according to UK REACH Regulation

Orthosin Uni Pulver					
Revision date: 29.10.2024	Product code: 65	201	Page 1 of 7		
SECTION 1: Identification of the substance/mixture and of the company/undertaking					
1.1. Product identifier					
Orthosin Uni Pulver					
Further trade names					
ArtNr.: 652010, 652020					
1.2. Relevant identified uses of the substance or mixture and uses advised against					
Use of the substance/mixture					
Orthodontic resin					
1.3. Details of the supplier of the sa	<u>fety data sheet</u>				
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				
1.4. Emergency telephone	+49 (0) 6003 814-0 Schütz Dental (8:00 - 17:00 Uhr) or +49 (0) 6131 19240				
number:	University Mainz (24 h)				
SECTION 2: Hazards identification					

## 2.1. Classification of the substance or mixture

#### **GB CLP Regulation**

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

## 2.2. Label elements

GB CLP Regulation

EUH208

EUH210

## Special labelling of certain mixtures

Contains dibenzoyl peroxide. May produce an allergic reaction.

Safety data sheet available on request.

## 2.3. Other hazards

No information available.

# **SECTION 3: Composition/information on ingredients**

# 3.2. Mixtures

## **Relevant ingredients**

CAS No	Chemical name	Chemical name		
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
94-36-0	dibenzoyl peroxide		< 2.5 %	
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Chronic 1; H241 H319 H317 H410			

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

# SECTION 4: First aid measures

## according to UK REACH Regulation

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## 4.1. Description of first aid measures

#### After inhalation

Rinse mouth. Provide fresh air. If experiencing respiratory symptoms: Call a doctor.

## After contact with skin

After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.

#### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

#### After ingestion

Rinse mouth immediately and drink 1 glass of of water. Call a doctor if you feel unwell.

#### 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 Extinguishing powder Foam

#### Unsuitable extinguishing media

Full water jet

## 5.2. Special hazards arising from the substance or mixture

Non-flammable.

#### 5.3. Advice for firefighters

No further relevant information available.

### **SECTION 6: Accidental release measures**

# 6.1. Personal precautions, protective equipment and emergency procedures

### General advice

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

Take up mechanically. 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

No special measures are necessary.

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### Advice on protection against fire and explosion No special fire protection measures are necessary.

## Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke. sniff.

#### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Recommended storage temperature 10 - 25 °C

#### Hints on joint storage

No special measures are necessary.

#### Further information on storage conditions

Store in a dry place.

## 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
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL

## 8.2. Exposure controls



#### 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

Use of protective clothing.

#### **Respiratory protection**

Usually no personal respirative protection necessary.

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

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

Physical state:	
Colour:	
Melting point/freezing point:	

110 °C

Powder

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# Safety Data Sheet

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		5
Boiling point or initial boiling point and	unbekannt	
boiling range:		
Flammability:	not determined	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Flash point:	>250 °C	
Auto-ignition temperature:	> 400 °C	
Decomposition temperature:	not determined	
pH-Value:	not determined	
Viscosity / kinematic:	not determined	
Water solubility:	No	
Solubility in other solvents not determined		
Partition coefficient n-octanol/water:	not determined	
Vapour pressure:	not determined	
Density:	1,16 g/cm <sup>3</sup>	
Bulk density:	700-750 kg/m³	
Relative vapour density:	not determined	
Particle characteristics:	not applicable	
. Other information		
Information with regard to physical hazard classes		
Explosive properties		
The product is not: Explosive.		
Oxidizing properties		
The product is not: oxidising.		
Other safety characteristics		
Solid content:	100 %	

#### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

## 10.2. Chemical stability

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The product is stable under storage at normal ambient temperatures.

# 10.3. Possibility of hazardous reactions

No known hazardous reactions.

### 10.4. Conditions to avoid

none

# 10.5. Incompatible materials

No information available.

# 10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours. constituent Methyl methacrylate

# **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.

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### **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

### Irritation and corrosivity

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

### Sensitising effects

Based on available data, the classification criteria are not met. Contains dibenzoyl peroxide. May produce an allergic reaction.

#### 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

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

## 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 not 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

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

The product has not been tested.

#### 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

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

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## List of Wastes Code - residues/unused products

070213 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste plastic

### 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: No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation. 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation. 14.4. Packing group: No dangerous good in sense of this transport regulation. Inland waterways transport (ADN) No dangerous good in sense of this transport regulation. 14.1. UN number or ID number: 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.3. Transport hazard class(es): 14.4. Packing group: No dangerous good in sense of this transport regulation. Marine transport (IMDG) No dangerous good in sense of this transport regulation. 14.1. UN number or ID number: No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.4. Packing group: Air transport (ICAO-TI/IATA-DGR) 14.1. UN number or ID number: No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.3. Transport hazard class(es): 14.4. Packing group: No dangerous good in sense of this transport regulation. 14.5. Environmental hazards ENVIRONMENTALLY HAZARDOUS: No 14.6. Special precautions for user No information available. 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 75	
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)
National regulatory information	
Water hazard class (D):	1 - slightly hazardous to water
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.

## 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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## Changes

This data sheet contains changes from the previous version in section(s): 1. Abbreviations and acronyms Org. Perox Eye Irrit: Eye irritation Skin Sens: Skin sensitisation 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 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). Relevant H and EUH statements (number and full text) H241 Heating may cause a fire or explosion. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H410 Very toxic to aquatic life with long lasting effects. EUH208 Contains dibenzoyl peroxide. May produce an allergic reaction. EUH210 Safety data sheet available on request.

# **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.)