1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING

INFORMATION ON THE PRODUCT

1.1 Product identifier

Trade name

ORTOPOLI LIQUID

1.2 Relevant identifier uses of the substance or mixture and uses advised against

Recommended use

Material for the fabrication of orthodontic appliances by using the spray-on technique and the cold curing.

1.3 Details of the supplier of the Safety Data Sheet

Manufacturer/supplier

Polident d.o.o.,
Dental Products Industry
Volčja Draga 42, 5293 Volčja Draga,
Slovenija
Tel.:00386 5 3304840, Fax: 00386 5 3304870
E-mail: polident@polident.si

Information provided by

00386 5 3304859

1.4 Emergency telephone number

00386 5 3304840

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Mixture

Clasification according to Regulation (EC) No. 1272/2008

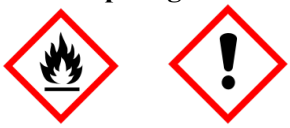
Flam. Liq. 2	H225	Highly flammable liquid and vapour.
Skin Irrit. 2	H315	Causes skin irritation.
Skin Sens. 1	H317	May cause an allergic skin reaction.
STOT SE 3	H335	May cause respiratory irritation.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS02 GHS07

Signal word

Danger

Hazard statements

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

Precautionary statements

P 210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3..1 COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures

Description

Product contents mainly methyl methacrylate, pigments and dimethacrylate.

Hazardous ingredients according to Regulation (EC) No. 1272/2008

Hazardous Ingredients

			Regulation (EC) No.1272/2008	
Name	**% W/W**	**Index No. EC No. CAS No.**	**Hazard Class and Category Codes**	**Hazard Statement Codes**
Methyl methacrylate	50-100	607-035-00-6 201-297-1 80-62-6	Flam. Liq. 2 Skin Irrit. 2 Skin Sens. 1 STOT SE 3	H225 H315 H317 H335
Ethane diol dimeth-acrylate	2,5-10	607-114-00-5 202-617-2 97-90-5	Skin Sens. 1 STOT SE 3	H317 H335
Reaction mass of 2,2`-[(4-methylphenyl) imino]bisethanol and 2-[[2-(2-hydroxyethoxy) ethyl](4-methylphenyl) amino]ethanol	*≤ 2*	*911-490-9*	*Eye Dam. 1* *Acute Tox.4* *Skin Irrit.2* *Skin Sens.1* *Aquatic Chronic 3*	*H318* *H302* *H315* *H317* *H412*
Poly(oxy-1,2-ethanediyl) .alpha.,.alpha.`- [[(4-methyl phenyl)imino]di-2,1-ethanediyl]bis[.omega.-hydroxy (polymer)	*≤ 2*	*103671-44-9*	*Eye Dam.1* *Acute Tox.4*	*H318* *H302*

4. FIRST AID MEASURES

4.1 Description of first aid measures

General information

Remove soiled, soaked clothing immediately.

Inhalation

Remove the casualty into fresh air. In case of complaints obtain medical attention.

Skin contact

Wash off immediately with water. If skin irritation occurs obtain medical attention.

Eye contact

Rinse opened eye with plenty of water and if it is necessary obtain medical attention.

Ingestion

Do not induce vomiting. Rinse mouth. Obtain immediately medical attention.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE – FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Water spray, foam, dry powder, carbon dioxide.

Unsuitable extinguishing media for safety reasons

Water with full yet.

5.2 Special hazards arising from the substance or mixture

Highly flammable liquid.

May polymerise on heating, the reaction is exoterm.

Dangerous gases may be released in case of fire.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and suitable protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Eliminate sources of ignition.

Ensure suitable personal protection (including respiratory protection) during removal of spillages. See Section 8.

6.2 Environmental precautions

Prevent product from getting into drains, surface water or ground water.

6.3 Methods and material for containment and cleaning up

Adsorb spillages onto sand, earth or any suitable adsorbent material.

