according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016 Product code: 10528 Page 1 of 9

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:

ProTech Professional Products, Inc

Street:

2900 NW Commerce Park Dr. Suite 10

Fax: 561/493-9825

Place:

D-76275 Ettlingen

Telephone:

561/493-9818

e-mail: Internet: <u>protechdental@bellsouth.net</u> www.dentallabproducts.com

1.4. Emergency telephone

Infotrac - 800/535-5053

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

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 eve 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:





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.

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016

Product code: 10528 Page 2 of 9

P235 P280

Keep cool.

)

Wear protective gloves/protective clothing/eye protection/face 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.

P501

Dispose of contents/ container in accordance with legal 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				
	EC No	Index No	REACH No		
	Classification according to Regulation (EC) No. 1272/2008 [CLP]				
141-78-6	ethyl acetate				
	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

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

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

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016 Product code: 10528 Page 3 of 9

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. Provide adequate ventilation. 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.

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 in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Advice on storage compatibility

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

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016

Product code: 10528

Page 4 of 9

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
141-78-6	Ethyl acetate	200	-		TWA (8 h)	WEL
		400			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 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: 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

Solid: Gas: not applicable

not applicable

Lower explosion limits:

2,1 vol. %

Upper explosion limits:

11,5 vol. %

Ignition temperature:

460 °C DIN 51794

Auto-ignition temperature

Solid:

not applicable

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016 Product code: 10528

Page 5 of 9

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

11.1. Information on toxicological effects

Acute toxicity

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

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016 Product code: 10528

Page 6 of 9

CAS No	Chemical name							
	Exposure route	Dose		Species	Source			
141-78-6	ethyl acetate							
	oral	LD50	>2000 mg/kg	Rat				
	dermal	LD50	>2000 mg/kg	Rabbit				
	inhalative (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			
141-78-6	ethyl acetate								
	Acute fish toxicity	LC50	>100 mg/l	1	Salmo trutta fario (L) (Freshwater trout)	OECD 203			
	Acute algae toxicity	ErC50	>100 mg/i	1	Desmodesmus subspicatus.	OECD 201			
	Acute crustacea toxicity	EC50	>100 mg/l	i	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.

Partition coefficient n-octanol/water

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

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016

Product code: 10528

Page 7 of 9

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 identivied 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

Advice on disposal

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

UN 1866

Contaminated packaging

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

SECTION 14: Transport information

Land	trans	port (ADR/RID)
14	.1. UN	number:

14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	11
Hazard label:	3
Classification code:	F1
Limited quantity:	5L
Transport category:	2
Hazard No:	33
Tunnel restriction code:	D/F

Other applicable information (land transport)

Flammable licquid

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
FmS:	F-F S-F

Other applicable information (marine transport)

Flash point: 3°C c.c.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1866

according to Regulation (EC) No 1907/2006

mollosil® plus Prime	mol	losil®	plus	Primer
----------------------	-----	--------	------	--------

Revision date: 09.12.2016 Product code: 10528 Page 8 of 9

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-rnax. 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 juvenils according to the 'juvenile

work protection guideline' (94/33/EC).

Water contaminating class (D):

1 - slightly water contaminating

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%

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 above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

according to Regulation (EC) No 1907/2006

mollosil® plus Primer

Revision date: 09.12.2016 Product code: 10528

Page 9 of 9

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