

According to directive 1907/2006/EC,2020/878
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Trade name: Stearic acid

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

1.1 Product identification:

Product name: Stearic acid
CAS No : 67701-03-5

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

Identified uses: Pharmaceutical adjuvant

1.3 Details of the supplier of the safety data sheet:

Responsible distributor : ASSYST bvba / A.S.O.W. bvba
Hellegatstraat 13a
2590 Berlaar
Belgium
Tel: +32 495 50 61 14 / +32 496 83 70 27
Website: www.assyst.org / www.artsuppliesonweb.com
Email: ao@assyst.org / vera.opsommer@assyst.org

1.4 Emergency phone number:

For Belgium:

Call the **Poison Control Centre (070 245 245 - free)**, if not available: **02 264 96 30** (normal rate) or your doctor. In life-threatening situations, always call the European emergency number **112**.

NHS 24 Direct

For help from a GP, visit your GP surgery's website, use an online service to contact your GP, or call the surgery. **For urgent medical help**, use the NHS 111 online service, or **call 111** if you are unable to get help online. **For life-threatening emergencies, call 999** for an ambulance. There is more information about getting medical help on the NHS website.

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture:

Classification in accordance with Regulation (EC) No 1272/2008 as amended.

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

2.2 Labelling elements:

No hazard pictogram, no signal word, no hazard indication(s) and no safety recommendations required.

2.3 Other hazards:

The product may cause dust explosion under certain conditions.

The product does not contain any substance meeting the PBT criteria (persistent/bioaccumulative/toxic) or the vPvB criteria (very persistent/very bioaccumulative).

The product does not contain any substance that exceeds the legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 due to endocrine disrupting properties or that has been identified as having endocrine disrupting properties according to the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition and information on ingredients

3.1 Substances:

Chemical description

Ph. Eur: Stearic Acid 50
fatty acids, C16-18-
CAS number: 67701-03-5
EC no: 266-928-5

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SECTION 4: First aid measures

4.1 Description of first-aid measures:

Remove contaminated clothing.

After inhalation:

Rest, fresh air.

After skin contact:

Wash thoroughly with soap and water.

After contact with eyes:

Rinse thoroughly with open eyelids for at least 15 minutes using running water.

After swallowing:

Rinse out mouth and then drink 200-300 ml of water.

4.2 Main acute and delayed symptoms and effects:

Symptoms: (Further) symptoms and/or effects are not known so far.

4.3 Indication of immediate medical attention and special treatment required:

Treatment: treatment of symptoms (removal of contaminant, monitoring of vital signs).

SECTION 5: Fire-fighting measures

5.1 Extinguishing media:

Suitable extinguishing agents:

Carbon dioxide, foam, extinguishing powder, atomised water.

Unsuitable extinguishing media:

Full water jet.

Additional instructions:

Avoid dust/product blow-up due to dust explosion hazard.

5.2 Special hazards arising from the substance or mixture:

Hazardous substances:

Carbon oxide, health-damaging fumes.

Opinion:

The listed substances/substance groups may be released during a fire. Dust explosion hazard.

5.3 Advice for firefighters:

Special protective equipment:

Wear self-contained breathing apparatus with compressed air cylinder.

Further details:

Treat fire debris and contaminated fire fighting water as waste in accordance with local government regulations.

Cool threatened containers with water spray.

Danger depends on the burning substances and fire conditions.

Dust can burn explosively in the presence of an ignition source with a stinging flame.

SECTION 6: Measures in case of accidental release of the substance or mixture

Dust can form an explosive mixture with air.

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective clothing.

Information on personal protective equipment see section 8.

Avoid formation of dust.

6.2 Environmental precautions:

Do not discharge into drains/surface water/groundwater.

6.3 Methods and materials for containment and cleaning:

For small quantities:

Absorb with dust-binding agent and dispose of as waste.

For large quantities:

Record by mechanical equipment.

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Avoid dust formation.

Dispose of the absorbed material as directed.