Do not adsorb onto sawdust or other combustible materials.

Transfer to a container for disposal or recovery.

Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

6.4 Reference to other sections

For information on safe handling see Section 7.

For information on personal protection equipment see Section 8.

For information on disposal information see Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling advice

Only adequate trained persons may deal with product. For use in dentistry only.

Keep away from children.

Ensure the area is well ventilated. Avoid inhalation of high concentrations of vapours.The vapour is heavier than air; beware of pits and confined spaces.

No eating, drinking or smoking during handling with product.

Follow the usual good standards of occupational hygiene. Avoid contact with skin and eyes.

Information on fire and explosion protection

Keep away from. sources of ignition – No smoking.

Take precautionary measures against static discharges.

In the event of fire, cool the endangered containers with water.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements for storage areas

Vessels must be tightly closed.

Keep in a coal, well ventilated place.

Keep away from sources of ignition - No Smoking.

Keep away from heat and direct sunlight.

Keep the liquid only in the original vessel at a temperature preferably not exceeding 25ºC.

Empiry date

Considering the instructions for safety storage and handling the expiry date of the liquid is three

years

7.3 Specific end use(s)
None.

8. EXPOSURE CONTROLS /PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

	LTEL ppm (8Hr TWA)	LTEL mg/m^3 (8Hr TWA)	STEL ppm	STEL mg/m^3
Methyl methacrylate	50	208	100	416
CAS No. 80-62-6				

8.2 Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. Follow the usual good standards of occupational hygiene and dental practise. Ensure adequate ventilation of work place.
Store work clothing separately. Remove contaminated or soaked clothing immediately.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear tightly sealed goggles.

Skin protection

Wear suitable protective gloves.

Material of gloves: Butyl rubber; EN 374
Suitability of gloves should be confirmed with glove manufacturer. Change gloves, if contamination occurs or duration of activity exceed break through time.Breakthrough time of the glove material: refer to the information provided by the glove´s producer.
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Respiratory protection

In the case of short term exposure use suitable mask with filter type A. In the event of particularly high levels of vapours a self contained breathing apparatus is appropriate.

Thermal hazards

None.

Environmental exposure controls

Ensure effective control measures when working within the boundaries as specified in section 6.2.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance
Form: liquid
Colour: colourless
Odour: characteristic strong
pH – value: not applicable
Changes in condition: /
Melting point (˚C): - 48
Boiling point (˚C): 100,5
Flash point (˚C): 10
Relative evaporation rate (Ether=1): Not available
Flammability (solid, gas): Not applicable
Auto Ignition temperature(˚C): 421
Decomposition temperature (˚C): Not applicable
Lower explosion limit (%vv/v): 2,1
Upper explosion limit (%vv/v): 12,5

Vapour pressure (Pa): 3600 at 20˚C
Vapour density (Air=1): 3,5
Density (g/cm^3): 0,949 at 15,5 ˚C
Viscosity (mPas): 0,6 at 20˚C
Solubility in water: slightly soluble, 1,6% at 20˚C
Solubility (quantitative): miscible with most organic solvents
Partition coefficient (n-Octanol/water): 1,38
Explosive properties: Not applicable
Oxidising properties: Not applicable

9.2 Other information
None.

10. STABILITY AND REACTIVITY

10.1 Reactivity
Will exotermically polymerise in the presence of initiators.

10.2 Chemical stability
The product is stable under normal handling and storage conditions.

10.3 Possibility of hazardous reactions
Susceptible to polymerisation initiated by prolonged heating or the presence of catalyst.

10.4 Conditions to avoid
Heat and direct sunlight.

10.5 Incompatible materials
Polymerisation catalysts, such as peroxy oz azo compounds, strong acids, alkalis and oxidising agents. Ovides and salts of transition metals. Organic Nitrogen containing compounds. Cyclohexanone/Cyclohexenol tautomer.

