

## Safety Data Sheet

according to Regulation (EG) Nr. 1907/2006

### mollosil® plus Primer

Revision date: 26.09.2023

Product code: 10528

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

### 1.1. Product identifier

mollosil® plus Primer

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

#### Use of the substance/mixture

Adhesive for denture relinings for use in dentistry.

### 1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
E-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	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.)	

### 1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC worldwide)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EG) Nr. 1272/2008

Flam. Liq. 2; H225  
Eye Irrit. 2; H319  
STOT SE 3; H336

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

#### Regulation (EG) Nr. 1272/2008

#### Hazard components for labelling

ethyl acetate

Signal word: Danger

#### Pictograms:



#### Hazard statements

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

#### Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

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P370+P378 In case of fire: Use Carbon dioxide (CO<sub>2</sub>), 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	
	Classification (Regulation (EG) Nr. 1272/2008)			
141-78-6	ethyl acetate			80 - < 100 %
	205-500-4	607-022-00-5	01-2119475103-46	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			

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

##### Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
141-78-6	205-500-4	ethyl acetate	80 - < 100 %
	inhalation: LC50 = >29,3 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg		

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

Provide fresh air. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

##### After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

##### 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

Observe risk of aspiration if vomiting occurs. 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

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#### 5.1. Extinguishing media

##### **Suitable extinguishing media**

Carbon dioxide (CO<sub>2</sub>), 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

In case of fire: Wear self-contained breathing apparatus.

#### **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

##### **General advice**

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. Explosion risk.

#### 6.3. Methods and material for containment and cleaning up

##### **Other information**

Absorb with liquid-binding material (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.

##### **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.

##### **Advice on general occupational hygiene**

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, drink, smoke, sniff.

#### 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.

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#### 7.3. Specific end use(s)

Adhesive for silicone based denture relinings.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
141-78-6	Ethyl acetate	200	734		TWA (8 h)	WEL
		400	1468		STEL (15 min)	WEL

#### 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.

##### Individual protection measures, such as personal protective equipment

##### 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: Butyl caoutchouc (butyl rubber)

##### Skin protection

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

##### 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:	orange
Odour:	Ethyl acetate

	Test method
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	72 °C DIN 51356
Flammability:	not applicable
Lower explosion limits:	not applicable
Upper explosion limits:	2,1 vol. %
Flash point:	11,5 vol. %
Auto-ignition temperature:	3 °C DIN 51755
Decomposition temperature:	460 °C DIN 51794
pH-Value:	>120 °C
Water solubility:	not determined
	partially miscible

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Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

97 hPa

(at 20 °C)

Vapour pressure:

375 hPa

(at 50 °C)

Density (at 20 °C):

0,90 g/cm<sup>3</sup> DIN 51757

Relative vapour density:

not determined

#### 9.2. Other information

##### Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

Not oxidizing.

##### Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic:

1 mPa·s BROOKFIELD

(at 23 °C)

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Highly flammable.

#### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

#### 10.3. Possibility of hazardous reactions

Reacts with : combustible materials.

#### 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.

#### 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 hazard classes as defined in Regulation (EG) Nr. 1272/2008

##### Acute toxicity

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

##### ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
141-78-6	ethyl acetate				
	oral	LD50 mg/kg	>2000	Rat	
	dermal	LD50 mg/kg	>2000	Rabbit	
	inhalation (4 h) vapour	LC50 mg/l	>29,3	Rat	

#### Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

#### 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 drowsiness or dizziness. (ethyl acetate)

#### STOT-repeated exposure

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

#### Aspiration hazard

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

#### Additional information on tests

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

## SECTION 12: Ecological information

### 12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
141-78-6	ethyl acetate					
	Acute fish toxicity	LC50 mg/l	>100	96 h	Salmo trutta fario (L) (Freshwater trout)	OECD 203
	Acute algae toxicity	ErC50 mg/l	>100	72 h	Desmodesmus subspicatus	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>100	48 h	Daphnia magna (Big water flea)	

### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
141-78-6	ethyl acetate				
	OECD 301D/ EEC 92/69/V, C.4-E	>70%	28		

### 12.3. Bioaccumulative potential

The product has not been tested.

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#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
141-78-6	ethyl acetate	0,68

#### BCF

CAS No	Chemical name	BCF	Species	Source
141-78-6	ethyl acetate	30	Leuciscus idus (golden orfe)	

#### 12.4. Mobility in soil

The product has not been tested.

#### 12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

Not identified as PBT/ vPvB substances

#### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

#### 12.7. Other adverse effects

No information available.

#### Further information

Avoid release to the environment.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Disposal recommendations

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

##### Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

<b>14.1. UN number or ID number:</b>	UN 1866
<b>14.2. UN proper shipping name:</b>	Resin solution
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	II
Hazard label:	3
Classification code:	F1
Limited quantity:	5 L
Transport category:	2
Hazard No:	33
Tunnel restriction code:	D/E

#### Other applicable information (land transport)

Flammable liquid

#### Marine transport (IMDG)

<b>14.1. UN number or ID number:</b>	UN 1866
<b>14.2. UN proper shipping name:</b>	Resin solution
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	II
Hazard label:	3
Marine pollutant:	-
Special Provisions:	-
Limited quantity:	5 L/ 30 kg

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EmS: F-E, S-E

**Other applicable information (marine transport)**

Flash point: 3°C c.c.

**Air transport (ICAO-TI/IATA-DGR)**

<b>14.1. UN number or ID number:</b>	UN 1866
<b>14.2. UN proper shipping name:</b>	Resin solution
<b>14.3. Transport hazard class(es):</b>	3
<b>14.4. Packing group:</b>	II
Hazard label:	3
Special Provisions:	A3
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. 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**

**EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 75

Information according to 2012/18/EU (SEVESO III): P5c FLAMMABLE LIQUIDS

**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): 1 - slightly hazardous to water

**Additional information**

NZ:

HSR number: HSR002556

Group standard: Dental Products Flammable Group Standard 2017

**15.2. Chemical safety assessment**

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

## SECTION 16: Other information



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#### 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  
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%  
CLP: Classification, labelling and Packaging  
REACH: Registration, Evaluation and Authorization of Chemicals  
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
UN: United Nations  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate  
NOEC: No Observed Effect Concentration  
BCF: Bio-concentration factor  
PBT: persistent, bioaccumulative, toxic  
vPvB: very persistent, very bioaccumulative  
RID: Regulations concerning the international carriage of dangerous goods by rail  
EmS: Emergency Schedules  
MFA: Medical First Aid Guide  
ICAO: International Civil Aviation Organization  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
VOC: Volatile Organic Compounds  
SVHC: Substance of Very High Concern  
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>  
Flam. Liq: Flammable liquids  
Eye Irrit: Eye irritation  
STOT SE: Specific target organ toxicity - single exposure

#### Classification for mixtures and used evaluation method according to Regulation(EG) Nr. 1272/2008

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Eye Irrit. 2; H319	Calculation method
STOT SE 3; H336	Calculation method

#### Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.  
EUH066 Repeated exposure may cause skin dryness or cracking.

#### 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.

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