6.4 Reference to other sections:

Information on exposure control, personal protection and handling conditions can be found in sections 8 and 13.

SECTION 7: Handling and storage:

7.1 Precautions for safe handling of the substance or mixture:

Good ventilation of storage and work area.

Provide extraction in case of dust formation.

Observe usual precautions when handling chemicals.

Fire and explosion protection:

Product is dust explosive.

Avoid formation of dust.

Take precautions against electrostatic charging - keep away from ignition sources - have fire extinguishers ready.

7.2 Conditions for safe storage, including incompatibilities:

Further details on storage conditions:

Keep container closed and in a cool place.

For other information, see the technical data sheet.

7.3 Specific end use:

For the relevant identified use(s) in section 1, the advice in section 7 should be taken into account.

SECTION 8: Exposure controls/personal protection measures

8.1 Control parameters:

Components with limit values that require monitoring at the workplace:

No substance-specific limit values are known.

8.2 Exposure control measures:

Appropriate technical measures:

If dust generation during work cannot be avoided, dust extraction is necessary.

Personal safety equipment

Respiratory protection:

Respiratory protection if formation of dust.

Particle filter with small reserve capacity for solid particles (e.g. EN 143 or 149, type P1 or FFP1)

Hand protection:

Chemical-resistant gloves (EN ISO 374-1).

Due to the wide variety of types, the manufacturer's operating instructions apply.

Eye protection:

Safety glasses with side flaps (spectacles with frames) (e.g. EN 166)

Body protection:

Choose body protection according to action and exposure.

General protection and hygiene measures

Observe usual precautions when handling chemicals.

Wearing closed work clothes is recommended.

While working, do not eat, drink, smoke, sniff.

Wash hands and/or face before breaks and at end of work. Separate storage of work clothes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Aggregation state:	fixed
Shape:	powder
Colour:	white

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Odour:	faint, waxy
Odour threshold value:	not applicable, odour not detectable
Melting range:	57 - 60°C
Boiling range:	200 - 225°C (1,013 hPa) (DIN 51751)
Flammability:	The product is not flammable.
Lower explosion limit:	For solids not relevant for classification and labelling.
Upper explosion limit:	For solids not relevant for classification and labelling.
Flash point:	not applicable, the product is a solid
Self-ignition temperature:	not applicable, the product is a solid
Self-ignition temperature:	Temperature: 350°C pressure: 1,013 hPa test type: Self-ignition at elevated temperature.
Thermal decomposition:	140°C (DSC (DIN 51007)). No self-decomposition possible.
SADT:	No data available.
pH value:	substance/mixture is not soluble (in water)
Viscosity, dynamic:	not applicable, the product is a solid
Solubility in water:	< 0.05 g/l (25°C) (other)
Partition coefficient n-octanol/water (log Kow):	6.96 - 7.94 (calculated)
Vapour pressure:	0.0000506 Pa (25°C)
Specific gravity:	0.85 - 0.9 g/cm ³ (20°C)
Relative vapour density (air):	The product is a non-volatile solid.

Particle properties

Particle size distribution: Typically > 50 µm (D50, Volumetric distribution, ISO 13320-1)

9.2. Other information

Information on physical hazard classes

Explosive substances

Explosion hazard: The product is not explosive but an air/dust mixture can cause dust explosion.

Oxidising properties

Fire-promoting properties: not fire-promoting

Pyrophoric properties

Self-ignition temperature: test type: possibility of spontaneous self-ignition at indoor temperature.
non-ignitable

Self-heating substances and mixtures

Self-heating potential: Due to the low melting point not investigated. It is not a substance, which will self-heat.

Substances and mixtures emitting flammable gases in contact with water

Formation of flammable gases: No formation of flammable gases with water.

Metal corrosion: No metal corrosion to be expected.

Other safety features

Bulk density: 510 kg/m³ (20°C)

SAPT Temperature: Study not scientifically justified.

Evaporation rate: The product is a non-volatile solid.

