according to UK REACH Regulation

	Orthosin Uni Flüss	igkeit	
Revision date: 29.10.2024	Product code: 652	061	Page 1 of 10
SECTION 1: Identification of th	ne substance/mixture and of the co	mpany/undertaking	
<u>1.1. Product identifier</u> Orthosin Uni Flüssigkeit			
Further trade names ArtNr.: 652062			
UFI:	DF30-E0EF-W00S-9A7C		
1.2. Relevant identified uses of th	e substance or mixture and uses advi	sed against	
Use of the substance/mixture			
Orthodontic resin			
1.3. Details of the supplier of the	safetv data sheet		
Company name:	Schütz Dental GmbH		
Street:	Dieselstrasse 5-6		
Place:	D-61191 Rosbach (Germany)		
Telephone:	+49 (0) 6003 814-0	Telefax: +49 (0) 6003 814-906	
E-mail:	info@schuetz-dental.de		
Contact person:	Dr. Uwe Krichbaum	Telephone: +49 (0) 6003 814-650	
Internet:	www.schuetz-dental.de		
Responsible Department:	Technische Dokumentation		
<u>1.4. Emergency telephone</u> number:	+49 (0) 6003 814-0 Schütz Dental University Mainz (24 h)	(8:00 - 17:00 Uhr) or +49 (0) 6131 19240	
SECTION 2: Hazards identifica	tion		
2.4. Classification of the substan			

# 2.1. Classification of the substance or mixture

# **GB CLP Regulation**

Flam. Liq. 2; H225 Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT SE 3; H335

Full text of hazard statements: see SECTION 16.

# 2.2. Label elements

# GB CLP Regulation

Hazard components for labelling

methyl methacrylate tetramethylene dimethacrylate

Danger

# Signal word: Pictograms:



# 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**

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

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	smoking.	
P241	Use explosion-proof electrical/ventilating/lighting equipment.	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.	
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.	
P405	Store locked up.	
P501	Dispose of waste according to applicable legislation.	
Labelling of packages v	where the contents do not exceed 125 ml	
Signal word:	Danger	
Pictograms:		
Hazard statements	· ·	
H317		
Precautionary statemer	nts	
P261-P501		
<u>2.3. Other hazards</u> No information availa	able.	
<b>SECTION 3: Compositio</b>	n/information on ingredients	
<u>3.2. Mixtures</u>		

## **Relevant ingredients**

CAS No	Chemical name			
	EC No	Index No	REACH No	
	Classification (GB CLF	P Regulation)	-	
80-62-6	methyl methacrylate			75 - < 100 %
	201-297-1	607-035-00-6		
	Flam. Liq. 2, Skin Irrit.			
2082-81-7	tetramethylene dimeth	2.5 - < 10 %		
	218-218-1	607-134-00-4		
	Skin Sens. 1B; H317			
99-97-8	N,N-dimethyl-p-toluidir	< 2.5 %		
	202-805-4	612-056-00-9		
	Acute Tox. 3, Acute To H412			

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

Specific Co	onc. Limits, M-fa	ctors and ATE	
CAS No	EC No	Chemical name	Quantity
	Specific Conc.	Limits, M-factors and ATE	
80-62-6	201-297-1	methyl methacrylate	75 - < 100 %
	oral: LD50 = 7.872 mg/kg mg/kg		
99-97-8	202-805-4	N,N-dimethyl-p-toluidine	< 2.5 %
		E = 3 mg/l (vapours); inhalation: ATE = 0,5 mg/l (dusts or mists); dermal: ATE = l: ATE = 100 mg/kg	

# **SECTION 4: First aid measures**

# 4.1. Description of first aid measures

## according to UK REACH Regulation

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### After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. In case of skin irritation, consult a physician.

### 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 1 glass of of water. Do NOT induce vomiting. Call a physician immediately.

### 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

Water spray jet

Carbon dioxide (CO2), Foam, Extinguishing powder.

