

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name

Cetearyl alcohol & polysorbate 60

Product code

[AL00155]

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

Relevant identified uses

No information.

Uses advised against

No information.

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

Supplier

Farmadria DOO  
Heroja Pinkija 44  
26300 Vršac, Serbia  
+381695565029  
info@avenalab.com

#### 1.4 Emergency Telephone Number

Emergency

111

Supplier

+381695565029

### 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 Causes skin irritation.

Eye Irrit. 2; H319 Causes serious eye irritation.

Aquatic Chronic 4; H413 May cause long lasting harmful effects to aquatic life.

#### 2.2 Label elements

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



**Signal word: WARNING**

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

H315 Causes skin irritation.  
 H319 Causes serious eye irritation.  
 H413 May cause long lasting harmful effects to aquatic life.  
 P102 Keep out of reach of children.  
 P264 Wash ... thoroughly after handling.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P302 IF ON SKIN:  
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P332 + P313 If skin irritation occurs: Get medical advice/attention.  
 P337 + P313 If eye irritation persists: Get medical advice/attention.  
 P362 Take off contaminated clothing.  
 P420 Store separately.  
 P501 Dispose of contents/container in accordance with national regulation.

### 2.3 Other hazards

PBT/vPvB

No information.

Endocrine disrupting properties

The product does not contain substances with the potential for endocrine disorders.

Additional information

No information.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

For mixtures see 3.2.

### 3.2 Mixtures

Name	CAS EC Index Reach	%	Classification according to Regulation (EC) No 1272/2008 (CLP)	Specific Concentration Limits	Notes for substances
Cetearyl Alcohol	67762-27-0 267-008-6 -	60-90	/	/	/
Polysorbate 60	9005-67-8 500-020-4 -	10-40	/	/	/

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Following inhalation

Remove patient to fresh air - move out of dangerous area. If symptoms develop and persist, seek medical attention.

Following skin contact

Wash affected skin areas immediately with plenty of water and soap. If symptoms develop and persist, seek medical

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

attention.

Following eye contact

Immediately flush eyes with running water, keeping eyelids apart. If irritation persists, seek professional medical attention.

Following ingestion

Do not induce vomiting! Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. In case of doubt or if feeling unwell seek medical help. Show the physician the safety data sheet or label.

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

Following inhalation

No information.

Following skin contact

Contact with skin may cause irritation (redness, itching).

Following eye contact

Contact with eyes can cause irritation (redness, tearing, pain).

Following ingestion

May cause nausea/vomiting and diarrhea. May cause abdominal discomfort.

#### 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 measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

Full water jet.

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

Hazardous combustion products

In case of a fire toxic gases can be generated; do not inhale gases/smoke.

#### 5.3 Advice for firefighters

Protective actions

In case of fire or heating do not breathe fumes/vapours. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters

Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (BS EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (BS EN 137).

Additional information

No information.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

For non-emergency personnel

Protective equipment

No information.

Precautionary measures

Ensure adequate ventilation.

Emergency procedures

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

No action shall be taken involving any personal risk or without suitable training. Avoid breathing dust. Avoid contact with skin, eyes and clothing.

For emergency responders

Use personal protective equipment.

### 6.2 Environmental precautions

Do not allow product to reach water/drains/sewage systems or permeable soil. In case of release into the environment, inform the relevant authorities.

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

For containment

No information.

For cleaning up

Clean contaminated area with plenty of water.

Other information

No information.

### 6.4 Reference to other sections

See also sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Protective measures

Measures to prevent fire

Ensure adequate ventilation.

Measures to prevent aerosol and dust generation

Prevent dust formation.

Measures to protect the environment

Avoid release to the environment.

Other measures

No information.

Advice on general occupational hygiene

Use good personal hygiene practices – wash hands at breaks and when done working with material. Do not eat, drink or smoke while working. Avoid contact with skin, eyes and clothes.

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

Technical measures and storage conditions

Keep in a cool, dry and well ventilated place. Keep away from food, drink and animal feeding stuffs.

Packaging materials

No information.

Requirements for storage rooms and vessels

Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers.

Storage temperature

No information.

Storage class

No information.

Further information on storage conditions

No information.

### 7.3 Specific end use(s)

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

**Product name:** Cetearyl alcohol & polysorbate 60

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Recommendations

No information.

Industrial sector specific solutions

No information.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Occupational Exposure limit values

No information.

Information on monitoring procedures

BS EN 14042:2003 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. BS EN 689:2018 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values. BS EN 482:2021 Workplace exposure. Procedures for the determination of the concentration of chemical agents. Basic performance requirements.

DNEL/DMEL values

For product

No information.

