying (lanette SX)

## Safety Data Sheet

**248630**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 20/05/2015 Revision date: 15/03/2017

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

#### 1.1. Product identifier

Product form : Article  
 Product name : Cetostearyl alcohol emulsifying (lanette SX)  
 EC-No. : 273-257-1  
 CAS-No. : 68955-19-1  
 REACH registration No : 01-2119485905-24-0007, 01-2119485905-24-0006, 01-2119485907-20-0006, 01-2119485907-20-0005  
 Product code : 248630  
 Synonyms : Lanette SX  
 Product group : Blend  
 Other means of identification : A mixture of C16- and C18-alcohols, Sulfuric acid, mono-C12-18 alkyl esters and sodium salts

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

##### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical  
 Function or use category : Bases for creams and ointments

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Duchefa Farma BV  
 A. Hofmanweg 71  
 2031BH Haarlem - The Netherlands  
 T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

#### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
 +31(0)23-5319093 (M-F 09:00-17:00)  
 +31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Not classified

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### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

According to EC directives or the corresponding national regulations there is no labelling obligation for this product.

#### 2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

## 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]
Cetostearyl alcohol	(CAS-No.) 67762-27-0 (EC-No.) 267-008-6 (REACH-no) 01-2119485905-24-0007, 01-2119485905-24-0006, 01-2119485907-20-0006, 01-2119485907-20-0005	> 80	Not classified
SODIUM C12-18 ALKYL SULFATE	(CAS-No.) 68955-19-1 (EC-No.) 273-257-1	5 - 10	Not classified

Full text of H-statements: see section 16

## SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : Not applicable.  
First-aid measures after skin contact : Rinse with plenty of water.  
First-aid measures after eye contact : Rinse with water. If eye irritation persists, take medical advice.  
First-aid measures after ingestion : Rinse mouth. Drink two glasses of water. If you feel unwell, seek medical advice.

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

No additional information available

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

Treat symptomatically.

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### SECTION 5: Fire-fighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : dry chemical powder. Water spray. Alcohol resistant foam.  
Unsuitable extinguishing media : Carbon dioxide.

#### 5.2. Special hazards arising from the substance or mixture

Explosion hazard : Product is not explosive.  
Hazardous decomposition products in case of fire : Carbon oxides (CO, CO<sub>2</sub>).

#### 5.3. Advice for firefighters

Precautionary measures fire : Exercise caution when fighting any chemical fire.  
Firefighting instructions : Prevent fire fighting water from entering the environment.  
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Prevent product from entering drains.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up, shovel or vacuum.

#### 6.4. Reference to other sections

Reference to other sections (8, 13).

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Store away from heat. Protect from moisture.  
Storage temperature : 15 - 25 °C  
Packaging materials : PE.

#### 7.3. Specific end use(s)

Pharmaceutical industry.

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

##### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

##### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

##### Skin and body protection:

Wear suitable protective clothing

##### Respiratory protection:

None necessary

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Pellets/tablets.
Colour	: White.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 50 - 54 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 159 - 161 °C
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
Density	: 0.8 - 1 g/cm <sup>3</sup> 60°C
Solubility	: Insoluble in water.
Log Pow	: 6.7 - 7.4
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

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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

No additional information available

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal conditions.

### 10.4. Conditions to avoid

heat. High temperature. Moisture.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified  
Additional information : Considered as non toxic

Cetostearyl alcohol emulsifying (lanette SX) (68955-19-1)	
LD50 oral rat	> 5000 mg/kg

Cetostearyl alcohol (67762-27-0)	
LD50 oral rat	> 5000 mg/kg

Skin corrosion/irritation : Not classified  
Serious eye damage/irritation : Not classified  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified

Reproductive toxicity : Not classified  
STOT-single exposure : Not classified  
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

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<b>Cetostearyl alcohol emulsifying (lanette SX) (68955-19-1)</b>	
LC50 fish 1	< 100 mg/l

<b>Cetostearyl alcohol (67762-27-0)</b>	
LC50 fish 1	> 100 mg/l

### 12.2. Persistence and degradability

<b>Cetostearyl alcohol emulsifying (lanette SX) (68955-19-1)</b>	
Persistence and degradability	readily degradable in water.

<b>Cetostearyl alcohol (67762-27-0)</b>	
Persistence and degradability	readily degradable in water.
BOD (% of ThOD)	> 60 % ThOD

### 12.3. Bioaccumulative potential

<b>Cetostearyl alcohol emulsifying (lanette SX) (68955-19-1)</b>	
Log Pow	6.7 - 7.4

<b>Cetostearyl alcohol (67762-27-0)</b>	
Log Pow	6.7 - 7.4

### 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

Additional information : No other effects known

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

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

## SECTION 14: Transport information

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

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

### 14.6. Special precautions for user

#### - Overland transport

No data available

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### - Air transport

No data available

### 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

Contains no substance on the REACH candidate list

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : 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. Handbook Of Pharmaceutical Excipients.

SDS EU (REACH Annex II) Version 2017

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*