

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

1. Identification of the substance/mixture and company

Trade name: Polysorbate 20
I.N.C.I. Polysorbate 20
CAS No. : 9005-64-5
EC No. : na
REACH pre-registration No. : na
Utilization: Raw material for cosmetics
Supplier company identification: Elemental SRL, Piața Cazărmii no.15, 410188-Oradea, jud.Bihor, Romania
Tel/Fax: +40259-436.755, www.ellemental.com
Emergency: RO: număr național pentru cazuri de urgență: 021 3183606 Institutul de Sănătate Publică București.
International emergency number: +49 180 2273-112

2. Hazards Identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Not a hazardous product according to Regulation (EC) No 1272/2008.

2.3 Other hazards

Results of PBT and vPvB assessments

This substance/mixture does not contain components considered to be either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher

Endocrine Disrupting Properties-Toxicity The substance/preparation does not contain components considered to have endocrine disrupting properties in accordance with Article 57(f) of the REACH Regulation or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at concentrations of 0.1% or higher.

Endocrine Disrupting Properties-Ecotoxicity The substance/preparation does not contain components considered to have endocrine disrupting properties in accordance with Article 57(f) of the REACH Regulation or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at concentrations of 0.1% or higher.

3. Declaration of ingredients

3.1 Substances

Sorbitan Fatty Acid Ester

Contains no hazardous ingredients.

4. First aid measures

4.1 Description of first-aid measures

After inhalation: Transport the affected person to fresh air and lay down in a relaxed position. In the event of the appearance of symptoms, perform medical treatment.

In case of skin contact, wash immediately with plenty of water and soap. If skin irritation persists, call a doctor.

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

In case of eye contact: After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed it is recommended to rinse the mouth and drink plenty of water. Do not induce vomiting. In case of the appearance of symptoms, to perform medical treatment.

4.2 Most important symptoms and effects, both acute and delayed

There is so far no information on acute and/or delayed symptoms and effects after exposure

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically

5. Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: - Carbon dioxide, carbon monoxide. In certain fire conditions, traces of other toxic materials cannot be excluded.

5.3 Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

5.4 Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system. Do not inhale explosion or combustion gases. A breathing protection mask will be used independently of the recirculation air, and an appropriate protective suit will be worn.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

For disposal see section 13.

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

7. Handling and storage

7.1 Precautions for safe handling

No data available

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Tightly closed, in a cool and dry place.

7.3 Specific end use(s)

There are no additional recommendations

8. Exposure controls / personal protection

8.1 Control parameters

Occupational Exposure Limit Values

None of the components have assigned exposure limits.

Biological Limit Values

No biological exposure limits have been recorded for the ingredient(s).

DNEL values

Remarks: There are no DNEL/DMEL values

PNEC values

Remarks: There are no PNEC values.

8.2 Exposure controls

Appropriate engineering controls: No data available.

Individual protection measures, such as personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

Light protective clothing

Full contact Material: Nitrile rubber

Splash contact Material: Nitrile rubber

Respiratory protection

Not required; except in case of aerosol formation.

Hygiene measures: Do not eat, drink or smoke during use. Hands will be washed before breaks and immediately after handling the product. Remove soiled, soaked clothing immediately

Control of environmental exposure: Do not let product enter drains. The provisions regarding environmental protection must be respected and environmental exposure must be supervised

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

Physical state: liquid
Color: yellowish
Odor: characteristic mild
Boiling point: > 100 °C
Flash point: > 149°C
Flammability (solid,gas): No data available
Upper/lower flammability or explosive limits: No data available
Autoignition temperature: No data available
Decomposition temperature: No data available
pH: 5.5 - 7.5 (100 g/l, 25 °C)
Viscosity, dynamic: 300-500 mPa.s at 25 °C
Water solubility: soluble
Partition coefficient: n-octanol/water - No data available
Vapor pressure < 133 Pa at 20 °C
Density 1,00-1,20 g/cm³ at 25 °C
Relative vapor density: No data available
Particle characteristics: No data available
Explosive properties: No data available
Oxidizing properties: none

9.2 Other safety information

No data available

10. Stability and reactivity

10.1 Reactivity

Under normal conditions the product is stable.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature)

10.3 Possibility of hazardous reactions

Reactions possible with: Strong oxidizing agents

10.4 Conditions to avoid

Unknown

10.5 Incompatible materials

Unknown

10.6 Hazardous decomposition products

In the event of fire: see section 5

11. Toxicological information

11.1 Information on the hazard classes defined in Regulation (EC) no. 1272/2008

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

Information on likely routes of exposure

Inspiration: With proper handling, there is no relevant route of exposure. Information on related effects is below.

Skin contact: Relevant route of exposure. Information on related effects is below

Eye contact: Relevant route of exposure. Information on related effects is below.

Ingestion: With proper handling, there is no relevant route of exposure.

Acute toxicity (list all possible routes of exposure)

Swallowing

Product: LD 50 (Rat): > 2,000 mg/kg N toxicological studies with the product are available, (analogy)

Skin contact

Product: It is not classified from the point of view of acute toxicity according to the available data.

The inspiration

Product: It is not classified from the point of view of acute toxicity according to the available data.

Repeated dose toxicity

Product: No data available.

Skin Corrosion/Irritation

Product: Low irritant effect # marking is not mandatory

OECD 404 (Rabbit): Low irritant effect # marking is not mandatory; (Analogy)

Causes Serious Eye Damage/Irritation

Product: irritating OECD 405 (Rabbit): Non-irritant; (Analogy)

Skin or Respiratory Sensitivity

Product: OECD 406 (Guineas) Non-sensitizing (Analogy)

Carcinogenicity Product: No data available.

Germ Cell Mutagenicity No data available.

In vitro Product: No data available.

In vivo Product: No data available.

Reproductive toxicity Product: No data available.

Specific Target Organ Toxicity - Single Exposure No data available.

Product:

Specific Target Organ Toxicity – Repeated Exposure No data available.

Product:

Aspiration Hazard Product: It is not classified

11.2 Additional Information

Endocrine disrupting properties

Product: The substance/preparation does not contain components considered to have endocrine disrupting properties, in accordance with Article 57(f) of the REACH Regulation or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 to concentrations of 0.1% or higher.;

Other hazards

Product: No health effects have been reported so far when used as intended. The product has not been tested.

Statements are derived from products with similar composition.

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

Handle in accordance with good industrial hygiene and safety practice.

12. Ecological information

12.1 Toxicity

Toxicity to fish No data available

Toxicity to daphnia and other aquatic invertebrates No data available

Toxicity to bacteria No data available

12.2 Persistence and degradability

Biodegradability

Product: 77 % (28 d, OECD 301 F) Own research, aerobic, Rapidly biodegradable

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/preparation does not contain components considered to have endocrine disrupting properties, in accordance with Article 57(f) of the REACH Regulation or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 to concentrations of 0.1% or higher.

12.7 Other adverse effects

Discharge into the environment must be avoided. Do not allow to reach soil, water or sewage.

13. Disposal considerations

13.1 Waste treatment methods

Product

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste..

14. Transport information

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG:-

IATA: -

14.4 Packaging group

ADR/RID:-

IMDG:-

IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

Further information

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

A substance safety assessment has not been performed for this product.

16. Additional information

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

POLYSORBATE 20

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

Disclaimer:

This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.