

# Cetostearyl alcohol type B emulsifying (lanette W)

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: :

Version: 1.0

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

### 1.1. Product identifier

Product form : Mixture  
Product name : Cetostearyl alcohol type B emulsifying (lanette W)  
Product code : 9248630  
Synonyms : Cera Lanette W  
Product group : Raw material  
Other means of identification : Mixture of cetostearyl alcohol and sodium laurilsulfate

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

#### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry  
Industrial/Professional use spec : Industrial  
For professional use only  
Use of the substance/mixture : Exipient  
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

Duchefa FARMA BV  
A. Hofmanweg 71  
2031BH Haarlem - Nederland  
T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.com](mailto:info@duchefa.com) - [www.duchefa.com](http://www.duchefa.com)

### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	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]

Skin Irrit. 2 H315  
Eye Irrit. 2 H319

Full text of H-phrases: see section 16

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### Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Xi; R36/38

Full text of R-phrases: see section 16

«\_SDS\_PPP\_CLASSIF&disp=value&clr=1»

«\_SDS\_PPP\_ADD\_TEXT&disp=value&clr=1»

### Adverse physicochemical, human health and environmental effects

No additional information available

## 2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H315 - Causes skin irritation  
H319 - Causes serious eye irritation

Precautionary statements (CLP)

: P280 - Wear protective gloves and eye protection  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water  
P305 - IF IN EYES:  
P351 - Rinse cautiously with water for several minutes  
P337+P313 - If eye irritation persists: Get medical advice/attention

No labelling applicable

## 2.3. Other hazards

vPvB: not relevant – no registration required

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC
sodium dodecyl sulphate	(CAS No) 151-21-3 (EC no) 205-788-1 (REACH-no) 01-2119489461-32	10 - 20	Xi; R38 Xn; R22 Xi; R41

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
sodium dodecyl sulphate	(CAS No) 151-21-3 (EC no) 205-788-1 (REACH-no) 01-2119489461-32	10 - 20	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412

Full text of R- and H-phrases: 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 : Allow victim to breathe fresh air. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Give water to drink if victim completely conscious/alert. Obtain emergency medical attention.

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

- Symptoms/injuries after eye contact : Causes serious eye 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 : Foam. Dry powder. Water spray. Sand.
- Unsuitable extinguishing media : Carbon dioxide.

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

- Fire hazard : May release hazardous gases. Combustible, but not flammable.

### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering 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

- Emergency procedures : Evacuate unnecessary personnel.

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### 6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.  
Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

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

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

### 6.4. Reference to other sections

For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

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

Storage conditions : Keep container closed when not in use. Keep only in the original container in a cool, well-ventilated place.  
Incompatible products : Store away from heat/moisture.  
Incompatible materials : Sources of ignition. Heat sources. Sparks. Moisture. No open flames. No smoking.  
Storage temperature :  $\leq 30\text{ }^{\circ}\text{C}$   
Packaging materials : PE.

### 7.3. Specific end use(s)

Pharmaceutical industry.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Cetostearyl alcohol type B emulsifying (lanette W)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	$\leq$
Long-term - systemic effects, dermal	4060 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	285 mg/m <sup>3</sup>
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	24 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	85 mg/m <sup>3</sup>
Long-term - systemic effects, dermal	2440 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0,137 mg/l
PNEC aqua (marine water)	0,0137 mg/l

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Cetostearyl alcohol type B emulsifying (lanette W)	
PNEC aqua (intermittent, freshwater)	0,055 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	4,82 mg/kg dwt
PNEC sediment (marine water)	0,482 mg/kg dwt
PNEC (Soil)	
PNEC soil	0,882 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	1084 mg/l

### 8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Wear gloves to EN374 to protect against skin effects from powders. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Gloves made of nitrile rubber: Glove thickness: 0.11 mm, Break through time: 480 min.
Eye protection	: Safety glasses (to European standard EN 166 or equivalent).
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: Wear appropriate mask. Dustmask with filter type P1.
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	: Solid
Appearance	: Tablets.
Colour	: white.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 6,5 - 8
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: > 30 °C
Freezing point	: 50 - 54 °C
Boiling point	: No data available
Flash point	: 159 - 161 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available

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Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0,81 - 0,83 g/cm <sup>3</sup>
Solubility	: Emulsifiable in 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

Other properties : Bulk density: 0.900 g/cm<sup>3</sup> (20 °C).

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Not established.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Heat. Moisture.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Cetostearyl alcohol type B emulsifying (lanette W)	
LD50 oral	> 5000 mg/kg

sodium dodecyl sulphate (151-21-3)
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Skin corrosion/irritation	: Causes skin irritation. Based on available data, the classification criteria are not met pH: 6,5 - 8
Serious eye damage/irritation	: Causes serious eye irritation. pH: 6,5 - 8
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
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
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (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
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

Cetostearyl alcohol type B emulsifying (lanette W)	
LC50 fish 1	> 100 mg/l
EC 0 (Bacteria)	>, 100, mg/l

### 12.2. Persistence and degradability

Cetostearyl alcohol type B emulsifying (lanette W)	
Persistence and degradability	Readily biodegradable.

### 12.3. Bioaccumulative potential

Cetostearyl alcohol type B emulsifying (lanette W)	
Bioaccumulative potential	Not established.

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### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

<b>Cetostearyl alcohol type B emulsifying (lanette W)</b>
vPvB: not relevant – no registration required

### 12.6. Other adverse effects

Additional information : Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste 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 / RID / IMDG / IATA / ADN

### 14.1. UN number

Not regulated for transport

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) :

Proper Shipping Name (IMDG) :

Proper Shipping Name (IATA) :

Proper Shipping Name (ADN) :

Proper Shipping Name (RID) :

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR) :

#### IMDG

Transport hazard class(es) (IMDG) :

#### IATA

Transport hazard class(es) (IATA) :

#### ADN

Transport hazard class(es) (ADN) :

#### RID

Transport hazard class(es) (RID) :

### 14.4. Packing group

Packing group (ADR) :



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Packing group (IMDG)	:
Packing group (IATA)	:
Packing group (ADN)	:
Packing group (RID)	:

### 14.5. Environmental hazards

Dangerous for the environment	:	No
Marine pollutant	:	No
Other information	:	No supplementary information available

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

#### 14.6.2. Transport by sea

#### 14.6.3. Air transport

#### 14.6.4. Inland waterway transport

Carriage prohibited (ADN)	:	No
Not subject to ADN	:	No

#### 14.6.5. Rail transport

Carriage prohibited (RID)	:	No
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### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 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 substances with Annex XVII restrictions  
Contains no substance on the REACH candidate list  
Contains no REACH Annex XIV substances

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

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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.
Other information	: REACH Disclaimer: This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). <b>DISCLAIMER OF LIABILITY</b> The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

Full text of R-, H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
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
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H412	Harmful to aquatic life with long lasting effects
R22	Harmful if swallowed
R36/38	Irritating to eyes and skin
R38	Irritating to skin
R41	Risk of serious damage to eyes
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II) Duchefa

*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*