SECTION 10: Stability and reactivity

10.1 Reactivity:

No hazardous reaction, if storage and use instructions are observed.

Metal corrosion:

No metal corrosion to be expected.

Formation of flammable gases:

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Notes:

With water, no formation of flammable gases.

10.2. Chemical stability

The product is stable when the regulations/guidelines for storage and use are observed.

10.3. Possible hazardous reactions

The accumulation of fine dust can pose explosion hazards in the presence of air.

10.4 Conditions to avoid:

Avoid formation of dust.

Avoid electrostatic charging.

Avoid all ignition sources: heat, sparks, open flames.

See section 7 of the MSDS - Handling and storage.

10.5. Incompatible materials

Substances to avoid:

None of these known during use and storage as used as directed.

10.6. Hazardous decomposition products

Hazardous decomposition products:

No hazardous decomposition products, if regulations/indication are observed during storage and handling

SECTION 11: Toxicological information

11.1 Information on toxicological effects:

Acute toxicity

Evaluation of acute toxicity:

Practically non-toxic after single oral ingestion.

Practically non-toxic in one-time contact with skin.

Practically non-toxic after single inhalation ingestion.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Experimental/calculated data:

LD50 mouse (oral): > 5,000 mg/kg

LD50 rabbit (dermal): > 5,000 mg/kg

Irritant effect

Evaluation irritation:

Not irritating to eyes and skin.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Experimental/calculated data:

Skin corrosion/irritation

Rabbit: non-irritant (OECD Guideline 404)

Severe eye damage/irritation

Rabbit: not irritant (Draize test)

Respiratory/skin sensitisation

Sensitisation evaluation:

Does not cause hypersensitivity The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Germ cell mutagenicity

Mutagenicity assessment:

Based on available data, the classification criteria have not been met.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Carcinogenicity

Assessment of carcinogenicity:

Not classified, due to lack of data.

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Reproductive toxicity

Reproductive toxicity assessment:

Based on available data, the classification criteria have not been met.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Developmental toxicity

Assessment of teratogenicity:

Based on available data, the classification criteria have not been met.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Specific organ toxicity (single exposure)

STOT assessment singular:

Based on available information, no organ-specific toxicity is to be expected in case of a single exposure.

Repeated-dose toxicity and specific organ toxicity (repeated exposure)

Evaluation on toxicity with repeated administration:

Based on available data, the classification criteria have not been met.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Inhalation hazard

Not applicable

Interactions

No data available.

11.2. Information on other hazards

Endocrine-disrupting properties

The substance has not been identified as having endocrine disrupting properties in accordance with Regulation (EU) 2017/2100 or Regulation 2018/605, nor has it been included in the candidate list of substances of very high concern under EU REACH Article 59 due to this property.

SECTION 12: Ecological information

12.1 Toxicity:

Aquatic toxicity evaluation:

With high probability harmless to aquatic organisms.

When expertly introduced at low concentrations in biological wastewater treatment plants, breakdowns in the degradability of activated sludge are not to be expected.

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

Vistoxicity:

LC50 > 100 mg/l (DIN EN ISO 7346-2)

Microorganisms/effects on activated (organic) sludge:

ECO > 100 mg/l

The product has not been tested.

The statement is derived from substance/products with similar structure or composition.

12.2 Persistence and Degradability:

Assessment of biodegradability and elimination (H20):

Readily biodegradable (according to OECD criteria).

Data on elimination:

62 - 63 % (30 d) (Directive 84/449/EEC, C.6) (other) other

12.3 Bioaccumulation:

Bioaccumulation potential:

No data available.

12.4 Mobility in soil:

Assessment of transport between environmental compartments:

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Adsorption in soil: No data available.

12.5. Results of PBT and vPvB assessment

In accordance with Annex XIII of Regulation (EC) No.1907/2006 on REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals):

The product does not meet the criteria for PBT (Persistent/bioaccumulative/toxic) and vPvB (very persistent/very bioaccumulative)

12.6. Endocrine-disrupting properties

The substance has not been identified as having endocrine disrupting properties in accordance with Regulation (EU) 2017/2100 or Regulation 2018/605, nor has it been included in the candidate list of substances of very high concern under EU REACH Article 59 due to this property.

