

according to Regulation (EC) No 1907/2006

Revision date: 20.07.2018

mollosil® plus polish (base)

Product code: 920

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

1.1. Product identifier

mollosil® plus polish (base)

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

Use of the substance/mixture

Lacquer for denture relinings for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Manufacturer

| | | |
|-------------------------|--|---------------------------|
| Company name: | DETAX GmbH & Co. KG | |
| Street: | Carl-Zeiss-Strasse | |
| Place: | D-76275 Ettlingen | |
| Telephone: | +49 7243/510-0 | Telefax: +49 7243/510-100 |
| e-mail: | post@detax.de | |
| Internet: | www.detax.de | |
| Responsible Department: | Emergency number: | |
| | +49 7243/510-0 | |
| | This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.) | |

Importer / Distributer

| | |
|-------------------------|---|
| Company name: | Durodent Dental Supplies |
| Place: | Unit 6 / 51 Jersey Road, Bayswater, VIC 3153 AUS |
| Telephone: | + 61 (03) 9720 6700 |
| e-mail: | sales@durodent.com.au |
| Responsible Department: | For non-urgent inquiries refer to: |
| | Durodent Dental Supplies (Office) Phone: (03) 97206700 |
| | This number is only available during the following office hours : |
| | Mon-Thurs 09:00am - 5:00pm / Friday 09:00am – 4.30pm AEST |
| | Australian Poisons Information Centre (National) 13 11 26 – 24 Hours / 7 Days |

1.4. Emergency telephone number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

- Flammable liquid: Flam. Liq. 2
- Skin corrosion/irritation: Skin Irrit. 2
- Serious eye damage/eye irritation: Eye Irrit. 2
- Specific target organ toxicity - single exposure: STOT SE 3
- Specific target organ toxicity - repeated exposure: STOT RE 2
- Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

- Highly flammable liquid and vapour.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause respiratory irritation.
- May cause damage to organs through prolonged or repeated exposure.
- Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

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Hazard components for labelling

xylene

Signal word:

Danger

Pictograms:



Hazard statements

| | |
|------|--|
| H225 | Highly flammable liquid and vapour. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H412 | Harmful to aquatic life with long lasting effects. |

Precautionary statements

| | |
|-----------|---|
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P233 | Keep container tightly closed. |
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| P370+P378 | In case of fire: Use Carbon dioxide (CO ₂), Foam, Extinguishing powder to extinguish. |
| P403+P235 | Store in a well-ventilated place. Keep cool. |
| P501 | Dispose of contents/ container in accordance with local and national regulations. |

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Alkyl silicone resin in organic solvent.

Hazardous components

| CAS No | Chemical name | | | Quantity |
|-----------|---|--------------|------------------|-------------|
| | EC No | Index No | REACH No | |
| | GHS Classification | | | |
| 1330-20-7 | xylene | | | 25 - < 30 % |
| | 215-535-7 | 601-022-00-9 | 01-2119488216-32 | |
| | Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Asp. Tox. 1, Aquatic Chronic 3; H226 H332 H312 H315 H319 H335 H373 H304 H412 | | | |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. Medical treatment necessary.

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After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water.
Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

No 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 (CO₂), Foam, Extinguishing powder.

Unsuitable extinguishing media

Water.

5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove all sources of ignition. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow uncontrolled discharge of product into the environment. Danger of explosion

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

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Advice on protection against fire and explosion

Keep away from sources of ignition. - No smoking. Take precautionary measures against static discharges.
Vapours can form explosive mixtures with air.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints on joint storage

Do not store together with: Oxidising agent . Pyrophoric or self-heating substances.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Component B of a silicone lacquer for use in dentistry.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure limits (EH40)**

| CAS No | Substance | ppm | mg/m ³ | fibres/ml | Category | Origin |
|-----------|-----------------------|-----|-------------------|-----------|---------------|--------|
| 1330-20-7 | Xylene: mixed isomers | 50 | 220 | | TWA (8 h) | WEL |
| | | 100 | 441 | | STEL (15 min) | WEL |

Biological Monitoring Guidance Values (EH40)

| CAS No | Substance | Parameter | Value | Test material | Sampling time |
|-----------|-------------------------------------|-----------------------------------|--------------|---------------|---------------|
| 1330-20-7 | Xylene, o-, m-, p- or mixed isomers | methyl hippuric acid (creatinine) | 650 mmol/mol | urine | Post shift |

8.2. Exposure controls**Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.
Wash hands and face before breaks and after work and take a shower if necessary . When using do not eat or drink.