For components

Name	Type	Exposure route	exp. frequency	Remark	Value
Cetearyl Alcohol	Worker	inhalation	long term systemic effects	/	237.76 mg/m <sup>3</sup>
Cetearyl Alcohol	Worker	inhalation	short term systemic effects	/	237.76 mg/m <sup>3</sup>
Cetearyl Alcohol	Worker	inhalation	long term local effects	/	6.52 mg/m <sup>3</sup>
Cetearyl Alcohol	Worker	inhalation	short term local effects	/	6.52 mg/m <sup>3</sup>
Cetearyl Alcohol	Worker	dermal	long term systemic effects	/	200 mg/kg bw/day
Cetearyl Alcohol	Worker	dermal	short term systemic effects	/	400 mg/kg bw/day
Cetearyl Alcohol	Worker	dermal	long term local effects	/	1.124 mg/cm <sup>2</sup>
Cetearyl Alcohol	Worker	dermal	short term local effects	/	1.124 mg/cm <sup>2</sup>
Cetearyl Alcohol	Consumer	inhalation	long term systemic effects	/	118.88 mg/m <sup>3</sup>
Cetearyl Alcohol	Consumer	inhalation	short term systemic effects	/	118.9 mg/m <sup>3</sup>
Cetearyl Alcohol	Consumer	inhalation	long term local effects	/	0.652 mg/m <sup>3</sup>
Cetearyl Alcohol	Consumer	inhalation	short term local effects	/	0.652 mg/m <sup>3</sup>

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

Name	Type	Exposure route	exp. frequency	Remark	Value
Cetearyl Alcohol	Consumer	dermal	long term systemic effects	/	100 mg/kg bw/day
Cetearyl Alcohol	Consumer	dermal	short term systemic effects	/	200 mg/kg bw/day
Cetearyl Alcohol	Consumer	dermal	long term local effects	/	0.562 mg/cm <sup>2</sup>
Cetearyl Alcohol	Consumer	dermal	short term local effects	/	0.562 mg/cm <sup>2</sup>
Cetearyl Alcohol	Consumer	oral	long term systemic effects	/	75 mg/kg bw/day
Cetearyl Alcohol	Consumer	oral	short term systemic effects	/	75 mg/kg bw/day

PNEC values

For product

No information.

For components

Name	Exposure route	Remark	Value
Cetearyl Alcohol	fresh water	/	0.13 mg/L
Cetearyl Alcohol	water, intermittent release	/	1 mg/L
Cetearyl Alcohol	marine water	/	0.12 mg/L
Cetearyl Alcohol	water treatment plant	/	1000 mg/L
Cetearyl Alcohol	fresh water sediment	dry weight	13.61 mg/kg
Cetearyl Alcohol	marine water sediment	dry weight	1.361 mg/kg
Cetearyl Alcohol	soil	dry weight	100 mg/kg
Cetearyl Alcohol	secondary poisoning	food	86.7 mg/kg

### 8.2 Exposure controls

Appropriate engineering control

Substance/mixture related measures to prevent exposure during identified uses

Use good personal hygiene practices – wash hands at breaks and when done working with material. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe dust.

Structural measures to prevent exposure

No information.

Organisational measures to prevent exposure

No information.

Technical measures to prevent exposure

Provide good ventilation and local exhaust in areas with increased concentration. Keep away from food, drink and animal feeding stuffs.

Personal protective equipment

Eye and face protection

No requirements under normal use conditions. If there is a risk of eye contact use safety glasses.

Hand protection

No requirements under normal use conditions. In case of prolonged exposure, wear protective gloves (BS EN ISO 374).

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

Appropriate materials

Skin protection

No requirements under normal use conditions. With excessive exposure wear protective working clothing (overalls and boots). Cotton protective clothing and shoes that cover the entire foot (EN ISO 20345:2022).

Respiratory protection

Not needed under normal use and adequate ventilation.

Thermal hazards

No information.

Environmental exposure controls

Substance/mixture related measures to prevent exposure

No information.

Instruction measures to prevent exposure

No information.

Organisational measures to prevent exposure

No information.

Technical measures to prevent exposure

Do not allow product to reach drains, sewage systems or ground water.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Important health, safety and environmental information

Physical state	solid
Shape	No information.
Colour	white
Odour	No information.
Odour threshold	No information.
Melting/freezing point	50 — 54 °C
Boiling point or initial boiling point and boiling range	260 °C
Flammability	No information.
Lower and upper explosion limit	No information.
Flash point	200 °C
Auto-ignition temperature	No information.
Decomposition temperature	No information.
pH	No information.
Viscosity	No information.
Solubility	No information.
Partition coefficient n-octanol/water (log value)	No information.
Vapour pressure	No information.
Density / weight	No information.
Relative vapour/gas density	No information.