12.7. Other adverse effects

The substance is not included in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

12.8. Additional instructions

Other ecotoxicological indications:

The product has not been investigated.

The assessment regarding ecotoxicology was derived from products with similar structure or composition.

SECTION 13: Disposal instructions

13.1 Waste treatment methods:

Product

National and local legal requirements must be observed.

Uncleaned packaging:

Uncontaminated packaging can be used again.

Dispose of containers that cannot be cleaned in the same waste stream as the contents.

SECTION 14: Information relating to transport

14.1 UN number

The transport of this substance is not subject to regulations.

14.2 Proper cargo name according to UN model regulations

The transport of this substance is not subject to regulations.

14.3 Transport hazard class(es)

The transport of this substance is not subject to regulations.

14.4 Packing group

The transport of this substance is not subject to regulations.

14.5 Environmental hazards

The transport of this substance is not subject to regulations.

14.6 Special precautions for the user

The transport of this substance is not subject to regulations.

14.7 Transport in bulk in accordance with Annex II to MARPOL 73/78 and the IBC Code

Notes: Not applicable for product as supplied.

SECTION 15: Statutory information

15.1 Safety, health and environmental regulations and legislation specific to the substance or mixture:

Directive 2012/18/EU - on the control of major-accident hazards involving dangerous substances (EU):

State in the above regulation: no.

If any other legal requirements apply that are not mentioned elsewhere in this safety data sheet, it is described in this subsection.

15.2 Chemical safety assessment:

Chemical safety assessment (CSA) not required.

SECTION 16: Other information

Further intended applications should be discussed with the manufacturer.

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Appropriate occupational safety measures must be followed.

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road (ADR Agreement); AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Association for the Testing of Materials; bw - Body Weight; CMR - Carcinogenic, Mutagenic or Toxic to Reproduction; DIN - Standard of the German Institute for Standardisation; DSL - List of substances used indoors (Canada); ECx - Concentration associated with x% response; ELx - Loading capacity associated with x% response; EmS - Emergency schedule; ENCS - Existing and new chemicals (Japan); ErCx - Concentration associated with x% growth response; GHS - Globally Harmonised System; GLP - Good laboratory practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - IMO International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk; IC50 - Half-Maximum Inhibitory Concentration; ICAO - International Civil Aviation Organisation; IECSC - Inventory List of Existing Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korean Inventory List of Existing Chemicals; LC50 - Lethal concentration for 50% of a test population; LD50 - Lethal dose for 50% of a test population (lethal dose median); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not otherwise specified; NO(A)EC - No discernible (negative) effect on concentration; NO(A)EL - No discernible (negative) effect on Level; NOELR - No discernible effect on cargo capacity; NZIoC - New Zealand inventory of chemicals; OECD - Organisation for Economic Co-operation and Development OECD; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, bioaccumulative and toxic substance; PICCS - Philippine inventory of chemicals and chemical substances; (Q)SAR - (Quantitative) structure-activity relationships; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); RID - Regulations concerning the International Carriage of Dangerous Goods by Rail (RID); SADT - Self-accelerating decomposition temperature; SDS - Safety Data Sheet; TCSI - Taiwan Inventory of Chemical Substances; TECl - Inventory of Chemicals Existing in Thailand; TSCA - Toxic Substances Control Act (USA); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

The data in this safety data sheet are based on our current knowledge and experience and describe the product in view of safety requirements. This safety data sheet is neither a Certificate of Analysis (CoA) nor a technical data sheet and should in no way be regarded as a specification agreement. Identified uses in this safety data sheet are in no way to be regarded as an agreement on an agreed contractual quality of the substance/mixture nor as a contractually designated use. It is the responsibility of the recipient of our product to ensure that any proprietary rights and existing laws and regulations are observed.