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: FKM (fluoro rubber)

Skin protection

Flame-retardant protective clothing. Wear anti-static footwear and clothing .

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Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid:
Colour: colourless
Odour: Benzene

Test method

pH-Value: not determined

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: 95 °C DIN 51356

Flash point: 10 °C DIN 51755

Flammability

Solid: not applicable

Gas: not applicable

Lower explosion limits: 4 vol. %

Upper explosion limits: 32 vol. %

Ignition temperature: >450 °C DIN 51794

Auto-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: >150 °C

Oxidizing properties

Not oxidizing.

Vapour pressure: 29 hPa

(at 20 °C)

Vapour pressure: 1100 hPa

(at 50 °C)

Density (at 20 °C): 0,95 g/cm³ DIN 51757

Water solubility: insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: 200 mPa·s BROOKFIELD
(at 23 °C)

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable.

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10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air. Reacts with : strong oxidising agents. The product may attack some plastic materials.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

The following applies for the silicone content of the product: At temperature of appr. 150°C/ 302 °F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

| CAS No | Chemical name | | | | |
|-----------|-------------------------|---------------|----------|--------|--------|
| | Exposure route | Dose | Species | Source | Method |
| 1330-20-7 | xylene | | | | |
| | oral | LD50 mg/kg | 3500 | Rat | GESTIS |
| | dermal | LD50 mg/kg | >1700 | Rabbit | GESTIS |
| | inhalation (4 h) vapour | LC50 mg/l | 29,08 | Rat | GESTIS |
| | inhalation aerosol | ATE | 1,5 mg/l | | |

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause respiratory irritation. (xylene)

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure. (xylene)

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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| CAS No | Chemical name | | | | | |
|-----------|--------------------------|-----------------------|-----------|-------------------------------------|--------|--------|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 1330-20-7 | xylene | | | | | |
| | Acute fish toxicity | LC50 2,661-4,093 mg/l | 96 h | Oncorhynchus mykiss (Rainbow trout) | | |
| | Acute crustacea toxicity | EC50 3,82 mg/l | 48 h | | | |

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|-----------|---------------|---------|
| 1330-20-7 | xylene | 3,15 |

BCF

| CAS No | Chemical name | BCF | Species | Source |
|-----------|---------------|--------|---------|--------|
| 1330-20-7 | xylene | 0,6-15 | | |

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

| | |
|--|----------------|
| 14.1. UN number: | UN 1866 |
| 14.2. UN proper shipping name: | Resin solution |
| 14.3. Transport hazard class(es): | 3 |
| 14.4. Packing group: | II |
| Hazard label: | 3 |
| Classification code: | F1 |
| Limited quantity: | 5 L/ 30 kg |
| Transport category: | - |
| Hazard No: | 33 |

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Tunnel restriction code: D/E

Other applicable information (land transport)

Flammable liquid

Marine transport (IMDG)

14.1. UN number: UN 1866
14.2. UN proper shipping name: Resin solution
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3
Marine pollutant: -
Special Provisions: -
Limited quantity: 5 L / 30 kg
EmS: F-E, S-E

Other applicable information (marine transport)

Flash point: 10°C c.c.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1866
14.2. UN proper shipping name: Resin solution
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3
Limited quantity Passenger: 1 L / 30 kg
Passenger LQ: Y341
IATA-packing instructions - Passenger: 353
IATA-max. quantity - Passenger: 5 L
IATA-packing instructions - Cargo: 364
IATA-max. quantity - Cargo: 60 L

14.6. Special precautions for user

Warning: Combustible liquid.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D): 2 - obviously hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

| Classification | Classification procedure |
|-------------------------|--------------------------|
| Flam. Liq. 2; H225 | On basis of test data |
| Skin Irrit. 2; H315 | Calculation method |
| Eye Irrit. 2; H319 | Calculation method |
| STOT SE 3; H335 | Calculation method |
| STOT RE 2; H373 | Calculation method |
| Aquatic Chronic 3; H412 | Calculation method |

Relevant H and EUH statements (number and full text)

| | |
|------|--|
| H225 | Highly flammable liquid and vapour. |
| H226 | Flammable liquid and vapour. |
| H304 | May be fatal if swallowed and enters airways. |
| H312 | Harmful in contact with skin. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H335 | May cause respiratory irritation. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H412 | Harmful to aquatic life with long lasting effects. |

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Identified uses

| No | Short title | LCS | SU | PC | PROC | ERC | AC | TF | Specification |
|----|-------------|-----|----|----|------|-----|----|----|---------------|
| 1 | Gewerblich | - | - | - | - | - | - | - | 2 |

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)