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

Particle characteristics

No information.

### 9.2 Other information

Information with regard to physical hazard classes

No information.

Other safety characteristics

No information.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No information.

### 10.2 Chemical stability

Product is stable under normal conditions of use, recommended handling and storage conditions.

### 10.3 Possibility of hazardous reactions

No information.

### 10.4 Conditions to avoid

It is recommended to avoid any contact with sources of heating, open flames or strong oxidizing agents.

### 10.5 Incompatible materials

No information.

### 10.6 Hazardous decomposition products

Burning can produce the following combustion products: Oxides of carbon and Soot

## SECTION 11: TOXICOLOGICAL INFORMATION

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

#### (a) Acute toxicity

For components

Name	Exposure route	Type	Species	Time	Value	Method	Remark
Cetearyl Alcohol	oral	LD <sub>50</sub>	rat	/	> 2000 mg/kg	/	/
Cetearyl Alcohol	dermal	LD <sub>50</sub>	rat	/	> 2000 mg/kg	/	/

#### Additional information

The product is not classified as acutely toxic.

#### (b) Skin corrosion/irritation

No information.

#### Additional information

The product is not classified as irritating to skin and eyes.

#### (c) Serious eye damage/irritation

No information.

#### (d) Respiratory or skin sensitisation

No information.

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

**Product name:** Cetearyl alcohol & polysorbate 60

**Creation date:** 23.07.2024, **Revision:** 23.07.2024, **Version:** 1.0

**Additional information**

The product is not classified as sensitising.

(e) (Germ cell) mutagenicity

No information.

(f) Carcinogenicity

No information.

(g) Reproductive toxicity

No information.

**Summary of evaluation of the CMR properties**

The product is not classified as carcinogenic, mutagenic or toxic for reproduction.

(h) STOT-single exposure

No information.

**Additional information**

STOT SE (single exposure): Not classified.

(i) STOT-repeated exposure

No information.

**Additional information**

STOT RE (repeated exposure): Not classified.

(j) Aspiration hazard

No information.

**Symptoms related to the physical, chemical and toxicological characteristics**

No information.

**Interactive effects**

No information.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

The product does not contain substances with the potential for endocrine disorders.

**Other information**

No information.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

**Acute (short-term) toxicity**

**For components**

Name	Type	Value	Exposure time	Species	organism	Method	Remark
Cetearyl Alcohol	LC <sub>50</sub>	> 100 mg/L	96 h	fish	<i>Carassius auratus</i>	/	/
Cetearyl Alcohol	EC <sub>50</sub>	> 100 mg/L	48 h	crustacea	<i>Daphnia</i>	/	/
Cetearyl Alcohol	EC <sub>50</sub>	> 100 mg/L	72 h	algae	/	/	/
Polysorbate 60	LC <sub>50</sub>	240 mg/L	48 h	fish	<i>Oryzias latipes</i>	/	/

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

**Product name:** Cetearyl alcohol & polysorbate 60

**Creation date:** 23.07.2024, **Revision:** 23.07.2024, **Version:** 1.0

Name	Type	Value	Exposure time	Species	organism	Method	Remark
Polysorbate 60	EC50/LC50	> 100 mg/L	/	fish	most sensitive species	/	Translation required (81838)

Chronic (long-term) toxicity  
 No information.

### 12.2 Persistence and degradability

Abiotic degradation, physical- and photo-chemical elimination  
 No information.

Biodegradation  
 For components

Name	Type	Rate	Time	Evaluation	Method	Remark
Cetearyl Alcohol	biodegradability	> 60 %	28 days	readily biodegradable	OECD 301 F	/

### 12.3 Bioaccumulative potential

Partition coefficient n-octanol/water (log value)  
 No information.

Bioconcentration factor (BCF)  
 No information.

### 12.4 Mobility in soil

Known or predicted distribution to environmental compartments  
 No information.

Surface tension  
 No information.

Adsorption/Desorption  
 No information.

### 12.5 Results of PBT and vPvB assessment

No evaluation.

### 12.6 Endocrine disrupting properties

The product does not contain substances with the potential for endocrine disorders.

### 12.7 Other adverse effects

No information.

### 12.8 Additional information

For product  
 Product is not classified as hazardous for environment.

For components  
**Polysorbate 60**  
 This substance has not been assessed for persistence, bioaccumulation and toxicity (PBT). This substance is not included in the list attached to the Montreal Protocol on Substances that Deplete the Ozone Layer.

**SAFETY DATA SHEET**

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60  
 Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

13.1 Waste treatment methods

Product / Packaging disposal

Waste chemical

Dispose the product to an authorised collector/remover of waste/company performing waste recovery.