### Unsuitable extinguishing media

Full water jet

### 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

## 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 to enter into surface water or drains.

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

### For cleaning up

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**

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# 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. Recommended storage temperature 10 - 25 °C

## 7.3. Specific end use(s)

Orthodontic resin

### **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
80-62-6	Methyl methacrylate	50	208		TWA (8 h)	WEL
		100	416		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

Wear eye/face protection.

### Hand protection

Tested protective gloves must be worn Suitable material: Butyl caoutchouc (butyl rubber) NBR (Nitrile rubber) Permeation time (maximum wear duration): 0,3 mm: 60 min. Permeation time (maximum wear duration): 0,11 mm: 10 min.

### Skin protection

Protective clothing.

### **Respiratory protection**

Usually no personal respirative protection necessary.

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In case of inadequate ventilation wear respiratory protection. Filter type: A

## **SECTION 9: Physical and chemical properties**

### 9.1. Information on basic physical and chemical properties

3.1. Information on basic physical and che		
Physical state:	Liquid	
Colour:	colourless	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and		100 °C
boiling range:		
Flammability:		not determined
Lower explosion limits:		2,1 vol. %
Upper explosion limits:		12,5 vol. %
Flash point:		10 °C
Auto-ignition temperature:		430 °C
Decomposition temperature:		not determined
pH-Value:		not determined
Viscosity / kinematic:		not determined
Water solubility:		15 g/l
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		47 hPa
(at 20 °C)		
Density:		0,95 g/cm <sup>3</sup>
Relative vapour density:		not determined
Particle characteristics:		not applicable
9.2. Other information		
Information with regard to physical haz	ard classes	

Explosive properties The product is not: Explosive. Oxidizing properties The product is not: oxidising.

# Other safety characteristics

Solid content:

**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

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

## 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.

0 %

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# 10.6. Hazardous decomposition products

No known hazardous decomposition products.

# **SECTION 11: Toxicological information**

## 11.1. Information on hazard classes as defined in GB CLP Regulation

### Acute toxicity

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

# ATEmix calculated

ATE (oral) > 5000 mg/kg; ATE (dermal) > 5000 mg/kg; ATE (inhalation vapour) > 50 mg/l; ATE (inhalation dust/mist) > 12,5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
80-62-6	methyl methacrylate				
	oral	LD50 7.872 mg/kg mg/kg			
99-97-8	8 N,N-dimethyl-p-toluidine				
	oral	ATE 100 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 3 mg/l			
	inhalation dust/mist	ATE 0,5 mg/l			

### Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

### Sensitising effects

May cause an allergic skin reaction. (methyl methacrylate; tetramethylene dimethacrylate)

#### Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met. Carcinogenicity: Based on available data, the classification criteria are not met. Reproductive toxicity: Based on available data, the classification criteria are not met.

### STOT-single exposure

May cause respiratory irritation. (methyl methacrylate)

### 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.

# 11.2. Information on other hazards

### Other information

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

### **SECTION 12: Ecological information**

## 12.1. Toxicity

Based on available data, the classification criteria are not met. The product is not: Ecotoxic.

# 12.2. Persistence and degradability

The product has not been tested.

# 12.3. Bioaccumulative potential

according to UK REACH Regulation

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The product has not been tested.

# 12.4. Mobility in soil

The product has not been tested.

# 12.5. Results of PBT and vPvB assessment

The product has not been tested.

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

# 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. Send to a hazardous waste incinerator facility under observation of official regulations.

