

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 9/25/2017 Revision date: 12/28/2022 Supersedes version of: 9/25/2017 Version: 3.0

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

1.1. Product identifier

Product form : Mixture

Trade name : SEPARADOR SILICONA

Product code : 5072

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Dental laboratories

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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T +34 972 526 169

protechno@protechno.com - www.protechno.com

E-mail address of competent person responsible for the SDS: SDS@protechno.com

1.4. Emergency telephone number

Emergency number : +34 972 526 169

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2 H225
Serious eye damage/eye irritation, Category 2 H319
Specific target organ toxicity – Single exposure, Category 3, Narcosis H336

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

Hazard pictograms (CLP)





GHS02

GHS07

Signal word (CLP) : Danger
Contains : ethyl acetate

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.

H319 - Causes serious eye irritation. H336 - May cause drowsiness or dizziness.

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P233 - Keep container tightly closed.

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

P242 - Use non-sparking tools.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Mixture of the substances listed below with harmless additives

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---------------|--|---|---|
| ethyl acetate | CAS-No.: 141-78-6 EC-No.: 205-500-4 EC Index-No.: 607-022-00-5 | | Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 |

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Symptoms of poisoning may even occur after several hours; therefore medical observation

for at least 48 hours after the accident.

First-aid measures after inhalation : Allow affected person to breathe fresh air. Remove person to fresh air and keep comfortable

for breathing. Get medical advice/attention.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do. Continue rinsing. Get medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional information available

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. Sand. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

12/28/2022 (Revision date) EN (English) 2/10

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

5.3. Advice for firefighters

Protection during firefighting

: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures

: Ventilate spillage area. Avoid breathing vapours.

6.1.2. For emergency responders

Protective equipment

: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Do not allow to enter drains or water courses.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

: Take up liquid spill into absorbent material. Do not flush with water or aqueous cleansing

agents. Provide adequate ventilation.

Other information

: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Use only by appropriate trained persons. Ensure good ventilation of the work station. Wear personal protective equipment. Keep in original containers closed. Prevent formation of aerosols. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

Hygiene measures

: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Store in a well-ventilated place. Keep cool. Only store product in original container. Keep container tightly closed. Protect from sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

| ethyl acetate (141-78-6) | |
|---|---------------|
| United Kingdom - Occupational Exposure Limits | |
| Local name | Ethyl acetate |
| WEL TWA (OEL TWA) [1] | 734 mg/m³ |
| WEL TWA (OEL TWA) [2] | 200 ppm |

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| ethyl acetate (141-78-6) | |
|---------------------------|---------------------------------------|
| WEL STEL (OEL STEL) | 1468 mg/m³ |
| WEL STEL (OEL STEL) [ppm] | 400 ppm |
| Regulatory reference | EH40/2005 (Fourth edition, 2020). HSE |

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Common hygienic measures in a dental laboratory. Ensure good ventilation of the work station. Keep away from foodstuffs and beverages. Remove contaminated clothing. Wash hands before break and at end of works.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves. Butyl rubber. Since the product consists of several substances, the durability of the glove material cannot be estimated and needs to be tested before use. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Wear appropriate mask

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Colour : Colourless.

Odour : Characteristic.

Odour threshold : Not determined

Melting point : Not applicable

Freezing point : -84 °C

Boiling point : 76 - 77 °C

Flammability : Not applicable

Not applicable

Explosive properties : Not explosive.

Explosive limits : Not available

Lower explosion limit : 2.2 vol %

Upper explosion limit : Not available

Flash point : -4 °C

Auto-ignition temperature : Product is not selfigniting

Decomposition temperature : Not determined рΗ : Not determined Viscosity, kinematic : Not determined Viscosity, dynamic : Not determined Solubility : Not miscible. Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density : Not determined Relative density : 0.9 g/cm³ Relative vapour density at 20°C : Not available Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified Acute toxicity (dermal) : Not classified Acute toxicity (inhalation) : Not classified

| ethyl acetate (141-78-6) | |
|--------------------------|-------------|
| LD50 oral rat | 11.3 ml/kg |
| LD50 dermal rabbit | 20000 mg/kg |

Skin corrosion/irritation : Not classified

pH: Not determined

Serious eye damage/irritation : Causes serious eye irritation.

pH: Not determined

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified

STOT-single exposure : May cause drowsiness or dizziness.

| ethyl acetate (141-78-6) | |
|--------------------------|------------------------------------|
| LOAEL (oral, rat) | 3600 mg/kg bodyweight |
| NOAEL (oral, rat) | 900 mg/kg bodyweight |
| STOT-single exposure | May cause drowsiness or dizziness. |
| STOT-repeated exposure : | Not classified |

Aspiration hazard : Not classified

Viscosity, kinematic Not determined

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse

effects in the environment.