Waste codes / waste designations according to LoW

No information.

Packaging

Deliver completely emptied containers to approved waste disposal authorities.

Waste codes / waste designations according to LoW

No information.

Waste treatment-relevant information

No information.

Sewage disposal-relevant information

No information.

Other disposal recommendations

No information.

**SECTION 14: TRANSPORT INFORMATION**

ADR/RID	IMDG	IATA	ADN
14.1 UN number or ID number			
Not dangerous according to transport regulations.	Not dangerous according to transport regulations.	Not dangerous according to transport regulations.	Not dangerous according to transport regulations.
14.2 UN proper shipping name			
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable
14.3 Transport hazard class(es)			
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable
14.4 Packing group			
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable
14.5 Environmental hazards			
NO	NO	NO	NO
14.6 Special precautions for user			
Limited quantities Not given/not applicable	Limited quantities Not given/not applicable		Limited quantities Not given/not applicable
14.7 Maritime transport in bulk according to IMO instruments			
	Not given/not applicable		

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

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Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

### SECTION 15: REGULATORY INFORMATION

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

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (including last amendment Commission Regulation (EU) 2020/878)

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Information according 2004/42/EC about limitation of emissions of volatile organic compounds (VOC-guideline)  
not applicable

Ingredients according to Regulation (EC) No 648/2004 on detergents  
No information.

Special instructions  
No information.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

### SECTION 16: OTHER INFORMATION

Indication of changes  
No information.

Key literature references and sources for data  
No information.

Abbreviations and acronyms

ATE - Acute Toxicity Estimate

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

CEN - European Committee for Standardisation

C&L - Classification and Labelling

CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

CAS# - Chemical Abstracts Service number

CMR - Carcinogen, Mutagen, or Reproductive Toxicant

CSA - Chemical Safety Assessment

CSR - Chemical Safety Report

DMEL - Derived Minimal Effect Level

DNEL - Derived No Effect Level

DPD - Dangerous Preparations Directive 1999/45/EC

DSD - Dangerous Substances Directive 67/548/EEC

DU - Downstream User

EC - European Community

ECHA - European Chemicals Agency

EC-Number - EINECS and ELINCS Number (see also EINECS and ELINCS)

EEA - European Economic Area (EU + Iceland, Liechtenstein and Norway)

EEC - European Economic Community

EINECS - European Inventory of Existing Commercial Substances

ELINCS - European List of notified Chemical Substances

EN - European Standard

EQS - Environmental Quality Standard

EU - European Union

Euphrac - European Phrase Catalogue

EWG - European Waste Catalogue (replaced by LoW – see below)

GES - Generic Exposure Scenario

GHS - Globally Harmonized System

IATA - International Air Transport Association

## SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Cetearyl alcohol & polysorbate 60

Creation date: 23.07.2024, Revision: 23.07.2024, Version: 1.0

ICAO-TI - Technical Instructions for the Safe Transport of Dangerous Goods by Air  
IMDG - International Maritime Dangerous Goods  
IMSBC - International Maritime Solid Bulk Cargoes  
IT - Information Technology  
IUCLID - International Uniform Chemical Information Database  
IUPAC - International Union for Pure Applied Chemistry  
JRC - Joint Research Centre  
Kow - octanol-water partition coefficient  
LC50 - Lethal Concentration to 50 % of a test population  
LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)  
LE - Legal Entity  
LoW - List of Wastes (see <http://ec.europa.eu/environment/waste/framework/list.htm>)  
LR - Lead Registrant  
M/I - Manufacturer / Importer  
MS - Member States  
MSDS - Material Safety Data Sheet  
OC - Operational Conditions  
OECD - Organization for Economic Co-operation and Development  
OEL - Occupational Exposure Limit  
OJ - Official Journal  
OR - Only Representative  
OSHA - European Agency for Safety and Health at work  
PBT - Persistent, Bioaccumulative and Toxic substance  
PEC - Predicted Effect Concentration  
PNEC(s) - Predicted No Effect Concentration(s)  
PPE - Personal Protection Equipment  
(Q)SAR - Qualitative Structure Activity Relationship  
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006  
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail  
RIP - REACH Implementation Project  
RMM - Risk Management Measure  
SCBA - Self-Contained Breathing Apparatus  
SDS - Safety data sheet  
SIEF - Substance Information Exchange Forum  
SME - Small and Medium sized Enterprises  
STOT - Specific Target Organ Toxicity  
(STOT) RE - Repeated Exposure  
(STOT) SE - Single Exposure  
SVHC - Substances of Very High Concern  
UN - United Nations  
vPvB - Very Persistent and Very Bioaccumulative

List of relevant H phrases

No information.