10.6 Hazardous decomposition products
None when used and stored as prescribed.
Does not decompose up to auto-ignition temperature.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
Ingestion
Low oral toxicity, but ingestion may cause iritation of the gastrointestinal tract.
LD/LC50 values relevant for classification:
80-62-6 methyl methacrylate: LD50 (oral)=7872 mg/kg (rat)
Inhalation: May cause respiratory irritation. May cause drowsiness or dizziness.
Inhalation toxicity data: LC50 (vapour) 7093 ppm (29,8 mg/l)(4hr)

Skin irritation
May cause an allergic skin reaction. Causes skin irritation. Repated and/or prolonged contact may cause dermatitis.

Eye contact
High vapour concentration will cause irritation.

Sensitization
Sensitization possible through skin contact. Not a respiratory sensitizer.

CMR effects
Carcinogenity
No evidence of carcinogenicity.
Mutagenicity
Germ cell mutagenicity data: negative.
Toxicity for reproduction
Teratogenic and fetotoxic effects only observed in presevce of maternal toxicity.

Repeated dose toxicity
Chronic exposure
Repeated exposure to high levels produces adverse effects on the heart, lungs, liver and kidneys. Repeated exposure of animals by inhalation to levels at or above the occupational exposure level produces adverse effects on the nasal epithelium (levels of 100 and 400 ppm).

There is no reason to believe that methyl methacrylate represents a carcinogenic or mutagenic hazard to man based upon evidence from well conducted animal studies, relevant mutagenicity studies and adequate epidemiology studies in relevant cohorts.
Recent studies in animals have shown that high exposures do not produce embryo or foetotoxic nor teratogenic effects in the presence of maternal toxicity.
Further information on toxicology
Avoid contact with skin and eyes and inhalation of the vapours.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
Hazardous to the aquatic environment
Low toxicity to fish. .
LC_{50} (fish) > 100 mg/l
LC_{50} (96 our) (static) : 130 mg/l
Harmful to aquatic invertebrates
EC 50 (Daphia magna) (48 hour) 69 mg/l
Low toxicity to algae.
EC 50 (selenastrum capricornutum) (96 hour) 170 mg/l

12.2 Persistence and degradability
Readily biodegradable.
Chemical oxygen demand (COD) 88% (28 days).

12.3 Bioaccumulative potential
The product has low potential for bioacumulation.

12.4 Mobility in soil
The product is predicted to have high mobility in soil.

12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product: Must not be disposed together with household garbage. Do not allow product to reach sewage system. Disposal should be made in accordance with local, state and national legislation.
Uncleaned packaging: Disposal should be made in accordance with local, state and national legislation.

14. TRANSPORT INFORMATION

14.1 UN number: 1247

14.2 UN proper shipping name
METHYL METHACRYLATE MONOMER, STABILIZED

14.3 Transport hazard class(es)
ADR, IMDG, IATA

Class: 3 Flammable liquids
Label: 3

14.4 Packing group
ADR, IMDG, IATA: II

14.5 Environmental hazards
Marine pollutant: Not classified as a marine pollutant.

14.6 Special precautions for user
Warning: Flammable liquids.
Danger code (Kemler): 339
EMS Number: F-E,S-E

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

14.8 Transport additional information

ADR
Limited quantities (LQ): 1L
Transport category: 2
Tunnel restriction code: D/E

15. REGULATORY INFORMATION

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

Product is a medical device class IIa according to Directive 93/42/EEC.

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this micture.

16. OTHER INFORMATION

This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a quarantee of certain product`s features.

Relevant phrases

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

New versions of Safety Data Sheet will be *laying printed* for the data compared to the previous version altered.

SAFETY DATA SHEET
according to regulation 1907/2006/EC
ORTOPOLI LIQUID

Pripravil: Janja Lipušček	Pregledal: Dejan Kolšek	Odobril: Janja Lipušček