Hazardous to the aquatic environment, short-term

(acute)

: Not classified

Hazardous to the aquatic environment, long-term : Not classified

(chronic)

| ethyl acetate (141-78-6) | |
|--------------------------|-----------|
| LC50 - Fish [1] | 230 mg/l |
| NOEC chronic fish | 9.65 mg/l |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

| ADR | IMDG | IATA | RID |
|-----------------------------------|--|-----------------------------------|-----------------------------------|
| 14.1. UN number or ID n | umber | | |
| UN 1173 | UN 1173 | UN 1173 | UN 1173 |
| 14.2. UN proper shippin | g name | | ' |
| ETHYL ACETATE | ETHYL ACETATE | Ethyl acetate | ETHYL ACETATE |
| 14.3. Transport hazard | class(es) | | |
| 3 | 3 | 3 | 3 |
| 3 | 3 | 3 | 3 |
| 14.4. Packing group | | | |
| II | II | П | II |
| 14.5. Environmental haz | ards | | |
| Dangerous for the environment: No | Dangerous for the environment: No Marine pollutant: No | Dangerous for the environment: No | Dangerous for the environment: No |
| lo supplementary informatio | n available | | I |

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Limited quantities (ADR) : 11
Excepted quantities (ADR) : E2

Packing instructions (ADR) : P001, IBC02, R001

Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T4
Portable tank and bulk container special provisions : TP1

(ADR)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 2
Special provisions for carriage - Operation (ADR) : S2, S20
Hazard identification number (Kemler No.) : 33

Orange plates :

33 1173

Tunnel restriction code (ADR) : D/E EAC code : •3YE

Transport by sea

Limited quantities (IMDG) : 1L : E2 Excepted quantities (IMDG) Packing instructions (IMDG) : P001 IBC packing instructions (IMDG) : IBC02 Tank instructions (IMDG) : T4 Tank special provisions (IMDG) : TP1 EmS-No. (Fire) : F-E EmS-No. (Spillage) : S-D Stowage category (IMDG) : B : -4°C c.c. Flash point (IMDG)

Properties and observations (IMDG) : Colourless liquid with a fragrant odour. Flashpoint: -4°C c.c. Explosive limits: 2.18% to

11.5% Immiscible with water.

Air transport

PCA Excepted quantities (IATA) : E2 PCA Limited quantities (IATA) : Y341 PCA limited quantity max net quantity (IATA) : 1L PCA packing instructions (IATA) : 353 PCA max net quantity (IATA) : 5L : 364 CAO packing instructions (IATA) : 60L CAO max net quantity (IATA) : 3L ERG code (IATA)

Rail transport

Classification code (RID) : F1
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2

Packing instructions (RID) : P001, IBC02, R001

Mixed packing provisions (RID) : MP19
Portable tank and bulk container instructions (RID) : T4
Portable tank and bulk container special provisions : TP1

(RID)

Tank codes for RID tanks (RID) : LGBF
Transport category (RID) : 2
Colis express (express parcels) (RID) : CE7
Hazard identification number (RID) : 33

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

SDS EU format according to COMMISSION REGULATION (EU) 2020/878.

| Abbreviations and acronyms: | | |
|-----------------------------|---|--|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways | |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road | |
| ATE | Acute Toxicity Estimate | |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 | |
| EC50 | Median effective concentration | |
| IATA | International Air Transport Association | |
| IMDG | International Maritime Dangerous Goods | |
| LC50 | Median lethal concentration | |
| LD50 | Median lethal dose | |
| vPvB | Very Persistent and Very Bioaccumulative | |
| PBT | Persistent Bioaccumulative Toxic | |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 | |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail | |

Data sources

: Classification according to Classification, Labelling and Packaging of Substances and Mixtures (SEA) Regulation published in the Official Journal numbered 28848 on December 11, 2013. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Training advice

: Normal use of this product shall imply use in accordance with the instructions on the packaging.

| Full text of H- and EUH-statements: | | |
|-------------------------------------|--|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 | |
| Flam. Liq. 2 | Flammable liquids, Category 2 | |
| H225 | Highly flammable liquid and vapour. | |
| H319 | Causes serious eye irritation. | |
| H336 | May cause drowsiness or dizziness. | |
| H373 | May cause damage to organs through prolonged or repeated exposure. | |
| STOT RE 2 | Specific target organ toxicity – Repeated exposure, Category 2 | |
| STOT SE 3 | Specific target organ toxicity – Single exposure, Category 3, Narcosis | |

| Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]: | | |
|---|------|-----------------------|
| Flam. Liq. 2 | H225 | On basis of test data |
| Eye Irrit. 2 | H319 | Calculation method |
| STOT SE 3 | H336 | Calculation method |

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.