

SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Polysorbate 20

Creation date: 20.06.2024, Revision: 20.06.2024, Version: 1.0

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

1.1 Product identifier

Product name
Polysorbate 20

Product code
[AL00131]

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

Relevant identified uses
Surfactant for industrial use

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)
According to the regulation, the chemical is not classified as hazardous.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not subject to labelling according to Regulation (EC) 1272/2008.

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

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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
Polysorbate 20	9005-64-5 500-018-3 -	n/a	/	/	/

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes

Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. When in doubt or if feeling unwell seek medical assistance. Show the safety data sheet and label to the physician.

Following inhalation

Remove patient to fresh air - move out of dangerous area. Obtain professional medical help!

Following skin contact

Take off all contaminated clothing. Areas of the body that have come into contact with the product must be rinsed with water. If symptoms develop and persist, seek medical 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. Consult a physician. Show the physician the safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

Following inhalation

Excessive exposure to spray mist, fog, or vapours may cause respiratory irritation.

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

Carbon dioxide. Dry chemical powder. Water spray. Alcohol resistant foam.

Unsuitable extinguishing media

Full water jet.

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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

No action shall be taken involving any personal risk or without suitable training. Prevent access to unprotected personnel. Evacuate the danger zone. Do not breathe vapour or mist. 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

Stem the spill if this does not pose risks.

For cleaning up

Absorb product (with inert material), collect it in special container and dispose it to a licensed hazardous-waste disposal contractor. Prevent release into the sewer, water, basements or confined areas. Ventilate the premises. 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

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Ensure adequate ventilation.

Measures to prevent aerosol and dust generation

Use general or local exhaust ventilation to prevent inhaling vapours and aerosols.

Measures to protect the environment

Do not discharge into drains, surface water and soil. After use immediately close container tightly.

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. Do not breathe vapours/mist. Avoid contact with skin, eyes and clothes. Remove contaminated clothes and wash them before reuse. Wear suitable protective equipment; see Section 8.

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

Store only in original container.

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)

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

No information.

PNEC values

For product

No information.

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For components

No information.

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. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe vapours/aerosols.

Structural measures to prevent exposure

No information.

Organisational measures to prevent exposure

Remove all contaminated clothes immediately and wash them before reuse.

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

Safety glasses with side protection (BS EN ISO 16321-1:2022).

Hand protection

Protective gloves (EN ISO 374-1:2016). Observe the manufacturer's instructions regarding the use, storage, maintenance and replacement of gloves. In case of damage or at the first signs of wear and tear, change the gloves immediately. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. The penetration time is determined by the protective glove manufacturer and must be observed.

Appropriate materials

Skin protection

Cotton protective clothing and shoes that cover the entire foot (EN ISO 20345:2022). At high risk of skin exposure chemical suits (BS EN 13034:2005+A1:2009) and boots may be required (BS EN ISO 20345:2022+A1:2024).

Respiratory protection

In case of insufficient ventilation wear suitable respiratory protection. Wear suitable protective breathing mask (EN 136) with filter A2-P2 (EN 14387).

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	liquid
Shape	No information.

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Colour	yellow
Odour	characteristic
Odour threshold	No information.
Melting/freezing point or softening point	No information.
Boiling point or initial boiling point and boiling range	No information.
Flammability	No information.
Lower and upper explosion limit	No information.
Flash point	> 61 °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.
Relative density	1.11
Relative vapour/gas density	No information.
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

No information.

10.5 Incompatible materials

No information.

10.6 Hazardous decomposition products

Under normal use conditions no hazardous decomposition products are expected. In case of fire/explosion vapours/gases

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that pose a health hazard are released.

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
Polysorbate 20	dermal	LD ₅₀	guinea pig	/	> 3000 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.

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

For components

Name	Exposure route	Type	Species	Time	Exposure organ	Value	result	Method	Remark
Polysorbate 20	oral	NOAEL	rat	730 days	/	/	< 5 %	/	/

Additional information

STOT RE (repeated exposure): Not classified.

(j) Aspiration hazard

No information.

Additional information

Aspiration hazard: Not classified.

Symptoms related to the physical, chemical and toxicological characteristics

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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

No information.

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
Polysorbate 20	aerobic	48 %	/	/	ISO 14593	/

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.

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12.8 Additional information

For product

Product is not classified as hazardous for environment. Do not allow to reach ground water, water courses or sewage system.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / Packaging disposal

Waste chemical

Do not allow product to reach drains/sewage systems. Disposal must be made according to official regulations: deliver it to authorised collector/remover/transformer of hazardous waste.

Waste codes / waste designations according to LoW

No information.

Packaging

Deliver completely emptied containers to approved waste disposal authorities. Uncleaned containers are classified as hazardous waste - they should be handled in the same manner as the contents.

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

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ADR/RID	IMDG	IATA	ADN
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		

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

Observe the regulations on employment and protection against dangerous substances for young people, pregnant women and nursing mothers.

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

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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
EWC - European Waste Catalogue (replaced by LoW – see below)
GES - Generic Exposure Scenario
GHS - Globally Harmonized System
IATA - International Air Transport Association
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.

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