

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

1.1. Product identifier

Product form : Mixture
Trade name : LABOSIL 80
Product code : 5020

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

FAMADENT S.L.U.
Garrotxa, 6 Polígono Empordà Internacional
ES- 17469 Vilamalla
España
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]

Not classified

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]

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ 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

LABOSIL 80

Safety Data Sheet

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

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. |
| First-aid measures after skin contact | : Wash skin with plenty of water. Wash contaminated clothing before reuse. |
| First-aid measures after eye contact | : Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing. |
| First-aid measures after ingestion | : Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person. 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. Water spray. 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.

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Precautionary measures fire | : Use jets of water to cool containers to prevent product decomposition and the development of substances potentially hazardous for health. |
| 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

General measures : Block the leakage if there is no hazard.

6.1.1. For non-emergency personnel

Emergency procedures : Wear proper protective equipment.

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 | : Collect in closed containers for disposal. Collect the residue by means of a non-combustible absorbent material. Provide adequate ventilation. This material and its container must be disposed of in a safe way, and as per local legislation. |
| Other information | : Dispose of materials or solid residues at an authorized site. |

LABOSIL 80

Safety Data Sheet

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

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

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

No additional information available

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.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Eye protection (goggles)

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

LABOSIL 80

Safety Data Sheet

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

Hand protection:

In case of repeated or prolonged contact wear gloves. Chemical resistant gloves (according to European standard EN 374 or equivalent)

8.2.2.3. Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection.

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 | : Solid |
| Colour | : Light grey. |
| Appearance | : Paste. |
| Odour | : odourless. |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not applicable |
| Boiling point | : Not available |
| Flammability | : Non flammable. |
| Explosive limits | : Not applicable |
| Lower explosion limit | : Not applicable |
| Upper explosion limit | : Not applicable |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : Not available |
| pH | : Not available |
| pH solution | : Not available |
| Viscosity, kinematic | : Not applicable |
| Solubility | : insoluble in water. |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50°C | : Not available |
| Density | : Not available |
| Relative density | : Not applicable |
| Relative vapour density at 20°C | : Not applicable |
| Particle size | : Not available |
| Particle size distribution | : Not available |
| Particle shape | : Not available |
| Particle aspect ratio | : Not available |
| Particle aggregation state | : Not available |
| Particle agglomeration state | : Not available |
| Particle specific surface area | : Not available |
| Particle dustiness | : Not available |

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

LABOSIL 80

Safety Data Sheet

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

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 normal conditions. However, the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

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 |
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

| | |
|----------------------|----------------|
| Viscosity, kinematic | Not applicable |
|----------------------|----------------|

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 (chronic) | : Not classified |

12.2. Persistence and degradability

No additional information available

LABOSIL 80

Safety Data Sheet

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

12.3. Bioaccumulative potential

No additional information available

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. Comply with local regulations for disposal.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

| ADR | IMDG | IATA | RID |
|---|---------------|---------------|---------------|
| 14.1. UN number or ID number | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.2. UN proper shipping name | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available | | | |

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Rail transport

Not regulated

LABOSIL 80

Safety Data Sheet

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

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)

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 |

LABOSIL 80

Safety Data Sheet

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

| Abbreviations and acronyms: | |
|-----------------------------|---|
| 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 |
| | Spain - BLV |
| BCF | Bioconcentration factor |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| DPD | Dangerous Preparations Directive 1999/45/EC |
| DSD | Dangerous Substances Directive 67/548/EEC |
| SDS | Safety Data Sheet |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| PNEC | Predicted No-Effect Concentration |
| TLM | Median Tolerance Limit |

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.

Training advice

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

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.