

Safety Data Sheet

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 16.09.2020

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

Manufacturer

Company name: DETAX GmbH & Co. KG
Street: Carl-Zeiss-Strasse
Place: D-76275 Ettlingen
Telephone: +49 7243/510-0
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.)
Telefax: +49 7243/510-100

Importer / Distributer

Company name: Ivoclar Vivadent Pty Ltd
Place: 1-5 Overseas Drive Noble Park North VIC 3174
Telephone: +61 3 9795 9599
e-mail: info@ivoclarvivadent.com
Telefax: Fax: +61 3 9795 9645

1.4. Emergency telephone number:

13 11 26
Poisons Hotline (24 hours / 7 days)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Flammable liquid: Flam. Liq. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:

Highly flammable liquid and vapour.

Causes serious eye irritation.

May cause drowsiness or dizziness.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

ethyl acetate

Signal word: Danger

Pictograms:



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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.
 P370+P378 In case of fire: Use Carbon dioxide (CO₂), 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			
141-78-6	ethyl acetate			> 90 %
	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.

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

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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

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**

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 in case of fire.

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.

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.

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Hints on joint storage

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

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 ³	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.

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, drink, smoke, sniff.

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

pH-Value: not determined

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: 72 °C DIN 51356

Flash point: 3 °C DIN 51755

Flammability

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Solid: not applicable
 Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: 2,1 vol. %
 Upper explosion limits: 11,5 vol. %
 Ignition temperature: 460 °C DIN 51794

Auto-ignition temperature

Solid: not applicable
 Gas: not applicable

Decomposition temperature: >120 °C

Oxidizing properties

Not oxidizing.

Vapour pressure: 97 hPa
 (at 20 °C)

Vapour pressure: 375 hPa
 (at 50 °C)

Density (at 20 °C): 0,90 g/cm³ DIN 51757

Water solubility: partially miscible

Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: 1 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.

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

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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
141-78-6	ethyl acetate				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation (4 h) vapour	LC50 >29,3 mg/l	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

This 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 >100 mg/l	96 h	Salmo trutta fario (L) (Freshwater trout)	OECD 203	
	Acute algae toxicity	ErC50 >100 mg/l	72 h	Desmodesmus subspicatus.	OECD 201	
	Acute crustacea toxicity	EC50 >100 mg/l	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		

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12.3. Bioaccumulative potential

The product has not been tested.

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

Not identified as PBT/ vPvB substances

12.6. 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)

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
Transport category:	2
Hazard No:	33
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

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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)

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
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. 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

EU regulatory information

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

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

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

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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
 MFAG: 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
 @1602.B016012

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
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.

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