



C4 380, C5 003 - Sorbitan monooleat

Date of compilation: 27/10/2020

Revised: 19/03/2025

Version: 3 (Replaced 2)

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

1.1 Product identifier: Sorbitan monooleate, ethoxylated

CAS: 9005-65-6

EC: 500-019-9

Index: Not relevant

REACH: Not relevant

Other means of identification:

Not relevant

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

Relevant uses (Professional users): Food additive

Relevant uses (Industrial user): Food additive

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

ECP d.o.o.

Brnčičeva 45

1231 Ljubljana - Slovenia

Phone: +386 1 562 05 84

office@ecp.eu

www.ecp.si

1.4 Emergency telephone number: 112

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) No 1272/2008:

The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

None

2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Additive/s

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 9005-65-6 EC: 500-019-9 Index: Not relevant REACH: Not relevant	Sorbitan monooleate, ethoxylated Not classified Regulation 1272/2008	95 - <100%

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

3.2 Mixture:

Not relevant

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Consult a doctor in case of discomfort showing the SDS for the product.

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SECTION 4: FIRST AID MEASURES (continued)

By inhalation:

In case of symptoms, move the person affected into fresh air.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EEC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

Not relevant

DNEL (General population):

Not relevant

PNEC:

Identification				
Sorbitan monooleate, ethoxylated CAS: 9005-65-6 EC: 500-019-9	STP	Not relevant	Fresh water	0,2 mg/L
	Soil	Not relevant	Marine water	0,02 mg/L
	Intermittent	0,588 mg/L	Sediment (Fresh water)	1,141 mg/kg
	Oral	Not relevant	Sediment (Marine water)	1,141 mg/kg

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

If the working conditions and/or safety measures adopted do not allow keeping the airborne concentration of the product below the exposure limits (if any) or at acceptable levels (if no exposure limits exist), suitable respiratory protection equipment chosen by a qualified professional should be used.

C.- Specific protection for the hands

Not relevant

D.- Eye and face protection

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

It is not necessary to take additional emergency measures.

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Not relevant
Average molecular weight:	Not relevant

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Solid
Appearance:	Not relevant *
Colour:	Not relevant *
Odour:	Not relevant *
Odour threshold:	Not relevant *

Volatility:

Boiling point at atmospheric pressure:	Not relevant *
Vapour pressure at 20 °C:	Not relevant *
Vapour pressure at 50 °C:	<300000 Pa (300 kPa)
Evaporation rate at 20 °C:	Not relevant *

Product description:

Density at 20 °C:	1080 kg/m ³
Relative density at 20 °C:	1,08
Dynamic viscosity at 20 °C:	Not relevant *
Kinematic viscosity at 20 °C:	Not relevant *
Kinematic viscosity at 40 °C:	Not relevant *
Concentration:	Not relevant *
pH:	Not relevant *
Vapour density at 20 °C:	Not relevant *
Partition coefficient n-octanol/water 20 °C:	Not relevant *
Solubility in water at 20 °C:	Not relevant *
Solubility properties:	Not relevant *
Decomposition temperature:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Melting point/freezing point: Not relevant *

Flammability:

Flash Point: Not relevant *

Flammability (solid, gas): Not relevant *

Autoignition temperature: Not relevant *

Lower flammability limit: Not relevant *

Upper flammability limit: Not relevant *

Explosive (Solid):

Lower explosive limit: Not relevant *

Upper explosive limit: Not relevant *

Particle characteristics:

Median equivalent diameter: Not relevant *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties: Not relevant *

Oxidising properties: Not relevant *

Corrosive to metals: Not relevant *

Heat of combustion: Not relevant *

Aerosols-total percentage (by mass) of flammable components: Not relevant *

Other safety characteristics:

Surface tension at 20 °C: Not relevant *

Refraction index: Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met
IARC: Not relevant
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

H- Aspiration hazard:

Based on available data, the classification criteria are not met

Other information:

Not relevant

Product-specific toxicological information:

Acute toxicity		Genus
LD50 oral	>5000 mg/kg	Rat

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
	LD50 oral	>5000 mg/kg	
Sorbitan monooleate, ethoxylated CAS: 9005-65-6 EC: 500-019-9	LD50 oral	>5000 mg/kg	Rat
	LD50 dermal		
	LC50 inhalation vapour		

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

Based on available data, the classification criteria are not met

12.1 Toxicity:

Not relevant

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SECTION 12: ECOLOGICAL INFORMATION (continued)

12.2 Persistence and degradability:

Not relevant

12.3 Bioaccumulative potential:

Not relevant

12.4 Mobility in soil:

Not relevant

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Type of waste (Regulation (EU) No 1357/2014):

Not relevant

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2025 and RID 2025:

- | | |
|--|---------------|
| 14.1 UN number or ID number: | Not relevant |
| 14.2 UN proper shipping name: | Not relevant |
| 14.3 Transport hazard class(es): | Not relevant |
| Labels: | Not relevant |
| 14.4 Packing group: | Not relevant |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Special regulations: | Not relevant |
| Tunnel restriction code: | Not relevant |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Not relevant |
| 14.7 Maritime transport in bulk according to IMO instruments: | Not relevant |

Transport of dangerous goods by sea:

With regard to IMDG 42-24:

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SECTION 14: TRANSPORT INFORMATION (continued)

- | | |
|--|---------------|
| 14.1 UN number or ID number: | Not relevant |
| 14.2 UN proper shipping name: | Not relevant |
| 14.3 Transport hazard class(es): | Not relevant |
| Labels: | Not relevant |
| 14.4 Packing group: | Not relevant |
| 14.5 Marine pollutant: | No |
| 14.6 Special precautions for user | |
| Special regulations: | Not relevant |
| EmS Codes: | |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Not relevant |
| Segregation group: | Not relevant |
| 14.7 Maritime transport in bulk according to IMO instruments: | Not relevant |

Transport of dangerous goods by air:

With regard to IATA/ICAO 2026:

- | | |
|--|---------------|
| 14.1 UN number or ID number: | Not relevant |
| 14.2 UN proper shipping name: | Not relevant |
| 14.3 Transport hazard class(es): | Not relevant |
| Labels: | Not relevant |
| 14.4 Packing group: | Not relevant |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Physico-Chemical properties: | see section 9 |
| 14.7 Maritime transport in bulk according to IMO instruments: | Not relevant |

SECTION 15: REGULATORY INFORMATION

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

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) No 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Not relevant

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

HACCP: Hazard analysis and critical control points, ISO: 22000

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

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SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Not relevant

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Not relevant

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

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: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

Product safety information sheet prepared in accordance with Article 32 of Regulation (EC) 1907/2006 (REACH)

this document does not constitute a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006, as a Safety Data Sheet is not mandatory for this product. The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified. The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy.

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