### List of Wastes Code - residues/unused products

070104 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the manufacture, formulation, supply and use (MFSU) of basic organic chemicals; other organic solvents, washing liquids and mother liquors; hazardous waste

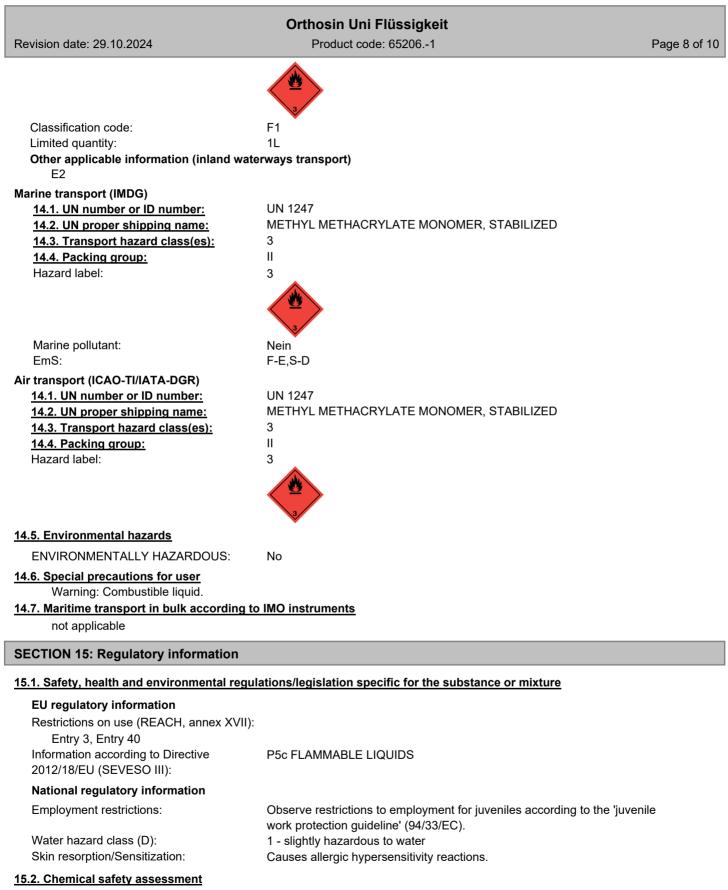
### Contaminated packaging

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

### **SECTION 14: Transport information**

#### Land transport (ADR/RID) 14.1. UN number or ID number: UN 1247 14.2. UN proper shipping name: 1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT 14.3. Transport hazard class(es): 3 Ш 14.4. Packing group: Hazard label: 3 Classification code: F1 Limited quantity: 11 Transport category: 2 Hazard No: 33 Tunnel restriction code: D/F Other applicable information (land transport) F2 Inland waterways transport (ADN) UN 1247 14.1. UN number or ID number: 1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT 14.2. UN proper shipping name: 14.3. Transport hazard class(es): 3 14.4. Packing group: Ш Hazard label: 3

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

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### **SECTION 16: Other information**

## Changes

This data sheet contains changes from the previous version in section(s): 1.

Abbreviations and acronyms Flam. Liq: Flammable liquids Acute Tox: Acute toxicity Skin Irrit: Skin irritation Skin Sens: Skin sensitisation STOT SE: Specific target organ toxicity - single exposure STOT RE: Specific target organ toxicity - repeated exposure Aquatic Chronic: Chronic aquatic hazard 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** EC/EEC: European Community/European Economic Community EU: European Union CAS: Chemical Abstracts Service **DNEL: Derived No Effect Level** DMEL: Derived Minimal Effect Level PNEC: Predicted No Effect Concentration ATE: Acute toxicity estimate LC50: Lethal concentration, 50% LD50: Lethal dose, 50% 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 M-factor: Multiplying factor ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) RID: Regulations concerning the international carriage of dangerous goods by rail ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures) IMDG: International Maritime Code for Dangerous Goods EmS: Emergency Schedules MFAG: Medical First Aid Guide IATA: International Air Transport Association DGR: Dangerous Goods Regulations ICAO: International Civil Aviation Organization TI: Technical Instructions MARPOL: International Convention for the Prevention of Marine Pollution from Ships IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

# according to UK REACH Regulation

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# Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method

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

Highly flammable liquid and vapour.
Toxic if swallowed.
Toxic in contact with skin.
Causes skin irritation.
May cause an allergic skin reaction.
Toxic if inhaled.
May cause respiratory irritation.
May cause damage to organs through prolonged or repeated exposure.
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.

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